COMMENTARY

Prostate Cancer Practice Patterns and Quality of Life: the Prostate Cancer Outcomes Study

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Prostate cancer is the most commonly diagnosed (non-skin) cancer among men in the United States, with 179 000 new cases and 37 000 deaths expected in 1999 *(1)*. Although $5 billion is spent annually for the care of those diagnosed with prostate cancer *(2)*, a systematic evaluation of practice patterns and the impact of treatments on health-related quality of life (HRQOL) on a national scale has yet to be conducted. In 1994, the National Cancer Institute (NCI) initiated the Prostate Cancer Outcomes Study (PCOS) to investigate variations in the initial treatment of prostate cancer and to describe HRQOL outcomes in a large, heterogeneous cohort of newly diagnosed prostate cancer patients treated in community medical practices. The study is the most comprehensive population-based outcomes study focusing on prostate cancer ever conducted and complements the national prostate cancer research agenda.

The main purpose of this commentary is to provide the rationale and objectives for the PCOS and to describe how the study fills a critical gap in the understanding of men's experiences with prostate cancer. Better knowledge of treatment outcomes is desired by thousands of patients, families, and clinicians who deal with prostate cancer every day. The PCOS was initiated to obtain more comprehensive and generalizable information about the effects of treatments on HRQOL outcomes.

Information about HRQOL is also important, from a cancer surveillance perspective, for providing a broader perspective for interpreting recent trends in prostate cancer incidence and mortality. Given the uncertainty about the efficacy of selected interventions, it is essential to document the complete burden of the disease in order to characterize the extent to which progress is being made.

A second purpose of this commentary is to describe the design, methods, and limitations of the PCOS in order to enhance the understanding and interpretation of numerous ongoing and planned research projects using the data collected.

BACKGROUND AND OBJECTIVES

The incidence rate of prostate cancer has increased dramatically during the past decade, largely as a result of the rapid dissemination of prostate-specific antigen (PSA) screening, although incidence rates have been declining in more recent years *(3,4)*. The use of radical prostatectomy has also increased, particularly among men 65 years old or older *(5,6)*. Mortality rates have changed little over the past two decades, although a declining trend has occurred since 1991, following an increase during the mid-1980s.

The failure to observe a more substantial and rapid impact of

interventions on mortality may be due to several reasons. First, the majority of men initially diagnosed with the disease die with, rather than of, prostate cancer *(7,8)*. This is due in part to the advanced median age at diagnosis of prostate cancer (age 71 years) as well as to the prolonged natural history of early-stage prostate cancer *(9)*. Therefore, it may take many years to observe an impact of some interventions on population rates. Second, screening and aggressive treatments may not reduce cause-specific mortality. To date, there are no completed randomized trials that have definitively established the efficacy of screening for prostate cancer or of aggressively treating patients with early-stage disease with either external-beam radiation therapy or radical prostatectomy *(10,11)*. Observational studies of large population-based cohorts demonstrate that 15-year survival of selected patients with localized tumors who are conservatively managed is quite favorable and appears similar to that of the age-matched U.S. population *(8,12)*. The prolonged natural history and late age at diagnosis, in addition to the lack of definitive evidence for the efficacy of interventions, have contributed to the uncertainty and disagreement about whether to screen asymptomatic men and how to best manage patients diagnosed with nonmetastatic prostate cancer *(13–16)*.

While there is a lack of convincing evidence on the effects of surgery or radiotherapy on prostate cancer mortality, there is evidence that these therapies can have detrimental effects on urinary, bowel, and sexual functions in some individuals. Given the incompleteness of information regarding mortality effects, it

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is difficult to quantify and reconcile the tradeoffs of specific treatment strategies. Uncertainty remains about the exact levels of impairment that patients can expect after receiving different treatments because, until recently, the impact of prostate cancer on long-term HRQOL outcomes had not been thoroughly investigated in representative cohorts.

