

# Surgical Outcomes of a Breast Cancer-Screening Program for Low-Income Women

Ricardo Jimenez-Lee, MD; Selene G. Oslak, MPH; Katrina Hedberg, MD, MPH; John T. Vetto, MD

**Hypothesis:** Surgical outcomes from a breast cancer-screening program of low-income women are similar to those of other screening programs.

**Design:** Prospective cohort.

**Setting:** Federally funded screening program.

**Patients:** A total of 15 730 women.

**Interventions:** A total of 23 149 mammograms, 20 396 with concomitant clinical breast examination, from January 1, 1997, through December 31, 2001.

**Outcome Measures:** American College of Radiology scores; associated surgery consultations, biopsies, operations, and pathology results.

**Results:** Most (20 868) of the 21 296 mammograms assigned an American College of Radiology score were benign; only 428 (2%) were suspicious. Resulting from suspicious clinical breast examinations, the group with American College of Radiology scores of 1 to 3 accounted for 45%, 18%, and 10% of recommended surgical consultations, biopsies, and cancers detected, respectively. A rate of 12.3 cancers per 1000 women was found, greater than with other screening programs. Compliance with therapy was 97%.

**Conclusions:** This screening program had a higher rate of advanced cancers. Clinical breast examination was an important component, and compliance with surgical recommendations was excellent.

*Arch Surg.* 2003;138:884-890

**T**HE OREGON Breast and Cervical Cancer Program (BCCP) was implemented in 1996 as a statewide screening program (SP) for medically underserved low-income women. We studied women enrolled in the program to determine incidence and stage of breast cancer, the role of the clinical breast examination (CBE), and patient compliance with treatment. We also compared these results with those from other SPs found in a review of the literature.

In theory, a true SP should enroll asymptomatic women. However, because of the frequent incomplete disclosure of symptoms among initial participants, screening is often done on a heterogeneous population of asymptomatic and symptomatic women (prevalence screen). This is especially true during the initial phase of the SP, in contrast to subsequent rescreening of existing participants (incidence screen). We therefore hypothesized that the Oregon BCCP would demonstrate features of a prevalence SP, especially because we were ana-

lyzing the initial phase of the first federally funded large-scale SP in the state.

Because we believed our SP would represent a prevalence screen, we were particularly interested in knowing the compliance and outcomes of the participants in whom cancer was detected. We further hypothesized that CBE would be responsible for a greater diagnostic yield in the patient subgroup of mammographic findings with American College of Radiology (ACR) scores of 1 to 3, reinforcing the importance of CBE as a component of a breast SP.

## METHODS

### PROGRAM DESCRIPTION

The Oregon BCCP is a part of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and is funded by the Centers for Disease Control and Prevention, Atlanta, Ga, and the Oregon and Southwest Washington Affiliate of the Susan G. Komen Foundation, Portland. The program is administered through county health departments and one tribal health clinic. Women eligible for the

*From the Section of Surgical Oncology, Department of Surgery, Oregon Health & Science University (Drs Jimenez-Lee and Vetto), and the Oregon Breast and Cervical Cancer Program, Oregon Department of Human Services (Ms Oslak and Dr Hedberg), Portland.*

Oregon BCCP are 40 years or older, with incomes up to 250% of the federal poverty level, and uninsured or underinsured. Mammograms are performed in facilities certified under the Mammography Quality Standards Act, and diagnostic services are available through local providers, mammogram facilities, and hospitals. County-level Oregon BCCP staff assist participants in scheduling appointments and provide case management services in cases of abnormal screening results, to ensure timely and complete evaluation and treatment by associated physicians and facilities. The program is monitored by state staff and by the NBCCEDP.

#### DATA COLLECTION AND ANALYSIS

Data were extracted from the Oregon BCCP's clinical database, which is designed to track multiple screening cycles per patient. Screening data for the subset of patients receiving services from January 1, 1997, through December 31, 2001 (the initial phase of the SP), were exported to SPSS<sup>1</sup> for descriptive analyses. There were 23 149 mammograms, 20 396 with concomitant CBE, in 15 730 women. The main outcomes measured were ACR scores, associated surgery consultations, biopsies, and operations, with corresponding pathological examination results. Additional surgical outcomes, including stage of disease, therapy, and survival for the patients in whom cancers were detected, were abstracted from the Oregon State Cancer Registry database. Protocols were reviewed and approved by Oregon BCCP and Oregon State Cancer Registry review boards.

