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Seminar article

Delivering prostate cancer prevention messages to the public: how the National Cancer Institute (NCI) effectively spread the word about the Prostate Cancer Prevention Trial (PCPT) results

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Abstract

The Prostate Cancer Prevention Trial was the first clinical trial to show that a direct intervention (5 mg of finasteride daily for 7 years) could reduce a man's risk of developing prostate cancer. Initial results also suggested that men taking finasteride had an increased risk of developing what appeared to be higher-grade disease (Gleason score 7–10). The National Cancer Institute has a congressional mandate to communicate health information to the public and has established methods to reach the public directly and to reach information intermediaries in the media, professional societies, and advocacy groups. The groundbreaking yet complicated results of the Prostate Cancer Prevention Trial were widely disseminated by National Cancer Institute using the social marketing and public-relations strategies and tactics detailed here.

Keywords: PCPT; Public health message; Media; Diffusion of innovations theory; Consumer information processing; Finasteride; Prostate cancer prevention

Introduction

The Prostate Cancer Prevention Trial (PCPT) was a randomized, placebo-controlled clinical trial of more than 18,000 men aged 55 and older that demonstrated that a drug intervention—a 5-mg daily dose finasteride [4-azaandrost-1-ene-17-carboxamide, N-(1,1-dimethylethyl)-3-oxo-,(5a, 17b))] taken for 7 years—can reduce a man's risk of developing prostate cancer by 25% [1]. However, men in the PCPT who took finasteride and developed prostate cancer had an increased risk of developing tumors that appeared to be high-grade disease (Gleason score 7–10).

The PCPT was funded by the National Cancer Institute (NCI) and coordinated by the Southwest Oncology Group (SWOG), a cooperative research organization based in San Antonio, Texas. Via the 1971 National Cancer Act and its amendments, the NCI has a federal mandate to communicate cancer information to researchers, health professionals, and the public [2–4]. Using social marketing and public-relations principles, the NCI, with assistance and cooperation from the SWOG and the investigators within the PCPT, communicated the complicated results of this landmark prevention study to the public and to health professionals both directly and via specific intermediaries in the media, professional medical societies, and advocacy groups.

There were five main concerns about communicating the PCPT results: 1) to accurately convey the scientific excitement that prostate cancer risk was shown to be reduced with a drug intervention; 2) to appropriately explain the side effects, both well-documented and potential; 3) to discuss the risk-benefit trade off associated with any drug intervention; 4) to impress upon the public that prevention interventions such as finasteride are not acute medical decisions but should be made after careful consideration; and 5) to deliver these messages in a format understandable to the general public.

Results of the PCPT were published via the *New England Journal of Medicine's* "Early Release" mechanism on June 23, 2003, and in the July 17, 2003, print edition of the journal. Because the *New England Journal of Medicine* has more than 200,000 paying subscribers and because reporters routinely write stories about the articles featured in this journal, the early release of the PCPT results guaranteed widespread publicity about trial results [5].

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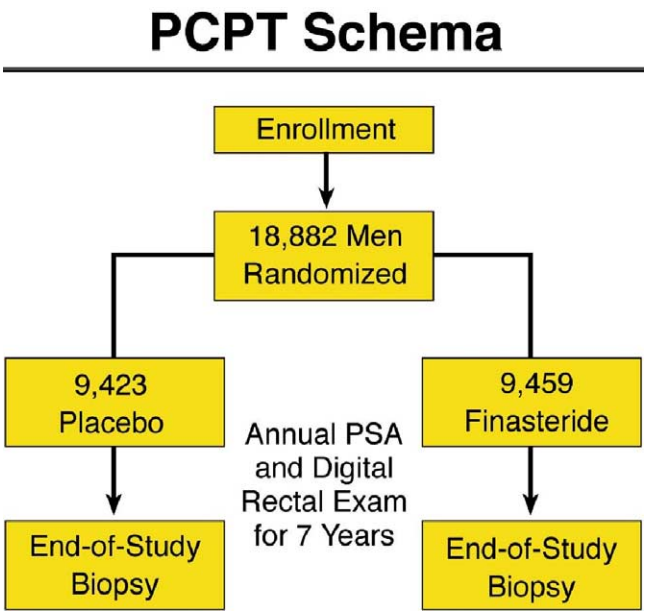

Fig. 1. PCPT schema. This graphic, used in communicating the results of the PCPT, diagrams the overall study design. (Color version of figure is available online.)

