The Economic Impact of False-Positive Cancer Screens

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Abstract

Objective: **Despite the promotion and widespread use of routine cancer screening, little is known about the economic consequences of false-positive screening results. We evaluated the medical and nonmedical costs associated with false-positive prostate, lung, colorectal, and ovarian cancer screens.**
Method: **We identified 1,087 Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial participants enrolled in a large managed care organization. Medical care use and costs were compiled from automated sources and trial data. Nonmedical care costs to patients with a false-positive lung cancer screen were obtained by telephone interview (n = 98).**
Results: **Forty-three percent of the study sample incurred at least one false-positive cancer screen. The majority of these patients (83%) received follow-up care. Prior to and after controlling for participant characteristics, significantly higher medical care expenditures in the year following screening were found among those with a false-positive screen. The adjusted mean difference was $1,024 for women and $1,171 for men. Among lung cancer screening patients, few nonmedical care costs were identified beyond the time (mean, 1.5 hours) spent receiving care.**
Conclusion: **The results here indicate that false-positive results among some available cancer screening tests are relatively common, that patients incurring a false-positive screen tend to receive follow-up testing, and that such follow-up is not without associated medical costs. Along with trials evaluating the health benefits of available cancer screening modalities, investigations into potential undesirable consequences of cancer screening are also warranted.** (Cancer Epidemiol Biomarkers Prev 2004;13(12):2126–32)

Introduction

Given the morbidity, mortality, and economic costs associated with cancer, it is not surprising that many advocate for routine screening (1-3). Yet, whereas many cancer screening recommendations are evidence based, some are not (1, 4-8), and screening is not without possible adverse consequences such as physical risks, anxiety, and added expenditures.

Little attention has been paid to the adverse effects of cancer screening including the consequences of a false-positive cancer screen. Although there is some evidence of increased medical care utilization following a positive (9) or false-positive (10, 11) cancer screen, the medical care cost of such increased utilization is generally not known (11). Nor is it known what the economic burden is to patients and their families. We determined the medical care utilization and costs associated with false-positive prostate, lung, colorectal, and ovarian cancer screens and the nonmedical care costs of false-positive lung cancer screens incurred by patients and their families. Understanding the magnitude of such costs is important, as they are critical to understanding the cost-effectiveness of available cancer screening programs.

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Materials and Methods

Study Setting, Population, and Data Sources. We identified a subsample of participants from one site in the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial (12-15), a 23-year multisite randomized trial. At enrollment, PLCO participants were free of cancer, with no history of any of the four study cancers. Participants were randomized to receive either annual cancer screening tests for 6 years or usual care. At baseline, men were screened with serum prostate-specific antigen test, digital rectal examination, flexible sigmoidoscopy (without biopsy or removal of lesions), and chest radiograph, whereas women were screened with serum CA-125 test, transvaginal ultrasound (TVU), flexible sigmoidoscopy (without biopsy or removal of lesions), and chest radiograph. All abnormal suspicious screen results were forwarded to the participant's usual physician. Receipt of diagnostic follow-up testing was at the discretion of that physician's recommendation.

For this study, all participants from one Midwestern site randomized to the intervention arm between December 15, 1993 and December 22, 1999 were identified (n = 10,550). From among this group, we selected those continuously enrolled in the group model division of a large managed care organization affiliated with the PLCO site, assuring the availability of comprehensive information on medical care utilization. This resulted in the identification of 1,087 eligible trial participants.

Data available from the trial included information on screening tests received, date of screening receipt, test results, and, via a baseline questionnaire, sociodemographic information (including education, occupation, marital status, age, and ethnic background), self and family histories of cancer, and smoking behavior history.

Information from the medical group's automated data systems were used to compile dates of health plan enrollment, street address, and medical care utilization and costs. The latter includes information on services delivered by external providers and billed to the managed care organization.

Participants with any abnormal suspicious result at baseline were categorized as incurring a positive cancer screen. Cancer diagnoses were ascertained through the cancer registry maintained by the medical group as well as from PLCO follow-up records. A screen result was considered false positive if cancer was not diagnosed within 1 year (10, 16-21). We identified 127 participants receiving a false-positive baseline chest radiograph in 1998 to interview regarding costs to families and caregivers. Between May and June 2001, we successfully contacted 105 of these individuals, of whom 98 completed telephone interviews.