## RESULTS

### DEMOGRAPHICS

A total of 15 730 women received a total of 23 149 screening mammograms through the SP during the period of study; approximately two thirds of participants had only 1 mammogram during this period. Because some participants more frequently accessed the program, including extra films done for inconclusive imaging, there were more than 5 cycles in the study period. **Table 1** shows the details of each screening cycle, ages of the women, and frequency of symptoms. Participants reported symptoms in at least 14.4% of screenings; because the study uses the minimal data elements of the NBCCEDP, the details of these symptoms were not available for this report.

### MAMMOGRAM RESULTS

**Table 2** describes the results by ACR scores; **Table 3**, by associated CBEs; **Table 4**, by cancer diagnosis; and **Table 5**, by recommended biopsies. Of the mammograms, 21 296 (92%) resulted in an assigned ACR score (1-5). Most (20 868) of these mammograms were benign or probably benign (ACR score, 1-3), and only 428 (2%) were suspicious (ACR score, 4-5).

### CBE RESULTS

A concomitant CBE with documented results was recorded for 20 395 (88.1%) of the mammograms. Six percent of CBEs showed some abnormal finding, and 64% of these abnormal examinations were associated with ACR scores of 1 to 3. As shown in Tables 4 and 5, the ACR

**Table 1. Breast Screening, 1997-2001\***

Screening Data	No. (%)
Client's initial cycle (1)	14 472 (62.5)
Subsequent cycles	
2	5184 (22.4)
3	2194 (9.5)
4	899 (3.9)
5	301 (1.3)
6	74 (0.3)
7	19 (0.1)
8	4 (0.0)
9	2 (0.0)
<b>Total</b>	<b>23 149 (100.0)</b>
Age at screening, y	
40-49	10 772 (46.5)
50-64	11 445 (49.4)
≥65	932 (4.0)
Symptoms reported	
Yes	3343 (14.4)
No	15 714 (67.9)
Unknown	4092 (17.7)

\*N = 15 730 total unique clients.

**Table 2. Initial Mammogram Results by ACR Score**

ACR Score	No. (%)
1	13 411 (57.9)
2	6167 (26.6)
3	1290 (5.6)
4	346 (1.5)
5	82 (0.4)
Inconclusive*	1853 (8.0)

Abbreviation: ACR, American College of Radiology.

\*Including ACR of 0.

**Table 3. CBE Results by ACR Score**

ACR Score	No. (%)		
	Normal CBE	Abnormal CBE	Associated Screening CBE Data
1	11 686 (60.9)	339 (28.2)	1386 (50.3)
2	5056 (26.3)	274 (22.8)	837 (30.4)
3	866 (4.5)	153 (12.7)	271 (9.8)
4	194 (1.0)	107 (8.9)	45 (1.6)
5	16 (0.1)	62 (5.1)	4 (0.1)
Inconclusive*	1373 (7.2)	269 (22.3)	211 (7.7)
<b>Total</b>	<b>19 191 (100.0)</b>	<b>1204 (100.0)</b>	<b>2754 (100.0)</b>

Abbreviations: ACR, American College of Radiology; CBE, clinical breast examination.

\*Including ACR of 0.

benign or probably benign group accounted for 45%, 18%, and 10% of recommended surgical consultations, recommended biopsies, and cancers detected, respectively. As would be expected from the finding of 269 abnormal CBEs among the inconclusive mammograms, 61 (31.4%) of the 194 cancers found in the total SP (not shown in Table 4) were in the ACR 0 group and were presumably

**Table 4. Cancer Diagnosis by ACR Score**

ACR Score	No. (%)		
	Ductal Carcinoma In Situ	Invasive Breast Cancer	All Diagnoses
1-3	3 (17.6)	10 (8.6)	13 (9.8)
4-5	14 (82.4)	106 (91.4)	120 (90.2)
Total	17 (100.0)	116 (100.0)	133 (100.0)

Abbreviation: ACR, American College of Radiology.