PCPT: design and major findings

The PCPT was a double-blind trial of 18,882 men randomized to take either 5 mg of finasteride or a placebo once daily for 7 years, as described in detail in previous publications (Fig. 1) [6]. Participants were men age 55 and older with no evidence of prostate cancer, including a prostate-specific antigen (PSA) level of 3 ng/ml or less. The study design included a prostate biopsy at the end of 7 years of treatment to determine whether men who had not been diagnosed with prostate cancer were truly cancer free. Recruitment began in October 1993, and men participated at a network of 219 sites across the United States (Fig. 2). Participants were predominantly white (92%). African-American men represented 4% of participants, and other races made up the remaining 4%.

On February 21, 2003, the Data Safety and Monitoring Committee, an independent group that met every 6 months to review data on safety, adherence, and diagnoses of prostate cancer, recommended early termination of the study. Committee members felt the data already collected were sound and that the conclusions were unlikely to change with the addition of more data. More than 81% of the men had completed 7 years of drug or placebo.

Major findings

The major finding are thus summarized:

- Prostate cancer was detected in 18% of men in the finasteride group and 24% of men in the placebo group, a reduction of almost 25% over the 7-year trial.
- Tumors of Gleason score 5 and 6 were less common in the finasteride group (60% of tumors or 10.5% of all men evaluated) than in the placebo group (73% of tumors or 16.5% of all men evaluated). This reduction in mainly Gleason 6 tumors can have strong public

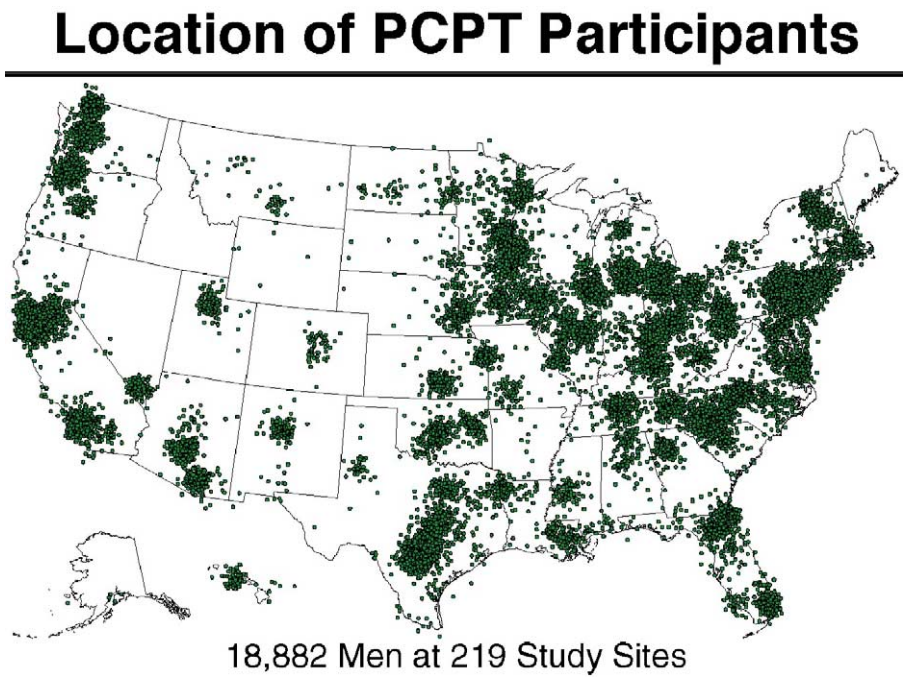

Fig. 2. Location of PCPT participants. This graphic, used in communicating the results of the PCPT, shows the nationwide participation in the study. (Color version of figure is available online.)

health implications since treatment for this stage of disease is subject to debate, and any treatment can have significant morbidity.
- Tumors of Gleason score 7 to 10 were more common in the finasteride group (37% of tumors or 6.4% of all men evaluated) compared with the placebo group (22.2% of tumors of 5.1% of all men evaluated).
- As expected, men taking finasteride were less likely to have urinary symptoms and more likely to have sexual side effects such as impotence than men on the placebo.
- Nearly half of all cancers were detected by end-of-study biopsy in men with a negative digital rectal exam (DRE) and a PSA of less than 4 ng/ml. The remainder was diagnosed after a suspicious screening exam or for other medical causes; this second group reflects how the majority of men in the US are diagnosed with prostate cancer today.