Analytic Variables. For all analyses, we used a continuous variable reflecting age at the time of screening. Other variables we considered included race (white versus other), marital status (currently married versus not currently married), employment status (currently working versus not currently working), education (less than high school, high school graduate, and any college or postgraduate degree/course), smoking status (current smoker, former smoker, and never smoker), and history of cancer among first-degree relatives (yes/no). Participant street address, in combination with U.S. Census Data, was used to construct an estimate of household income using the census block median household income estimate (22).

We evaluated the use of 44 specific procedures and tests considered by the trial to reflect likely and appropriate follow-up to an abnormal suspicious screening test result. An indicator variable was constructed reflecting receipt of each procedure/test in the 12 months following baseline screening. We also constructed two variables reflective of total medical care expenditures. The first reflects the participant's total medical care expenditures during the 12-month period before study enrollment. The second reflects total medical care expenditures during the 12 months following PLCO trial screening receipt. Costs were estimated using institutional cost-to-charge ratios for services delivered by the health plan's group model division; for services provided by other providers but reimbursed by the health plan, we used the amount paid to the external provider organization. Using the Consumer Price Index-U.S. Medical Care (23) conversion factor, all monetary amounts are expressed in year 2000 dollars.

From the telephone interviews, we constructed continuous variables including number of travel minutes required to receive the follow-up procedure(s), number of miles traveled, and total time (in minutes) spent receiving the procedure (from time of arrival to time of departure). We constructed indicator variables for whether additional expenses were incurred, time was taken off from work, and subjects were accompanied as a result of receiving the follow-up procedure(s). Continuous variables measuring out-of-pocket cost (in dollars and cents) associated with follow-up care receipt as well as any foregone income were also constructed.

Statistical Methods. Differences in participant characteristics by screening test outcome were evaluated using Wilcoxon rank sum tests for continuous constructs and χ^2 or Fisher exact tests, as appropriate, for categorical variables. Follow-up care differences by screening test outcome were evaluated using χ^2 tests. Differences in medical care expenditures by screening test outcome were evaluated using Wilcoxon rank sum tests (''unadjusted'') and multivariable models that controlled for subject characteristics (''adjusted''). Adjusted differences were assessed using multiple regression methods in which the log-transformed cost of care was modeled as a function of false-positive screen indicators, prior year expenditures, and participant characteristics. Retransformations of the log costs were done using a residual smearing estimate with corrections for heteroskedasticity (24). All analyses were stratified by sex.

Results

Forty-three percent of the participants (n = 466) had at least one false-positive test at baseline. Men incurred at least one false-positive test significantly more often than women (51% versus 36%; $P \leq 0.0001$). The proportion of false-positive results varied by screening test, ranging from 0.5% for CA-125 in women to 29.3% for flexible sigmoidoscopy in men (Table 1). We found few significant differences in patient characteristics between those participants with at least one false-positive test versus those without (Table 2). Men with a false-positive test were significantly older and more likely to reside in lower income areas. The only difference among females was that women who incurred a false-positive test were significantly more likely to be current smokers.

Among participants with a false-positive test, 19.0% did not receive any follow-up care in the 12 months

Table 1. Test outcome by sex and screening test

Sex	Screening test	False-positive result (%)	Negative result* (%)
Men (n = 501)	Prostate-specific antigen	8.0	92.0
	Digital rectal examination	7.2	92.8
	Chest radiograph	18.8	81.2
	Flexible sigmoidoscopy	29.3	70.7
	Any positive test	50.9	49.1
Women (n = 586)	CA-125	0.5	99.5
	TVU†	3.2	96.8
	Chest radiograph	16.9	83.1
	Flexible sigmoidoscopy	19.4	80.6
	Any positive test	36.0	64.0

*Includes negative, abnormal not suspicious, inadequate and incomplete test results.
†TVU: transvaginal ultrasound

Table 2. Baseline patient characteristics by sex and screening test result [mean ± SD for continuous variables and *n* (%) for categorical variables]