**Table 5. Recommendations by ACR Score**

ACR Score	No. (%)	
	Biopsy Recommended	Surgery Consultation Recommended
1-3	32 (18.1)	116 (45.1)
4-5	145 (81.9)	141 (54.9)
Total	177 (100.0)	257 (100.0)

Abbreviation: ACR, American College of Radiology.

found by CBE alone or other supplemental imaging studies (eg, ultrasonography and/or additional mammography; specifics on the evaluation of ACR 0 films were not captured by the minimal data elements).

#### CANCERS DETECTED

Within the SP for the entire period examined, 349 fine-needle aspirations were performed; 89 were suspicious for malignancy. Of the 583 histologic biopsies performed, 6.3% showed marker (atypical ductal hyperplasia, lobular carcinoma in situ) lesions, and 140 proved to be cancer. The remaining 54 of the 194 total cancers (including ductal carcinoma in situ) diagnosed in the SP were found by fine-needle aspiration-based triple testing.<sup>2,3</sup>

The overall cancer detection rate (unadjusted for age) among the screened women was 1.23% (12.3 per 1000 women screened during a 5-year period). However, 159 of the 194 cancers were found in participants' initial screening cycle, and diagnosis rates decreased from 11.0 per 1000 among the initial screening cycle (almost twice the reported rates from some other SPs; **Table 6**) to 3.3 per 1000 by cycle 5.

#### FOLLOW-UP AND TREATMENT

Of the 194 cancers detected, 82.5% were invasive, and 59% of these were greater than stage I. Of all patients with a diagnosis of breast cancer, 188 proceeded with the recommended first-course treatment, for an initial compliance rate of 96.9%. Of the 6 patients who did not proceed with treatment, 4 refused, 1 died before therapy, and in 1 case the reason cited was "financial problems."

Specifics on first course of treatment were available from Oregon State Cancer Registry data for 152 of

**Table 6. Initial Breast Cancer Detection Rates by Screening Program**

Source (SP)	Cancers/1000 Women
Moss et al <sup>4</sup> (UK)	6
Fracheboud et al <sup>5</sup> (Netherlands)	6.6
Bobo et al <sup>6</sup> (NBCCEDP)	6.6
Schootman and Fourtes <sup>7</sup> (Iowa BCCP)	7.1
Libstug et al <sup>8</sup> (Ontario)	8.8
Vejborg et al <sup>9</sup> (Denmark)	10
Present study (Oregon BCCP)	11

Abbreviations: BCCP, Breast and Cervical Cancer Program; NBCCEDP, National Breast and Cervical Cancer Early Detection Program; SP, screening program; UK, United Kingdom.

**Table 7. Cancers Detected and Outcomes**

Stage	Registry Data Available No.	Survival (8 mo) No. (%)	First Course of Treatment: No. (%) <sup>*</sup>		
			Partial Mastectomy	Mastectomy	No Operation
I	62	57 (92)	40 (64.5)	22 (35.5)	0
II	50	47 (94)	78 (56)	22 (44)	0
III	32	30 (94)	12 (37.5)	19 (59)	1 (3)
IV	8	5 (62.5)	2 (25)	3 (37.5)	3 (37.5)

\*N = 152 patients with registry data available.

the 160 participants with a diagnosis of invasive cancer. Three percent had no operation, 56% had partial mastectomy, and 41% had mastectomy; the breakdown of operation by stage is shown in **Table 7**. Chemotherapy was administered to 45% and 49% of patients who received partial mastectomy and mastectomy, respectively. Overall survival at a mean of 8 months by stage is also shown in Table 7.

#### COMMENT

In contrast to some other SPs<sup>4,5,8,10</sup> (Table 6), the low-income SP we report on detected a higher rate of more advanced cancers, suggesting that (at least in the initial period) such services are used for evaluation and treatment of nonocult lesions, as well as screening (Table 7). The CBE was an important component of our SP (Table 3), and compliance with surgical recommendations was excellent (Table 7).