Much of the early research on outcomes of prostate cancer treatment was limited to small samples from highly selected case series treated in tertiary referral centers *(14,17–20)*. Some of these influential reports may have underestimated the long-term effects of treatment. For example, estimates of incontinence were as low as 5% and impotence rates have been estimated at lower than 50% following radical prostatectomy in major treatment centers. Studies *(21–27)* have documented a more substantial decrement in urinary, bowel, and sexual functioning. These reports have been instrumental in identifying the long-term effects of prostate cancer treatment on outcomes, but they are also limited by one or more design characteristics, including *(a)* ascertaining HRQOL cross-sectionally at a single point in time, long after the acute effects of treatment; *(b)* including only long-term survivors, who may have better outcomes; *(c)* not including all age or racial/ethnic groups; *(d)* not stratifying outcomes by important clinical and nonclinical confounding characteristics associated with treatment choice; and *(e)* selecting patients treated in a particular health plan or major tertiary referral center. The PCOS was designed to address or overcome these limitations.

Information about HRQOL cannot by itself establish which treatments are desirable, since efficacy is likely to be the primary consideration for most men. Rather, the information to be collected in the PCOS can be used as part of a broader decision-making framework to assist clinicians and their patients, who desire information about HRQOL effects in order to make decisions tailored to their own preferences. Given the scientific uncertainty about efficacy, decisions about prostate cancer interventions should incorporate individual preferences. One study *(28)* has shown that preferences for prostate cancer screening and treatment are affected by information about medical uncertainties. A National Institutes of Health Consensus Development Conference *(29)* recommended radical prostatectomy or radiation therapy for treating locally confined tumors but noted that patient preferences and quality of life were important considerations when choosing among multiple therapies. Results from clinical decision models *(30–32)* suggest that both clinical and policy decisions may be based not only on the natural history of disease and treatment efficacy but also on patient preferences for outcomes of competing treatment strategies.

The uncertainties surrounding treatment have given rise to variable practice styles, illustrated by considerable geographic variations in the use of therapies for clinically localized prostate cancer across the United States and in different racial groups *(6,33)*. Therefore, another objective of the PCOS is to clarify the contributions of various clinical and nonclinical factors to variations in diagnostic and treatment practices. The PCOS will collect the most extensive data ever assembled for investigating patterns of prostate cancer care.

METHODS

PCOS Sample Design

The PCOS has a unique advantage over prior outcomes studies because it was designed within an existing population-based cancer registry system. Since 1973, the NCI's Surveillance, Epidemiology, and End Results (SEER) Program[1] has provided information on cancer incidence and survival for defined regions of the United States *(34)*. The SEER Program consists of 10 central cancer registries that routinely collect and report information on all cancers diagnosed in their catchment areas, including sociodemographic information and tumor characteristics, such as final pathologic stage and histologic grade. Active and passive follow-up is also conducted to ascertain vital status and underlying cause of death.

More than 11 000 men diagnosed with biopsy-proven, primary invasive carcinoma of the prostate during the period from October 1, 1994, through October 31, 1995, in six of the SEER cancer registries were eligible for the PCOS. Patients were diagnosed in the states of Connecticut, Utah, and New Mexico and in the Metropolitan areas of Atlanta (GA), Los Angeles (CA), and Seattle (WA). Men younger than age 90 years at diagnosis were eligible, except in Seattle where men younger than age 60 years were excluded because they were eligible for another ongoing study. All sampled men (with the exception of one man who had radiologic confirmation only) had microscopic confirmation of prostate cancer.

The six participating registries each employed a Rapid Case Ascertainment System (RCAS) to identify eligible patients within 6 months of diagnosis. The RCAS is a widely used, labor-intensive method employed by cancer registries. It requires frequent communication with pathology laboratories servicing the registry catchment areas, including some laboratories that are outside the registry areas. The proportion of cases missed by the RCAS, as determined by comparing the number of cases identified as eligible with all of the cases reported by participating SEER registries through February 1999, was approximately 5%.

Eligible patients were sampled according to a prespecified sampling design to ensure a sample representative of the population of eligible prostate cancer patients. Another objective of the sampling design was to obtain a sufficient number of minority men and younger men for assessments of HRQOL in different population subgroups. To achieve this objective, a random sample of non-Hispanic whites 60 years old or older at diagnosis was drawn from among eligible patients in each registry. Men younger than 60 years were over-sampled, with all registries other than Seattle sampling all men in this age group. Hispanic men in New Mexico and black men in Atlanta were over-sampled. Los Angeles, Connecticut, Utah, and Seattle selected all black and Hispanic men. Sample weights for the PCOS have been calculated as the inverse of the sampling proportions within each region–race–age group stratum. This method permits estimates of combined data across age–race–region strata that are appropriately weighted to the total number of eligible prostate cancer patients.