	Males (*n* = 501)		Females (*n* = 586)	
	Negative* (*n* = 246)	False positive (*n* = 255)	Negative* (*n* = 375)	False positive (*n* = 211)
Age†	63.0 ± 5.4	64.4 ± 6.0	62.7 ± 5.3	63.3 ± 5.5
Race				
White	198 (80.5)	201 (78.8)	287 (76.7)	146 (69.2)
Other	48 (19.5)	54 (21.2)	87 (23.3)	65 (30.8)
Education				
Less than high school	34 (13.9)	46 (18.0)	42 (11.2)	24 (11.4)
High school	41 (16.7)	38 (14.9)	115 (30.8)	66 (31.4)
Post–high school course/degree	170 (69.4)	171 (67.1)	217 (58.0)	120 (57.1)
Employment status				
Working	95 (38.8)	83 (32.9)	140 (37.4)	68 (32.4)
Marital status				
Married or living as married	218 (88.6)	215 (84.3)	253 (67.5)	132 (62.6)
Smoking (≥6 mo)‡				
Never	93 (37.8)	74 (29.1)	209 (55.7)	103 (48.8)
Former	125 (50.8)	137 (53.9)	138 (36.8)	62 (29.4)
Current	28 (11.4)	43 (16.9)	28 (7.5)	46 (21.8)
Family history of cancer				
Immediate family member	119 (48.6)	115 (45.5)	196 (53.0)	125 (59.5)
Household income ($)§	41,502 ± 17,206	38,254 ± 16,916	40,112 ± 16,127	38,032 ± 16,740
Costs in years prior to randomization ($)	3,147 ± 8,438	3,208 ± 6,623	2,148 ± 3,177	1,879 ± 3,726

*Includes negative, abnormal not suspicious, inadequate and incomplete test results.
†Men with a false-positive test result are significantly older than those without a false-positive result ($P < 0.007$).
‡Women with a false-positive test result are significantly more likely to be a current smoker than those without a false-positive result ($P < 0.0001$).
§Men with a false-positive result reside in areas with a significantly lower income than those without a false-positive result ($P = 0.0174$).

following screen receipt. This ranged from a high of 22.2% and 21.2% of those receiving a false-positive prostate and colon cancer screening test result, respectively, to a low of 16.7% and 15.2% among those receiving a false-positive ovarian and lung cancer screening test result, respectively.

Although some individuals who incurred a false-positive screening test result did not receive any follow-up, the majority did. The most frequently received tests for men with a false-positive prostate cancer screen were repeat prostate-specific antigen (66.7%) and prostate biopsy (38.9%; Table 3). The most frequently used follow-up tests for women with a false-positive ovarian cancer screen were repeat CA-125 (55.6%) and pelvic ultrasound (44.4%). The majority (79.7%) of those individuals with a false-positive lung cancer screen received a repeat chest X-ray. For those with a false-positive colon cancer screen, 60.1% received colonoscopy and 12.4% received a repeat flexible sigmoidoscopy. All procedures were significantly more likely to be experienced by those with a false-positive screening test.

Table 4 presents the unadjusted differences in medical care costs incurred in the 12-month period following screening receipt between those incurring and those not incurring a false-positive screening test. Both men and women with a false-positive screen experienced significantly higher medical care expenditures in the year following screening receipt. In both male and female multivariable models, a false-positive screen resulted in significantly higher medical care costs in the year following screening receipt (Table 5). Higher costs did not extend beyond this 12-month period (data not shown). Models controlling for which screening test(s) resulted in a false positive (Table 6) indicate that a false-positive flexible sigmoidoscopy was a primary cost driver for both males and females. For females, a false-positive TVU result also resulted in significant increases in expenditures.