The majority of the evidence suggests that mammography screening reduces breast cancer death among women 40 to 74 years of age, with a significant separation in survival curves observed with long-term follow-up of screened patient populations.<sup>11</sup> Younger women have more potential years of life to gain from screening,<sup>12</sup> and data from the Swedish Two-County Trial (1978-1985) indicate that the effective interval of time for breast cancer detection in younger women is shorter before it presents clinically.<sup>11</sup>

The Swedish Two-County Trial found a 32% reduction in breast carcinoma mortality on 20-year follow-up of 77 080 women aged 40 to 74 years at the time of their initial invitation to undergo screening.<sup>12</sup> Recently, the

Swedish Service SP reviewed data from previous trials and current data demonstrating that, with an average screening interval of 28 months and mean follow-up of 10.6 years, the reduction in excess mortality from breast cancer was estimated at 16%. After adjusting for biases due to inclusion of cases in the study cohorts diagnosed before invitation to screening and lead-time bias, the reduction increased to 20%. This reduction of mortality from breast cancer resulting from screening was consistent with previous Swedish randomized studies.<sup>13</sup>

As was also noted in our SP (Table 1), most mammograms performed in SPs of asymptomatic women are benign. Unadjusted rates of approximately 5.6 to 8.5 breast cancer cases per 1000 women were detected in mass mammographic screening studies.<sup>10</sup> Bobo et al<sup>6</sup> noted a cancer detection rate of 5.1 per 1000 women during initial NBCCEDP mammographic screening data.<sup>14</sup> Schootman and Fourtes,<sup>7</sup> reporting on data from the Iowa Breast and Cervical Cancer Early Detection Program (part of the NBCCEDP), noted a breast cancer detection rate of 7.1 per 1000 initial screenings. Thus, the NBCCEDP has reported a lower rate of cancer detection than we found for Oregon. In our SP we found an unadjusted initial rate of 11.0 per 1000, almost twice the reported initial screening rates of some other SPs, as noted at the beginning of this paragraph and in Table 6. Our finding is particularly intriguing, given that our participant pool is younger than that of most other SPs (ie, with a lower age limit of 40 years rather than 50 years).

We attribute this higher rate to the fact that these data from our SP represent the initial phase of the first federally funded large-scale SP in the state and was targeted at low-income women and that, therefore, the SP was used for evaluation and treatment of nonocult lesions, as well as screening (ie, our program is in the prevalence phase). As such, our particularly high prevalence-phase cancer detection rates probably reflect both the limited access this population had to breast care before the SP and the lack of public education regarding breast cancer. The National Cancer Institute identified that women below 200% of the poverty level were least likely to have mammographic screening.<sup>15</sup>

It is of further interest to note that within these first 5 years of data we are already observing a shift to lower cancer detection rates in subsequent cycles, indicating a shift to an incidence phase. Specifically, 159 of the 194 cancers we detected were found in participants' initial screening cycles, and diagnosis rates decreased from 11.0 per 1000 among initial screening cycles to 3.3 per 1000 by cycle 5. Other studies have also found higher detection rates among initial screenings when compared with subsequent screenings. For example, Vejborg et al<sup>9</sup> documented a detection rate of 10.0 per 1000 among first screens (in initial and subsequent screening invitation rounds), compared with 5.8 per 1000 among second screens.

In addition to being more frequent, tumors detected during the prevalence phase of an SP are also usually of a higher stage. The majority of invasive cancers detected in our study were greater than stage I (Table 7); similarly, Farley and Flannery<sup>16</sup> reported that women with a lower socioeconomic status were more likely than

women with a higher socioeconomic status to present with later-staged tumors at the time of diagnosis. Because the success of an SP can be measured by the improvement in the percentage of breast cancers diagnosed at an early stage, we anticipate that the stages of cancers we detect will "migrate downward" as we progress further into the incidence phase.

Most mass-screening studies focus on mammographic findings, yet some malignancies are missed by this modality, as illustrated in our study by the finding that 10% of cancers were detected in women with ACR scores of 1 to 3 (Table 4). False-negative mammographic findings are mostly secondary to image technique or misinterpretation. The combination of CBE with imaging increases event identification in breast cancer screening.<sup>6,17</sup> In recent reports, CBEs performed in community-based screening programs were found to detect breast cancer as effectively as CBEs performed in clinical trials and to modestly improve the results in early detection campaigns.<sup>6,18,19</sup>

Although CBE is clearly an important part of any breast cancer SP, the high false positivity of this test is clearly a limitation. For example, in a study by Bobo et al,<sup>6</sup> 1 of every 15 CBEs (6.9%, similar to the 6% found in our study; Table 3) was coded as abnormal, suspicious for cancer. A data review by Eddy<sup>18</sup> concluded that CBE sensitivity was about 50%, and specificity, about 98%. Barton et al<sup>19</sup> in a 1999 meta-analysis reported pooled CBE sensitivity and specificity rates of 54% and 94%, respectively.