HRQOL Survey

The centerpiece of the PCOS data collection effort was a survey questionnaire designed to obtain self-reported HRQOL at 6, 12, and 24 months after initial diagnosis. An essential premise of the PCOS is that patients are the best source of information about their HRQOL and the presence and severity of disease and treatment-related dysfunction. There is evidence showing substantial differences in reports of HRQOL by cancer patients and their clinicians *(35,36)*. In a study based on the "CaPSURE" Database *(37)*, which contains extensive data for more than 4000 men with prostate cancer, investigators documented that physicians' and patients' ratings of symptoms following treatment did not agree.

A mixed-mode survey approach was used to achieve a high response rate and to elicit accurate responses to sensitive questions because some men in focus groups indicated a preference for the self-administered versus a telephone format. After the necessary local Institutional Review Board approvals and (in some registries) physician consent were obtained, patients were sent a self-administered questionnaire along with a cover letter explaining the purpose of the study and requesting their participation. If no questionnaire was returned within 2 weeks, the men were called and a second survey was mailed, if necessary. After another 2 weeks, a second reminder call was made and a telephone interview was attempted. A second identical survey was sent at approximately 12 months after diagnosis. Men who actively refused participation at 6 months and men who had died or were lost to follow-up were not mailed a 12-month survey and are considered nonresponders. Some men who were passive refusers or not located at 6 months completed only the 12-month survey. A third survey, identical to the 12-month survey, was mailed at 24 months after diagnosis or 1 year after the 12-month survey. Those eligible to complete a 24-month survey included men who had completed a 6-month and/or a 12-month survey and who had not actively refused to participate at any previous contact.

Disease-specific HRQOL was measured with the use of an index derived from three existing instruments with demonstrated validity and reliability from prior studies *(21,24,38)*. A new index for measuring urinary, bowel, and sexual dysfunctions was adapted from existing items because of the need for an instrument specifically tailored to the setting of a large, population-based, self-administered survey across diverse patient subgroups. The newly adapted PCOS prostate cancer-specific index was tested with the use of several focus groups and a pilot study on 84 prostate cancer patients. This test was done to ensure the respondent's comprehension of the revised items and to verify the face validity of the scales. The final PCOS disease-specific index contains six scales, similar to the approach by Litwin et al. *(38)* (*see* "Appendix" section). For each of three domains (i.e., incontinence, bowel impairment, and sexual impairment), the index consists of two separate scales. One scale asks men to rate their level of function in each domain using four or five items, and the other single-item scale asks men to evaluate the extent to which their level of dysfunction is a "problem" for them, using a single item. The survey instrument was translated into Spanish and pretested among Spanish-speaking men with prostate cancer.

To measure changes over time due to prostate cancer, the 6-month survey asked responders to report their urinary, bowel, and sexual functions during the past month, as well as their functions just before prostate cancer diagnosis. A separate validation study among 133 men from a convenience sample is evaluating the accuracy of 6-month recall of disease-specific function and is comparing prospective and retrospective measures of change in function.

Other items on the survey were about symptoms of disease, satisfaction with treatment, and the presence and severity of major comorbid conditions hypothesized to be associated with treatment choice and HRQOL. Other questions were used to ascertain race/ethnicity, educational attainment, household income, and marital status.

To complement the disease-specific index and to capture other generic health domains that are part of HRQOL, selected scales from the Medical Outcomes Study (MOS) 36-item short form health survey (SF-36) were used *(39)*. Because of the need to minimize respondent burden and to preserve the focus on disease-specific function, we excluded three scales of the SF-36 (physical and social function scales and general health perceptions) that were judged to be least sensitive to detecting differences between treatment groups and changes over time. (Copies of the entire PCOS survey instrument are available from A. L. Potosky upon request.)

Medical Record Abstraction

Another unique component of the PCOS data collection effort involved extensive medical record abstraction to establish baseline characteristics and to permit stratification of long-term HRQOL outcomes according to these characteristics. The participating registries reviewed in detail medical records from hospitals, free-standing radiologic or surgical centers, Department of Veterans Affairs hospitals, Health Maintenance Organizations, and private physician offices. Information difficult to obtain accurately from patients was collected, such as diagnostic procedures, tumor characteristics, details of treatments given, and acute complications of therapies. The inclusion of physician office records was necessary to collect information not routinely collected by SEER, such as clinical stage and grade, PSA values, and specific hormonal therapies given. Records from multiple physicians (primarily urologists and radiation oncologists) were abstracted on the basis of listings of treating physicians obtained from patients at the time of the survey and from registry sources. Abstraction was conducted at least 1 year after diagnosis in physicians' offices to ensure more complete collection of treatments given within the first year.