NCI dissemination plan

Planning for the eventual dissemination of PCPT results began when NCI was notified of the planned early termination of the trial in late February 2003. These data represented only the second time that a chemoprevention intervention was found to reduce the chance of the primary development of a major cancer in a healthy population. The first occasion was the early termination of the Breast Cancer Prevention Trial (BCPT) in 1998, when tamoxifen was shown to reduce the development of breast cancer in women at increased risk of the disease [7]. Although critical parallels exist between the trials (large study size, major cancers, pharmaceutical intervention, early termination because of positive study results), one element that the PCPT had that the BCPT did not was the publication of trial results in a medical journal simultaneous with public release. For the BCPT, less than 2 weeks lapsed between the decision to close the trial and public announcement compared with about 3 months for the PCPT, thus allowing a full complement of communications activities to ensue for the PCPT.

NCI understood that data from the PCPT would need astute handling to avoid disseminating misleading or easily confused messages for the following reasons:

- Prostate cancer is one of the most frequently diagnosed cancers in men in the United States. About one in three new cases of cancer in men in 2004 will be prostate cancer [8]. Appropriately, the public has a great interest in prostate cancer and actively seeks information about this common disease: The NCI's Cancer Information Service records indicate that prostate cancer is the third most-common cancer site queried by all callers (female and male) to their service in 2003 (11,477 calls or 9% of the total call volume) and the second most common cancer query for men calling the service (3,444 calls or 19% of the total queries from men) [9].
- The PCPT was the first trial to show that any intervention could affect a man's likelihood of developing prostate cancer and, as such, was a landmark trial. Scientific enthusiasm at the proof-of-principle was appropriate, even if the message to the public was not a simple one of recommending the therapy for all men.
- Finasteride is a drug familiar and available to the public at two doses—as the 5-mg dose marketed as Proscar used to treat benign prostatic hypertrophy and as the 1-mg dose marketed as Propecia, which is used to treat male pattern baldness. Millions of men were already taking the drug for these indications, and the drug could be immediately available off-label if a physician chose to prescribe it. Likewise, if negative results were unduly emphasized, men taking finasteride currently might inappropriately stop therapy.
- The use of an end-of-study biopsy to make an absolute determination of the presence of prostate cancer does not reflect current standard of care for American men; however, data from biopsies performed "for cause" accurately reflect likely medical scenarios. Some interpretation of results to a real-world scenario would be necessary.

The announcement of the findings for PCPT was based on the consumer information processing model. This model, a health communications theory, states that individuals are limited in how much information they can process [10]. According to this concept, before people will process and accept health-related information, it must be available, be seen as directly useful to them, be new, and be presented in a friendly format. The complicated and seemingly contradictory findings of the PCPT made adhering to this model both critical and difficult.

The NCI also applied the diffusion of innovations theory to disseminate the information to the public. This theory states that a new idea or "innovation" is communicated through certain channels over time among members of a social system. The theory also states that an active approach for knowledge transfer must occur from the resource system to the user system, such as from the researchers to others who will make use of the information [11].

To ensure an active transfer of the PCPT results, plans were made for dissemination to be accomplished through four major initiatives: 1) dissemination to the participants themselves; 2) dissemination to the media; 3) dissemination via the Internet; and 4) dissemination to key intermediaries including professional medical organizations, advocacy organizations, and the internal cancer community of NCI employees, grantees, and affiliates. Reaching the public and key audiences via multiple channels increases the odds that a message is heard, and repeated messages are more likely to be remembered.