In another study, Vetto et al<sup>20</sup> reported on 205 primary health care physicians who were formally trained in CBE in an attempt to determine whether such an intervention could improve CBE accuracy. Group evaluation with the use of standardized silicone breast models took place before and after the CBE training. The percentage of primary care physicians examined who could detect 60% to 100% of the lumps rose from 59% in the pretest period to 94% in the posttest. Furthermore, false-positive lump detection declined in the posttest period to 59% of the pretest rate.

Compliance with treatment in our SP was approximately 97%, higher than in other reports.<sup>21</sup> Richardson et al<sup>22</sup> (part of NBCCEDP) reported that, in a study of early-stage breast cancer treatment among medically underserved women, only 88% received adequate initial operation (56% mastectomy and 32% partial mastectomy); data from our SP demonstrate a higher rate of partial mastectomy (56%, vs a 41% mastectomy rate). We believe that the high treatment and compliance rates in our study were due to at least 2 factors. First, our SP includes staff that serve as liaisons with the medical community and, in some cases, provide additional case management, transportation, and translation services. Second, program-associated physicians often provided patient care gratis.

The Breast Cancer Treatment Act (Centers for Disease Control and Prevention/Breast and Cervical Cancer Prevention and Treatment Act of 2000<sup>23</sup>) was implemented in Oregon on April 1, 2002. Since then, Oregon BCCP participants who were diagnosed through the program and were documented citizens of Oregon have

received treatment coverage through the Oregon Health Plan, which should further improve access to care. This law, which was not in effect during the time interval we report, may actually extend the prevalence phase of our SP.

At least in the initial (prevalence) phase, this SP for low-income women detected a higher rate of more advanced cancers, suggesting that it was used for evaluation and treatment of nonocult lesions, as well as screening. Although it is a test fraught with high false-positivity rates, CBE was an important component of our SP, solely responsible for detecting 10% of the cancers. Compliance with surgical recommendations was excellent, a fact we attribute to many unique features of this program. Given these findings, our future plans are to continue the SP into the incidence phase; step up our state-wide, university-based CBE training programs (to standardize and improve the accuracy of this test among our providers); and use the state cancer registry to compare outcomes of women with cancers detected through this program with the general state breast cancer data.

Accepted for publication April 20, 2003.

This study was presented at the 74th Annual Meeting of the Pacific Coast Surgical Association; February 16, 2003; Monterey, Calif; and is published after peer review and revision. The discussions that follow this article are based on the originally submitted manuscript and not the revised manuscript.

Corresponding author and reprints: John T. Vetto, MD, Section of Surgical Oncology, L223A, Department of Surgery, Oregon Health & Science University, 3181 SW Sam Jackson Park Rd, Portland, OR 97201 (e-mail: vettoj@ohsu.edu).

## REFERENCES

1. SPSS Inc. *SPSS Base 9.0 for Windows User's Guide*. Chicago, Ill: SPSS Inc; 1998.
2. Morris KT, Pommier RF, Schmidt WA, et al. Usefulness of the triple test score for palpable breast masses. *Arch Surg*. 2001;136:1008-1013.
3. Vetto JT, Pommier R, Schmidt W, et al. Use of the "triple test" for palpable breast lesions yields high diagnostic accuracy and cost savings. *Am J Surg*. 1995;169:519-522.
4. Moss SM, Michel M, Patrick J, Johns L, Blanks R, Chamberlain J. Results from the NHS breast screening programme 1990-1993. *J Med Screen*. 1995;2:186-190.
5. Fracheboud J, De Koning HJ, Beemstroboer PMM, et al. Nation-wide breast cancer screening in the Netherlands: results of initial and subsequent screening 1990-1995. *Int J Cancer*. 1998;75:694-698.
6. Bobo JK, Lee NC, Thames SF. Findings from 752,081 clinical breast examinations reported to a national screening program from 1995 through 1998. *J Natl Cancer Inst*. 2000;92:971-976.
7. Schootman M, Fourtes LJ. Early indicators of the effect of a breast cancer-screening program for low-income women. *Cancer Detect Prev*. 2001;25:138-146.
8. Libstug AR, Morovan V, Aitken SE. Results from the Ontario breast screening program, 1990-1995. *J Med Screen*. 1998;5:73-80.
9. Vejborg I, Olsen AH, Jensen MB, Rank F, Tange UB, Lynge E. Early outcome of mammography screening in Copenhagen 1991-1999. *J Med Screen*. 2002;9:115-119.
10. Blamey RW, Day NE, Young JR, et al. The frequency of breast cancer screening: results from the UKCCCR Randomized Trial. *Eur J Cancer*. 2002;38:1458-1464.
11. Humphrey LL, Helfand M, Chan BKS, Woolf SH. Breast cancer screening: a summary of the evidence for the US Preventive Services Task Force. *Ann Intern Med*. 2002;137(5, pt 1):347-360.
12. Feig SA. Effect of service screening mammography on population mortality breast carcinoma. *Cancer*. 2002;95:451-457.