Statistical Methods

For comparing responders and nonresponders, age at diagnosis, race/ethnicity, summary stage and grade (pathologic), and type of initial treatment were obtained from the SEER Program database. Education and income were measured with the use of information at the census tract level obtained from the U.S. Bureau of the Census and linked with SEER cases. Educational level was defined as the percentage of adults living in the census tract who had a college degree. Both education and median household income were grouped in quartiles, computed within each geographic region, with the first quartile representing the lowest level for each variable. Chi-squared tests were used to compare responders and nonresponders on all categorical variables, and the nonpaired *t* test was used to compare the mean age of the responders with that of the nonresponders. All *P* values reported are two-sided.

RESULTS

Response to the PCOS

More than 11 700 men with prostate cancer were initially identified for sampling for the PCOS. Approximately 1000 of these patients were excluded as "out of scope" for the PCOS. Excluded patients include those of race/ethnicity other than white, black, or Hispanic, those determined subsequent to accrual to have been diagnosed outside the study eligibility window or outside the registry catchment areas, and those who died before the 6-month survey mailing (n = 116 deaths). Approximately 430 patients missed by the RCAS and later registered by SEER between 1995 and February 1, 1999, were counted as eligible. After these adjustments, a total of 11 137 men comprised the eligible patient population for the PCOS.

The level of response for the study was computed as the number of men completing either a 6-month or a 12-month HRQOL survey, or both, divided by the total number of men sampled (n = 5672). Table 1 shows the reasons for no response. Among the sampled patients, 84% (n = 4736) were contacted at least once to complete a 6- and/or a 12-month survey. Among all sampled patients, 3533 men (62%) completed either a 6-month survey only (n = 458), a 12-month survey only (n = 337), or both a 6- and a 12-month survey (n = 2738). Response levels differed by registry, ranging from 54% to 76%. The two main reasons that contacted men did not participate in the PCOS included active refusal or "passive" refusal, defined as when a questionnaire was never returned or phone contact was not established. Most respondents participated by completing a self-administered mailed survey (91%), with the remaining participating by phone or in-person. About 83% (n = 2740) of those men eligible to complete the 24-month post-diagnosis follow-up survey (n = 3304) did so. The percentage of PCOS respondents for whom medical record reviews were completed was 68% (n = 3828). Among the 3533 men who participated in the 6- and/or the 12-month survey, all but 47 also had completed record abstracts.

Table 2 shows the levels of response to the PCOS according to age group and race/ethnicity. As expected, response levels declined with increasing age at diagnosis, with the lowest response among men aged 80–89 years, and were higher for non-Hispanic whites than for non-Hispanic blacks or Hispanics.

Representativeness

The intended population of inference for the PCOS is men diagnosed with malignant prostate cancer in the United States.

Table 1. Reasons for no response in the Prostate Cancer Outcomes Study*

Patient disposition	% (n = 5672)*
Ascertained too late or not located	7 (413)
Physician consent denied	7 (380)
Too ill or incompetent	3 (143)
Said no prostate cancer	2 (116)
Passive refusal†	8 (435)
Active refusal	12 (652)
Completed 6- and/or 12-mo survey	62 (3533)

*Values in column = % (No. of subjects). Percentages do not sum to 100 because of rounding.

†Includes 29 patients for whom language was other than English or Spanish.

Table 2. Prostate Cancer Outcomes Study survey response levels according to age at diagnosis and race/ethnicity

Race/ethnicity*	Age at diagnosis, y†				
	39–59 (n = 1146)	60–69 (n = 2075)	70–79 (n = 1920)	80–89 (n = 531)	All ages (n = 5672)
White non-Hispanic (n = 3584)	75%	70%	64%	49%	67%
Black non-Hispanic (n = 1028)	66%	63%	57%	41%	61%
Hispanic (n = 801)	71%	68%	55%	35%	62%
All races (n = 5672)‡	70%	66%	59%	44%	62%

*n = sampled patients.