There were limitations in these strategies and tactics,

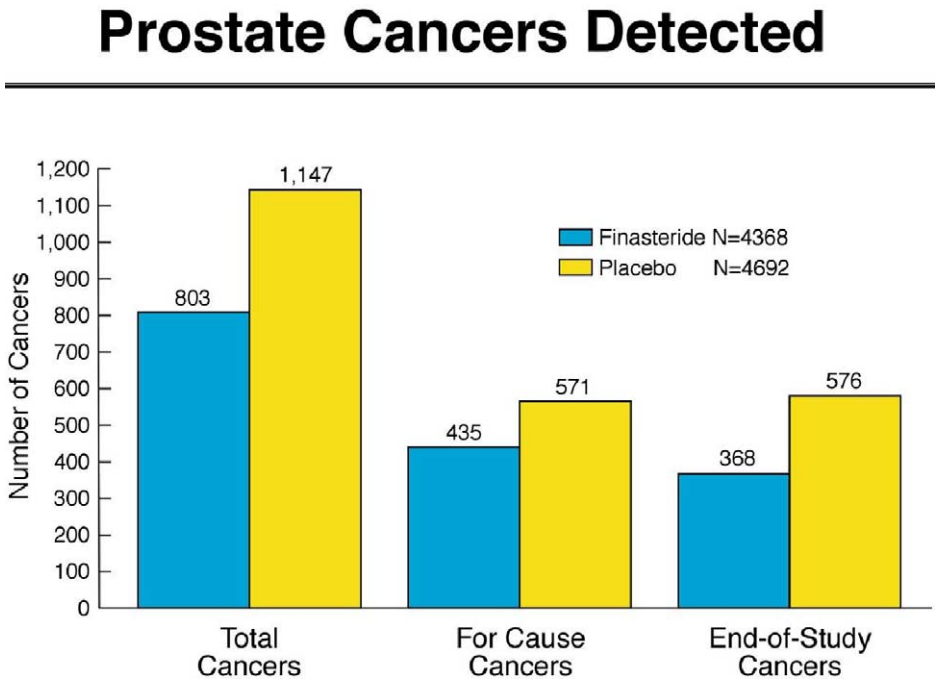

Fig. 3. Prostate cancers detected. This graphic, used in communicating the results of the PCPT, shows the overall trial results of a reduction in diagnosed prostate cancers, whether found by standard medical follow-up, such as an elevated PSA (for cause cancers) or by the end-of-study biopsies required in the study design (end-of-study cancers). (Color version of figure is available online.)

however, because the information was strictly embargoed in accordance with journal rules and because a priority was placed on notifying participants prior to any other audience. All communications occurred within a 24-hour window.

Notifying the participants

The SWOG, with assistance from NCI, drafted a letter for the participants in the PCPT, outlining the main study results and letting them know what to expect now that the study was closed. To ensure the continued secrecy of study results, copies of the letter were produced centrally and shipped in prestamped envelopes to each study site via FedEx on Wednesday, June 18, 2003. The sites were told to distribute the letters to participants either in person or through first-class mail; the letters were to be mailed out no sooner than Friday, June 20, in anticipation of a Tuesday, June 23 presentation of data. This way, no participant would likely receive the study data before Saturday, June 22; reducing the chance that partial information would get to the media prior to the agreed upon publication time.

Reaching the media

Press conference

Because complicated messages are better served in face-to-face environments, a central part of the NCI strategy was to hold a press conference to discuss the results. The conference was held at the National Press Club in downtown Washington, DC, to explain data from the trial and to allow the media to immediately ask questions of key researchers from the SWOG and the NCI. To permit reporters from outside the metropolitan area to hear the press conference, an Internet service that allowed reporters to listen in was activated. This was used in lieu of a telephone audio-conference because it permitted an infinite number of listeners at a flat fee compared to a telephone-based service.

Video news release (VNR)

A VNR is essentially a television news story written and produced by the organization releasing information. By creating a prepackaged news story, which is distributed via satellite to any news organization that wishes to download it, NCI created a succinct telling of the PCPT data from NCI's perspective. Although news organizations rarely use the prepackaged story in its complete format, they can and do use relevant parts of the footage. NCI also has the opportunity to reach the news editors with the story as told by the researchers, with an emphasis on factual information and understandable, key messages. The production of a VNR takes time. However, the needed time was available with this announcement (compared to with BCPT) and was considered a good investment based on reception of a VNR at the outset of the second large-scale prostate cancer prevention trial supported by NCI and the SWOG, the Selenium and Vitamin