13. Jonsson H, Nystrom L, Tornberg S, Lenner P. Service screening with mammography of women aged 50-69 years in Sweden: effects on mortality from breast cancer. *J Med Screen*. 2001;8:152-160.
14. May DS, Lee NC, Nadel MR, Henson RM, Miller DS. The National Breast and Cervical Cancer Early Detection Program: report on the first 4 years of mammography provided to medically underserved women. *AJR Am J Roentgenol*. 1998;170:97-104.
15. McGinnis LS, Menck HR, Eyre HJ, et al. National cancer data base survey of breast cancer management for patients from low income zip codes. *Cancer*. 2000;88:933-945.
16. Farley TA, Flannery JT. Late-stage diagnosis of breast cancer in women of lower socioeconomic status: public health implications. *Am J Public Health*. 1989;79:1508-1512.
17. Williams RS, Brook D, Monypenny IJ, Gower-Thomas K. The relevance of reported symptoms in a breast screening programme. *Clin Radiol*. 2002;57:725-729.
18. Eddy DM. Screening for breast cancer. *Ann Intern Med*. 1989;111:389-399.
19. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? the screening clinical breast examination: should it be done? how? *JAMA*. 1999;282:1270-1280.
20. Vetto JT, Petty JK, Dunn N, Prouser NC, Austin DF. Structured clinical breast examination (CBE) training results in objective improvement in CBE skills. *J Cancer Educ*. 2002;17:124-127.
21. Lawson H, Henson R, Bobo J, Kaeser M. Implementing recommendations for the early detection of breast and cervical cancer among low income women. *MMWR Morb Mortal Wkly Rep*. 2000;49:35-55.
22. Richardson LC, Schulman J, Sever LE, Lee NC, Coates RJ. Early breast cancer treatment among medically underserved women diagnosed in a national screening program. *Breast Cancer Res Treat*. 2001;69:133-142.
23. CDC/Breast and Cervical Cancer Prevention and Treatment Act. Pub L 106-354, Congressional Record 114 Stat 1381-1384 (2000).

## DISCUSSION

Charles P. Theuer, MD, San Diego, Calif: The authors describe an important topic, the surgical outcomes of a breast cancer-screening program. I would like to initiate the discussion by discussing key elements of a successful screening program. A successful screening program must be capable of detecting early disease. The program must have sufficiently high sensitivity and high specificity to ensure a high positive predictive value, given the disease prevalence. In simple words, the program must demonstrate that an ounce of prevention is indeed worth a pound of cure. The screening program must be acceptable to the population at risk. Importantly, the current paper clearly shows that low-income Oregon women will engage in breast cancer screening if cost is not an impediment. Successful treatment must be available to the screened population. It also must be utilized by the identified population. Again, importantly, the current paper indicates that 97% of low-income Oregon women utilized appropriate treatment. Finally, a successful screening program must save lives.

The issue of whether breast cancer screenings saved lives in this country has been a controversial topic. Although mammography is recommended for American women over the age of 40 years, a recent Cochrane meta-analysis concluded, "There is no reliable evidence that screening for breast cancer reduces mortality." The Cochrane group considered that only 2 trials actually met standards of quality in comparing screening mammography. One of these, a Swedish trial, had 11 years of follow-up. However, the overall risk mortality in that trial was equal between screened and unscreened women. The Cochrane group, however, did not consider that screening trials should show a survival benefit, not immediately at the time of screening, but rather at some later time when patients after receiving treatment would begin to show the benefits of cancer treatment.