Table 3. Commonly received follow-up care in the 12 months following screening test receipt by cancer site and test result (%)

Site and procedure	False positive (%)	Negative* (%)	*P*
Prostate	*n* = 36	*n* = 407	
Prostate-specific antigen	66.7	21.9	<0.0001
Prostate biopsy	38.9	1.7	<0.0001
Lung	*n* = 138	*n* = 868	
Chest X-ray	79.7	21.3	<0.0001
Colon	*n* = 193	*n* = 813	
Colonoscopy	60.1	2.3	<0.0001
Flexible sigmoidoscopy	12.4	1.8	<0.0001
Ovarian	*n* = 18	*n* = 545	
CA-125	55.6	1.1	<0.0001
Pelvic ultrasound	44.4	6.1	<0.0001
Pelvic magnetic resonance imaging	16.7	0.2	<0.0001
Pelvic computed tomography	16.7	1.1	0.0021
Laparoscopy	11.1	1.7	0.0448
Abdominal computed tomography	11.1	0.7	0.0134

NOTE: Because of the challenges in attributing care to a specific test result, 77 individuals with a false-positive screen result in more than one cancer site were excluded. Only procedures/tests considered appropriate follow-up and received by ≥10% of false-positive groups are presented.
*Includes negative, abnormal not suspicious, inadequate and incomplete test results.

Table 4. Unadjusted mean and median medical care expenditures in the year following cancer screening receipt by sex and screening test result

Screen result	Male			Female		
	n	Mean* (SD)	Median (range)	*n*	Mean* (SD)	Median (range)
False positive ($)	255	3,781 (5,577)	2,016 (0-39,232)	211	5,359 (19,451)	2,075 (0-265,636)
Negative† ($)	246	2,569 (5,337)	830 (0-35,764)	375	3,055 (5,926)	1,143 (0-50,142)

*P < 0.0001.
†Includes negative, abnormal not suspicious, inadequate and incomplete test results.

Table 7 presents the adjusted mean costs in the year following screening receipt by sex and screening test for those tests for which differences were statistically significant. Females who incurred a false-positive flexible sigmoidoscopy or TVU had significantly higher medical expenditures ($1,762 and $4,900, respectively), as did males with a false-positive flexible sigmoidoscopy ($2,001).

Among the participants with a false-positive chest radiograph, per subject self-report, an average of 53 minutes was spent receiving follow-up care and the mean time spent in travel was 42 minutes (round trip), for a total of just over 1.5 hours of time spent on follow-up testing (Table 8). The vast majority of subjects drove themselves to and from their follow-up appointment(s). Only two (both of whom walked) used a mode of transportation other than a private automobile. Only 17% of follow-up visits were accompanied and <8% of subjects missed work or forewent income to receive follow-up care.

Discussion

Surprisingly little is known about the consequences of false-positive cancer screens. Recent studies have explored the effect of a false-positive cancer screen on repeat cancer screening participation (11, 25-29) and one's likelihood to be diagnosed with cancer (30). False-positive screening results have consistently been shown to be anxiety producing (6, 19, 20, 28, 31-37) and lead to uncomfortable and potentially costly clinical work-ups (5-7, 28, 31, 37, 38). The actual costs of such clinical work-ups rarely have been studied.

Consistent with the findings of others documenting relatively high false-positive rates (10), we found a substantial number (~43%) of those undergoing cancer screening to incur at least one false-positive result. Our false-positive definition (12 months of follow-up post–positive test without a cancer diagnosis) is consistent with others. It should be noted however that extending the cutoff likely would not alter our results, as only 13 additional individuals with a baseline abnormal test result were diagnosed with cancer during the subsequent 12 months (i.e., months 12-24 of follow-up).

The majority of individuals who incurred a false-positive screen result received some type of follow-up care in the year following their screening. Despite some individuals not receiving any follow-up care, rates of medical utilization for specific follow-up tests were almost always higher in the false-positive group. This translated into significantly more medical care costs. We found the adjusted mean difference in medical care costs in the 12 months following screening receipt was $1,024 for women and $1,171 for men.

A substantial portion of this increase in medical care expenditures, regardless of sex, can be attributed to those

Table 5. Multiple regression results: log medical care costs in the year following screening receipt and screen test results