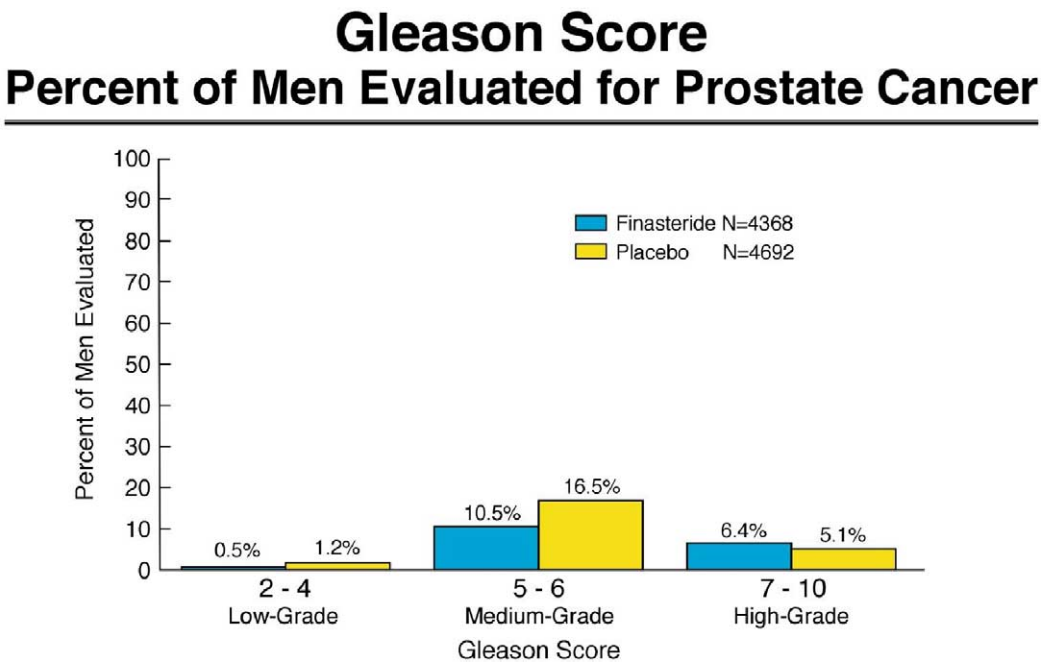

Fig. 4. Gleason score: percent of men evaluated for prostate cancer. This graphic, used in communicating the results of the PCPT, shows the percentage of men found to have prostate cancer and resulting Gleason grade both in men on finasteride and in men on placebo. (Color version of figure is available online.)

E Cancer Prevention Trial (SELECT) [12]. Portions of the SELECT VNR were viewed by more than 77 million people in 584 televised news stories.

Press release and question and answer (Q/A) document

NCI and the SWOG prepared both a press release discussing the findings and a detailed Q/A document to address and explain specific findings to both the media and the public. These documents addressed the major issues listed above, with the exception of the reduction in Gleason 6 disease in men on finasteride, which was emphasized at the press conference only. The Q/A document served as a key information item for the entire information dissemination process. These documents are available at http://cancer.gov/newscenter/pressreleases/PCPTresults.

Posters and graphics

For the press conference and for use in the Q/A described above, as well as the Internet site described below, graphics showing the key findings of the trial were created. Based on previous NCI research, we know that people better understand mathematical concepts when presented in graphical form [13]. The graphics chosen to emphasize key messages are listed below.

PCPT schema/location of PCPT participant

The PCPT Schema showed the basic study design (Fig. 1). The Location of Participants graphic showed a map of the United States with dots to indicate where each participant lived (Fig. 2). The map emphasized the national reach and large trial size.

Prostate cancers detected

Using a bar chart, actual numbers of prostate cancer cases for men taking finasteride versus men taking the placebo were shown. These numbers were further divided between cancers diagnosed “for cause” and by end-of-study biopsy. Separating the data in this fashion showed that while the PCPT design went beyond the standard of medical care in the United States, men diagnosed with prostate cancer prior to the end-of-study biopsy saw a benefit from finasteride (Fig. 3).

Gleason score: percent of men evaluated for prostate cancer

Using a bar chart, this graphic showed the percent of cases in each Gleason category (low-grade, medium-grade, and high-grade disease) for men on placebo versus men on finasteride. The graphic showed the reduction in low-grade and medium-grade tumors in men on finasteride compared to the increase in high-grade tumors in men on finasteride (Fig. 4).