As a result, a reanalysis of the Swedish trial data by year of follow-up indicates a significantly lower risk of dying. Those screened have half the risk of dying than those who were unscreened 8 to 11 years following the initiation of screening. So, yes, mammography does save lives.

The current study corroborates data indicating that the CBE complements mammography. Nearly 10% of invasive cancers occurred in women with benign findings on mammogram. The authors do not determine if mammography complements CBE, however. Do the authors, and this is my first question, plan to describe the proportion of invasive cancers found by mammography in asymptomatic women with a normal CBE? An analysis of the sensitivity, specificity, and positive predictive value of mammography and CBE, both individually and together, would help to determine the value of each test. Prior data by Bobo and coworkers, who analyzed a BCEDP database, found that mammography resulted in a higher yield than CBE when the other was normal. This study is important and may be critical to making allocations of precious health care dollars.

The authors indicate, importantly, that 97% of patients proceeded with the recommended first course of therapy. Could the authors comment even further on strategies employed that resulted in such an excellent rate of treatment compliance? However, 4 patients did refuse treatment; 1 died prior to therapy and in 1 case the reason cited was financial problems. Could the authors comment further on reasons why treatable patients refused treatment and discuss mechanisms to address these issues?

Finally, drawing reliable conclusions from the study requires a reliable database. The authors acknowledge that their screening program database was contaminated with symptomatic women. A true screening program, as they point out, addresses only asymptomatic patients. Sixty-seven percent of the screened population in this current study was defined as asymptomatic. I am curious to see, and a second question, do the authors plan to analyze data in the subset of asymptomatic patients who were truly screened? In addition, it is important to know how the database was validated. The symptom assessment was missing in 17% of cases. However, checks were made for accuracy of data entry. Are the authors certain that all breast cancer cases among screening program participants were actually captured?

William P. Schechter, MD, San Francisco, Calif: I rise to make some global comments about cancer care among the poor and disenfranchised. In surgery we focused on trauma and injury as a result of acts of violence in the disenfranchised community. I believe that cancer care among the poor is very poorly done—no pun intended—by medicine as a whole and surgery in particular. This particular problem has not been on our radar screen, and I want to commend the authors for bringing this to our attention.

We really need to look at programmatic cancer care for the poor and disenfranchised. The lack of access to screening programs and care is critically important. We are on a very steep curve in terms of our potential to improve care to poor and disenfranchised patients who have a malignancy. I commend the authors for bringing this to our attention.

Lawrence D. Wagman, MD, Duarte, Calif: One of the features of this paper is pointing out the true meaning of screening, but I think we are probably still using the wrong word. What we really mean is surveillance or repetitive screening. In all of the papers that have been written about screening, they have documented that screening at a specific interval of time is required to generate the improvement in mortality. My question from that is: how many of the women were rescreened? In California, we have the same federal program and we have run a state program in California also for about 13 years now, and one of the challenges has been unique identifiers to see if we were actually "rescreening," that is, putting women in this process of surveillance. Through the years, as breast cancer went from being a hidden disease to a grassroots disease, we have seen the development of programs to support the poor and un-

deserved. Being 250% below the federal poverty level is so phenomenally below anybody's expectation of quality of life that having to reach that before you are eligible for these programs is not tolerable. In California, we now have full medical care for any woman diagnosed with breast cancer via Medi-Cal resources. This creates a bridge between low-income screening programs and full-service care.

Maria D. Allo, MD, San Jose, Calif: I would like to underscore what both Dr Wagman and Dr Schechter have said. We have the same screening program. Our rescreening rates are incredibly low for a variety of factors: patients getting insurance transiently and then losing it, and also patients moving and being lost to follow-up. Such situations make data collection very difficult. One of the important things that these authors point out is the fact that having a program like this gives the community clinics a vehicle whereby patients can actually get studies that they wouldn't normally be able to get because they couldn't afford them. When we actually analyzed our data, we saw this same kind of trend, that lumps would be found in the clinic and women who would be offered a mammogram and had no way of paying, now would get mammography and follow-up care because they had a mechanism to pay. Thus, the real benefit of the program was actually in providing access as much as it was providing screening. The actual effort to get patients screened required a huge amount of health fairs and other kinds of things to get the word out. The challenge is to educate patients who are used to obtaining episodic care to participate, and also to adopt the program as a vehicle for continuing surveillance and regular rescreening.