†Numerator includes men who completed a 6- and/or a 12-month post-diagnosis survey. Overall response percentages were calculated with the use of all sampled patients in the denominator.

‡259 patients with unknown race at time of sampling are included in the all-races category.

Although the PCOS was carried out in six defined regions, the sampling design ensures a fairly representative sample of all eligible patients in those areas.

However, bias may be introduced in the survey by the high rate of survey nonresponse among the sampled patients, since responders may systematically differ from nonresponders. To assess the potential for bias, Table 3 compares the distribution of

Table 3. Comparison of Prostate Cancer Outcomes Study responders and nonresponders*

Characteristics	Responders (n = 3533)	Nonresponders (n = 2139)
Mean age at diagnosis, y	67.5 (SD = 11.3)	70.2 (SD = 12.2)
Race/ethnicity		
Non-Hispanic white	75%	69%
Non-Hispanic black	13%	15%
Hispanic	10%	11%
Unknown	2%	5%
Education, % adults in tract with college degree		
Quartile 1	20%	22%
Quartile 2	22%	26%
Quartile 3	25%	26%
Quartile 4	31%	22%
Unknown	2%	5%
Median household income, tract		
Quartile 1	19%	23%
Quartile 2	22%	26%
Quartile 3	27%	23%
Quartile 4	29%	23%
Unknown	2%	5%
SEER† summary stage		
Local	56%	60%
Regional	32%	21%
Distant	4%	6%
Unstaged	7%	13%
Histologic grade		
Well differentiated	13%	17%
Moderately differentiated	64%	56%
Poorly differentiated	20%	20%
Unknown	4%	7%
Initial treatment		
Radical prostatectomy	42%	26%
Radiotherapy	24%	22%
Hormonal therapy	13%	14%
None of the above	22%	39%

*For each variable, the number of responders statistically differed from that of nonresponders (two-sided P<.001; chi-squared test; t test for mean age at diagnosis). Column percentages are weighted to the total eligible pool of prostate cancer patients. Percentages do not sum to 100 because of rounding.

†SEER = Surveillance, Epidemiology, and End Results.

selected characteristics from the SEER Program database among PCOS survey responders and nonresponders.

Responders to the PCOS were younger than nonresponders, more likely to be non-Hispanic white, and more likely to be living in areas with higher levels of educational attainment (31% versus 22% in quartile 4) and median household income (29% versus 23% in quartile 4). The responders included more men with regional stage and moderately differentiated cancers than nonresponders, although this difference was not very clinically meaningful. The responders were much more likely than nonresponders to receive radical prostatectomy versus watchful waiting. These differences indicate that some estimates from PCOS that combine information across age, race, treatment, and socioeconomic status may not be generalizable to prostate cancer patients overall.

Two strategies will be used to reduce the extent of bias when practice patterns and treatment-outcome relationships are assessed. First, all planned studies using the PCOS data to evaluate outcomes after treatment will stratify by age and initial treatment received and will adjust for other clinical and sociodemographic characteristics with the use of standard statistical methods. In addition, survey nonresponse weights, equal to the inverse of the response level within each region–race–age stratum, have been developed. These weights may be multiplied by the sampling weights to produce estimates adjusted for nonresponse and weighted to the total eligible population of patients with prostate cancer.

These measures may succeed only to the extent that the responders represent all eligible case subjects within each region–age–race stratum. It is often assumed that survey nonresponders in general are in poorer health than responders. In the PCOS, nonresponders were slightly older and from lower socioeconomic status areas, partly supporting this assumption. However, it is also possible that some men experiencing more frequent and severe complications following their treatment for prostate cancer are more willing to participate, in which case responders may have systematically poorer disease-related outcomes. The precise direction and magnitude of this bias are impossible to assess without health status information about the nonresponders.

It has been well established that the mix of treatments for clinically localized prostate cancer does vary quite substantially by region (6,33). The SEER regions tend to be urban areas, with more socioeconomically affluent populations and more medical specialists than in the rest of the United States (40,41). Thus, weighted estimates from PCOS of treatment utilization may not be generalizable to the nation as a whole. However, the factors associated with selection among competing management strate-

gies and the associations of treatments and long-term effects are unlikely to substantially differ in the six PCOS regions compared with the rest of the United States.