Variable	Males (*n* = 482)			Females (*n* = 566)		
	β	SE	*P*	β	SE	*P*
Any false-positive screen	0.53	0.20	0.0099	0.62	0.20	0.0020
Multiple false-positive screens	0.57	0.31	0.0715	0.43	0.49	0.3799
Age	0.05	0.02	0.0129	0.01	0.02	0.4880
White race	0.78	0.25	0.0019	−0.23	0.24	0.3291
Education			0.4911			0.4873
Less than high school	0.00	—		0.00	—	
High school degree	0.28	0.34	—	0.36	0.32	—
Post–high school course/degree	0.34	0.28	—	0.35	0.31	—
Income*	−0.08	0.06	0.1793	−0.03	0.06	0.6686
Married	0.13	0.29	0.6626	−0.12	0.21	0.5750
Smoking status			0.4630			0.5867
Never	0.00	—	—	0.00	—	—
Current	−0.32	0.30	—	−0.16	0.30	—
Former	0.03	0.22	—	0.14	0.20	—
Currently working	−0.61	0.24	0.0109	−0.54	0.21	0.0110
Family history of cancer	0.15	0.19	0.4455	−0.33	0.18	0.0719
Prior year expenditures*	0.57	0.13	<0.0001	1.51	0.27	<0.0001
Intercept	2.62	1.37	0.0566	5.68	1.37	<0.0001

*Income and prior year expenditures reflect $10,000 increments.

Table 6. Multiple regression results: log medical care costs in the year following screening receipt by type of screening test

Variable	Males			Females		
	β	SE	*P*	β	SE	*P*
False-positive prostate-specific antigen	0.30	0.35	0.3892	—	—	—
False-positive digital rectal examination	0.16	0.37	0.6721	—	—	—
False-positive chest radiograph	0.26	0.24	0.2803	0.27	0.24	0.2727
False-positive flexible sigmoidoscopy	0.89	0.21	<0.0001	0.77	0.24	0.0013
False-positive TVU	—	—	—	1.17	0.53	0.0271
False-positive CA-125	—	—	—	1.57	1.54	0.3085
Age	0.05	0.02	0.0081	0.01	0.02	0.5332
White race	0.78	0.25	0.0020	−0.25	0.23	0.2898
Education			0.5459			0.3949
Less than high school	0.00			0.00		
High school degree	0.21	0.34		0.42	0.32	
Post−high school course/degree	0.31	0.28		0.40	0.31	
Income*	−0.08	0.06	0.1710	−0.03	0.06	0.6412
Married	0.12	0.29	0.6704	−0.12	0.21	0.5693
Smoking status			0.3834			0.5091
Never	0.00			0.00		
Current	−0.39	0.30		−0.22	0.30	
Former	−0.03	0.22		0.14	0.20	
Currently working	−0.65	0.24	0.0071	−0.56	0.21	0.0085
Family history of cancer	0.15	0.19	0.4234	−0.31	0.19	0.0982
Prior year expenditures*	0.57	0.13	<0.0001	1.52	0.27	<0.0001
Intercept	2.48	1.37	0.0713	5.94	1.33	<0.0001

*Income and prior year expenditures reflect $10,000 increments.

with a false-positive colorectal cancer screen. As is clinically indicated, almost two thirds of these patients, regardless of sex, went on to undergo colonoscopy. As it is generally believed that colorectal cancers have their origins in adenomatous polyps, in addition to early detection, one of the goals of colorectal cancer screening and follow-up is prevention via removal of such polyps. Among a convenience subsample of those with a false-positive colorectal cancer screening test result (n = 167), we found that the pathology reports for 32% of the 310 specimens contained ''adenoma,'' ''adenomatous,'' or ''villous adenoma'' in the pathologic diagnosis, thereby suggesting that a portion of this follow-up cost contributed to cancer risk reduction.

On a per person level, our findings do not support the notion that medical care costs associated with false-positive cancer screening tests contribute to exorbitant medical care expenditures. However, our findings may have implications for previously conducted cost-effectiveness analyses that ignore follow-up care beyond a few easily defined procedures. For example, previous studies evaluating the cost-effectiveness of colorectal cancer screening assume follow-up consists of one colonoscopy at a cost between a few hundred dollars and $1,000 (39, 40), We document cost differences approximately twice this amount. This amount ($1,700-2,000) is consistent with the average sum total of all professional and technical costs incurred on the day of the colonoscopy along with subsequent pathology costs among our sample. In a recent review of seven cost-effectiveness analyses of colorectal cancer screening, Pignone et al. (39) concluded that although colorectal cancer screening seems to be cost-effective compared with no screening there is no sufficient evidence to recommend one optimal screening modality. Whether using higher colonoscopy cost estimates such as those

Table 7. Adjusted mean costs in the year following cancer screening receipt by sex, screening test, and test result ($)

Screen result	Total*	Flexible sigmoidoscopy†	TVU‡
Female			
False positive	4,264	5,299	8,851
Negative*	3,240	3,537	3,951
Male			
False positive	3,741	4,880	
Negative*	2,570	2,879	

*Includes negative, abnormal not suspicious, inadequate and incomplete test results.
†Statistically significant effect of false-positive test result (see Table 5).
‡Statistically significant effect of false-positive test result (see Table 6).