Dr Vetto: I want to thank first my coauthors on the Oregon BCCP and especially all of the staff for all their excellent services to the women of Oregon and to the hours they also put in helping us collect and analyze the data. This gets directly to the last comment by Dr Allo. The 9-year association that our Section of Surgical Oncology has had directly with the BCCP has not only established follow-up algorithms for managing patients but also allowed us to develop a review system where cases requiring additional input are referred to the Section of Surgical Oncology; we actually review them for quality and for follow-up in a prospective fashion. We also have been directly instrumental in helping the BCCP design the state-wide guidelines, so we really have a very tight association with the program. It is an example of the mutually beneficial relationship that results when surgeons are involved in the design and implementation of a state breast cancer screening program from the outset.

I also want to thank Dr Jimenez-Lee, who is our breast fellow this year and a recent graduate of the surgical training program at the University of Puerto Rico in San Juan, for the fine work he did on this project and this great presentation. This was Ricardo's first presentation at a major medical meeting, and it was done in his second language. As for my second language, I am still working on my first, so bear with me as I get through all of these great questions.

I want to thank Dr Theuer for his insightful questions and congratulate him on his PCSA membership. He asked, does mammography complement CBE? As a matter of fact, he alluded to the very confusing paper by Gotzsche and Olson that came out of the Cochrane Institute but, as many of us know, did not actually bear the imprimatur of the Cochrane Institute and led kind of a firefight within *Lancet*, which was amazing to see, between the Cochrane researchers and the Cochrane staff. Gotzsche and Olson analyzed 7 trials and threw out 5 of them. One of the trials that they did not throw out was the Canadian National Breast Cancer Trial, which was a very unusual trial. It basically randomized patients to get mammography and CBE vs CBE alone, so it was the only trial that looked at screening with only CBE. Basically, there was no difference between the

arms, which led in part to the Gotzsche and Olson conclusion. When that trial was analyzed, it was discovered that half of the mammograms did not "measure up" in an independent screening; half were found to be of poor quality. What the trial really says to most of us is that the addition of poor mammography adds nothing to good CBE. Thus, we have to be very careful about the quality of mammography.

I give a lot of credit to Dr Gerald Dodd here in this country, who has been the head of radiology at the M. D. Anderson Cancer Institute, for really setting American standards of mammography and quality. Mammography does complement CBE, but it has to be good mammography.

Why such a high compliance rate? Dr Jimenez-Lee alluded to all of the reasons. The staff actually did the translation and transportation work. I think it is a compliment to the surgeons in the community who provided gratis care. Why did patients refuse therapy in our experience? They don't refuse it very often, but there are always some patients, even with all that good translation and other services, who are just not going to go along with the recommendation.

One statistic that was not mentioned was that about 60% of patients with partial mastectomy went on to radiation. Part of that is because some of these patients had low-grade DCIS [ductal carcinoma in situ] and didn't need it; part of it is because the data didn't capture it in time because it takes up to 6 months to get on to radiation and those patients may not yet have their radiation registered in the database. However,

some patients did refuse radiation. That continues to be a problem.

Dr Theuer's third question alludes to the fact that we are moving into the incidence phase, and I think that is the exciting phase of the program, to look at where we are screening truly asymptomatic women. As you know, most of the Swedish trials actually show their increase in survival in the incidence phase, after the prevalence phase has already treated the women who are out there but (and this is relevant to Dr Schecter's comment), unfortunately, because of our medical system, are waiting for programs like this to come forward, admit they are symptomatic, be discovered by a program, and get some treatment. This is a real part of what we were seeing in the first 5 years of this program.

How is the symptom assessment done? We work with what are called MDEs, minimal data elements, so the symptom data are somewhat sketchy, which is why we did not present a lot of it. I think one of the improvements in the program in the future will be to track symptom data better.

I thank Dr Wagman for his comment that this is surveillance and not screening. That is true. Prevalence-phase studies are surveillance studies, and, again, the exciting part is to move into the true screening or true incidence phase. How many women were rescreened? I agree with Dr Allo that those numbers are too low, but ours were not as depressingly low as some programs. About 33% of women went on to at least a second cycle.