COMMENT

The PCOS will describe variations in medical practices and HRQOL among men diagnosed with prostate cancer. The study will be a critical source of information for helping monitor the burden of the disease in the U.S. population, which is useful for developing new strategies and ideas aimed at achieving progress in reducing prostate cancer-related morbidity. The PCOS will also complement randomized trials, which typically evaluate interventions in controlled circumstances and specialized settings, by providing data on the impact of interventions in "real-world" community practice settings.

The feasibility of conducting an extensive population-based study of HRQOL among patients with cancer in diverse medical settings, building on the infrastructure and expertise of cancer registry staff, was demonstrated by the successful implementation of rapid case ascertainment systems by six separate registries. The study also demonstrates the willingness of men with prostate cancer and their physicians to be part of research about the disease. The ability to link longitudinal patient survey data with medical abstracts containing detailed clinical characteristics and treatments is an important advantage for conducting community-based HRQOL research.

The PCOS survey instrument was designed to focus on urinary, sexual, and bowel domains, previously known to be most relevant to men with prostate cancer *(38)*. The inclusion of both generic and disease-specific measures of HRQOL following prostate cancer is necessary to capture diverse outcomes of treatment, since specific measures may be more sensitive for the detection and measurement of small changes that are important to patients and clinicians *(42)*.

Continued vital status follow-up of the PCOS cohort is planned. There will be a 5-year post-diagnosis HRQOL survey initiated in the Fall of 1999 to track longer term changes. Several research efforts are currently active. They include the following: 1) examination of diagnostic and treatment practice patterns, 2) prediction of pathologic stage following radical prostatectomy, 3) patterns in the use of secondary treatments for recurrence and progression, and 4) tracking changes in HRQOL over a period of 24 months after various treatments for prostate cancer. The extensive data collected by the PCOS should provide important new information concerning the diagnosis and management of prostate cancer in the United States to benefit patients, clinicians, and policy makers.

APPENDIX: DISEASE-SPECIFIC INDEX (All items refer to "over the past month.")

I. Incontinence Function Scale

1) Which of the following best describes your urinary control?
Total control; occasional leaking; frequent leaking; no control
2) How often have you leaked or dripped urine (been incontinent)?
Not at all; less than once a week; about once a week; once or twice a day; more than twice a day
3) How many pads or adult diapers, if any, have you usually used to help with leaking or dripping?
No pads; one pad per day; two pads per day; three or more pads per day
4) How often have you had to urinate again less than 2 hours after finishing urinating?

Rarely or not at all; less than half the time; about half the time; more than half the time; almost always

II. Incontinence Bother Scale

Overall, how big a problem have you had with leaking or dripping urine?
No problem; very small problem; small problem; moderate problem; big problem

III. Bowel Function Scale

1) How often have you had more than three bowel movements on a single day?
2) How often have you had any pain or discomfort before, or during, bowel movements?
3) How often have you had urgent bowel movements (you could not wait to go to the bathroom)?
4) How often have you had wetness in the rectal area?
5) How often have you had problems with painful or bleeding hemorrhoids?
Response categories: almost every day; some days; rarely or not at all

IV. Bowel Bother Scale

Overall, how big a problem have you had with urgent, frequent, or painful bowel movements?
No problem; very small problem; small problem; moderate problem; big problem

V. Sexual Function Scale

1) How interested have you been in sexual activity (including kissing, hugging, fondling, having intercourse, or masturbating)?
A lot; somewhat; only a little; not at all
2) How often have you engaged in any sexual activity?
Several times a week; once a week; two to three times a month; once a month; not at all
3) Have you had any erections firm (hard) enough for sexual intercourse?
Yes/no
4) Have you had any partial erections that were not firm enough for sexual intercourse?
Yes/no
5) How much difficulty have you had keeping an erect penis during sexual activity?
No difficulty; a little difficulty; some difficulty; a lot of difficulty; do not get erections at all

VI. Sexual Bother Scale

Overall, how big a problem do you consider your sexual function to be?
No problem; very small problem; small problem; moderate problem; big problem

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NOTES

[1]*Editor's note:* SEER is a set of geographically defined, population-based, central cancer registries in the United States, operated by local nonprofit organizations under contract to the National Cancer Institute (NCI). Registry data are submitted electronically to the NCI on a biannual basis, and the NCI makes the data available to the public for scientific research.