Table 8. Nonmedical care costs of a false-positive lung cancer screening (n = 98)

	%	Mean (standard deviation)
Time costs		
No. minutes spent receiving care		53 (40.7)
No. minutes spent traveling (one-way)		21 (17.3)
Visits accompanied by someone else	17.2	
Lost employment*		
Visits requiring time off work	7.7	
Lost wages ($)		35.25 (37.7)
Distance traveled		
Miles traveled (one-way)		12 (13.1)
Incidental expenses		
Visits with incidental expenses (meals, child/elder care, etc.)	5.9	
Incidental expenses incurred ($)		32.10 (40.7)

*Thirteen visits involved time lost from work; of these, 7 (54%) resulted in actual lost wages.

found here would alter the results and conclusions from these studies is not known.

We did find that after the first year following baseline screening there were no significant differences in medical care expenditures between those with and those without a false-positive cancer screening result, implying that any differences in costs dissipate quickly. On the other hand, these estimates are likely conservative, as they do not include out-of-pocket expenditures. In addition to medical care costs, patients (at least those incurring a false-positive lung cancer screen) also invest their own time in receipt of such care. Although we found few nonmedical care costs beyond the average 1.5 hours spent by the patient receiving lung cancer screening follow-up care, at a population level, 1.5 hours add up quickly to a substantial time investment.

The weaknesses of our study should not be ignored. Sample members were enrollees in a clinical trial designed to evaluate the effectiveness of screening for prostate, lung, colorectal, and ovarian cancer. By definition, the effectiveness of these screening tools is therefore debatable. Whether this may lead to follow-up patterns that are reflective of other types of cancer screening where the clinical evidence of effectiveness is better documented is not known.

Further, although colonoscopy is now considered a viable colorectal cancer screening option, it was not considered one at the time of the study.

In addition, because sample members are enrolled in a clinical trial, their behavior and the recommendations of their physicians may not generalize beyond the current setting. It should be noted however that follow-up care was not part of the trial and was left to the discretion of each participant's usual physician. Further, the analyses were limited to subjects enrolled in one location. Finally, it is important to emphasize that the present study addresses only a small component of the economic consequences associated with cancer screening. In addition to the costs associated with false-positive screen results, a comprehensive economic evaluation would also consider the potential direct and indirect cost savings associated with early detection and reduced cancer-related morbidity and mortality.

Yet, findings here add to the growing body of literature highlighting the importance of understanding the morbidity and mortality benefits of available cancer screening tests as well as the specificity and sensitivity of available screening tools. For prostate, lung, colorectal, and ovarian cancer, the PLCO screening trial funded by NIH will provide needed information regarding both screening test characteristics and associated morbidity and mortality benefits. As the characteristics and health benefits of cancer screening tests are documented, so should the associated economic costs be evaluated. When false-positive findings and their consequences are explicitly considered in economic evaluations, model results are often sensitive to the assumed rate of false-positive screens (41-44). These results have led some to argue that the cost-effectiveness of different screening programs are primarily driven by rates of false-positive screens among other undesirable outcomes (e.g., overdiagnosis) (45, 46). The reality is that false-positive findings among those undergoing cancer screenings are relatively common, usually constituting the large majority of all positive findings and often leading to follow-up investigations that do not result in a cancer diagnosis (9, 28, 29, 47). Given the potential economic and other implications of a false-positive cancer screen result, it is important that when patients are offered cancer screening it is within a context that allows informed decision-making. This is especially critical for prostate, lung, colon, ovarian, and other cancers for which the clinical evidence regarding screening effectiveness is still evolving.

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