Estimated benefit and risk from finasteride on development of prostate cancer

This graphic, pictured in Fig. 5, combined study data on men diagnosed with prostate cancer ‘for cause’ and population-based data from NCI’s Surveillance Program to estimate the effects of 7 years of finasteride treatment on an average 63-year-old US male. This estimate of

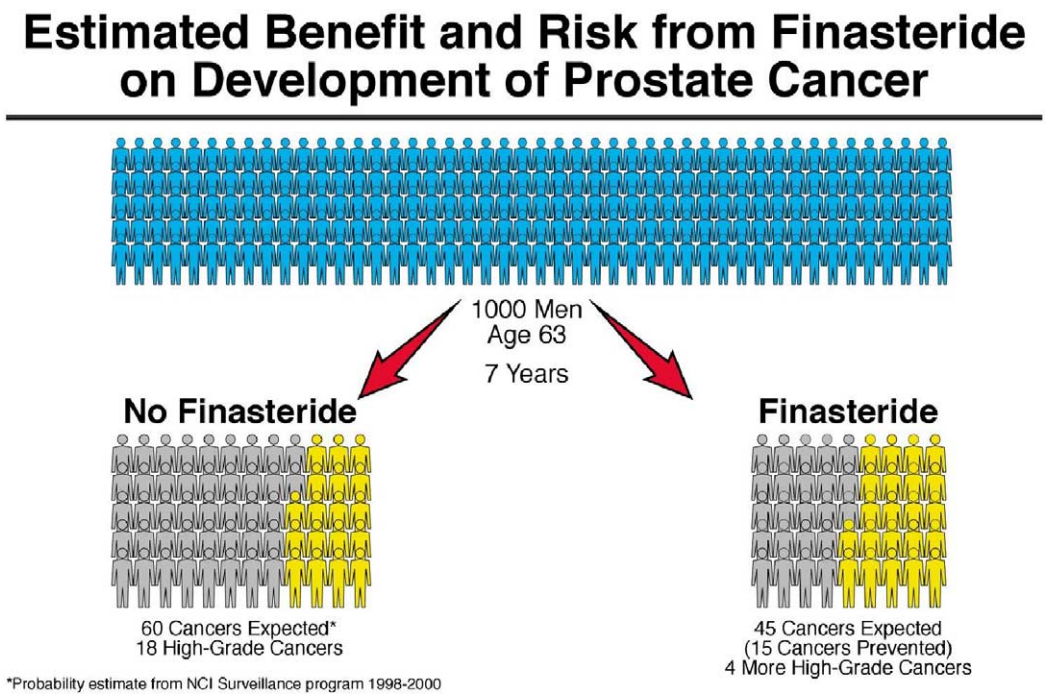

Fig. 5. Estimated benefit and risk from finasteride on development of prostate cancer. This graphic, used in communicating the results of the PCPT, estimates the number of cancers that would occur during the course of 7 years in 1000 men age 63 years and compares that outcome to 1000 men age 63 years who took finasteride for the same 7-year period. The reduction in cancers expected in the finasteride-treated group was calculated based on the reduction in "for cause" cancers in men taking finasteride compared to men on placebo in the PCPT. "For cause" cancers were diagnosed by a method similar to current medical practice. (Color version of figure is available online.)

actual risk/benefit versus relative risk/benefit was done to illustrate what someone could expect from using finasteride to reduce prostate cancer risk "in real life."

Building a Web site

A majority of Americans receive health information via the media, predominantly television, but now a majority of those with Internet access are researching health information with the Internet [14]. By creating a dedicated web page on the NCI web site devoted to information about the trial and trial results, NCI was able to provide direct access to information to all audiences, including to the public directly. A search using the Internet search engine, Google, and entering the search term, *PCPT*, continues to turn up this web page as one of its first ranking positions.

Contacting key intermediaries

Using predominately e-mail channels, NCI disseminated information about PCPT results to NCI staff, appropriate personnel at other government health agencies, NCI Community Clinical Oncology Program members, NCI cooperative clinical cancer groups, NCI-designated Cancer Centers, NCI advisory boards, advocacy organizations for all types of cancers and prostate cancer specifically, and to health professional societies. To increase attention in the news, NCI sent a preview e-mail to these parties noting that new information from a major prostate cancer prevention trial was to be available the next day at a press conference, and that more information would be made available at that time.

Measures of success

Using a variety of available objective and subjective measures, the dissemination of information on the PCPT can be judged successful in both communicating the scientific excitement at the trial results and not creating either false hope or undue alarm about the treatment.

Objective measures

Using standard public relations measures of the success of a media event, the release of data from PCPT was well received. These measures included the following. All the major news networks and affiliates sent camera crews to tape the press conference at the National Press Club. More than 80 individuals attended to report on the results of the PCPT. The following national media outlets reported on the results, generally both via broadcast and on their own Internet sites: CNN, CBS Evening News, CBS Up to the Minute, CBS Morning News, MSNBC, NBC Nightly News,

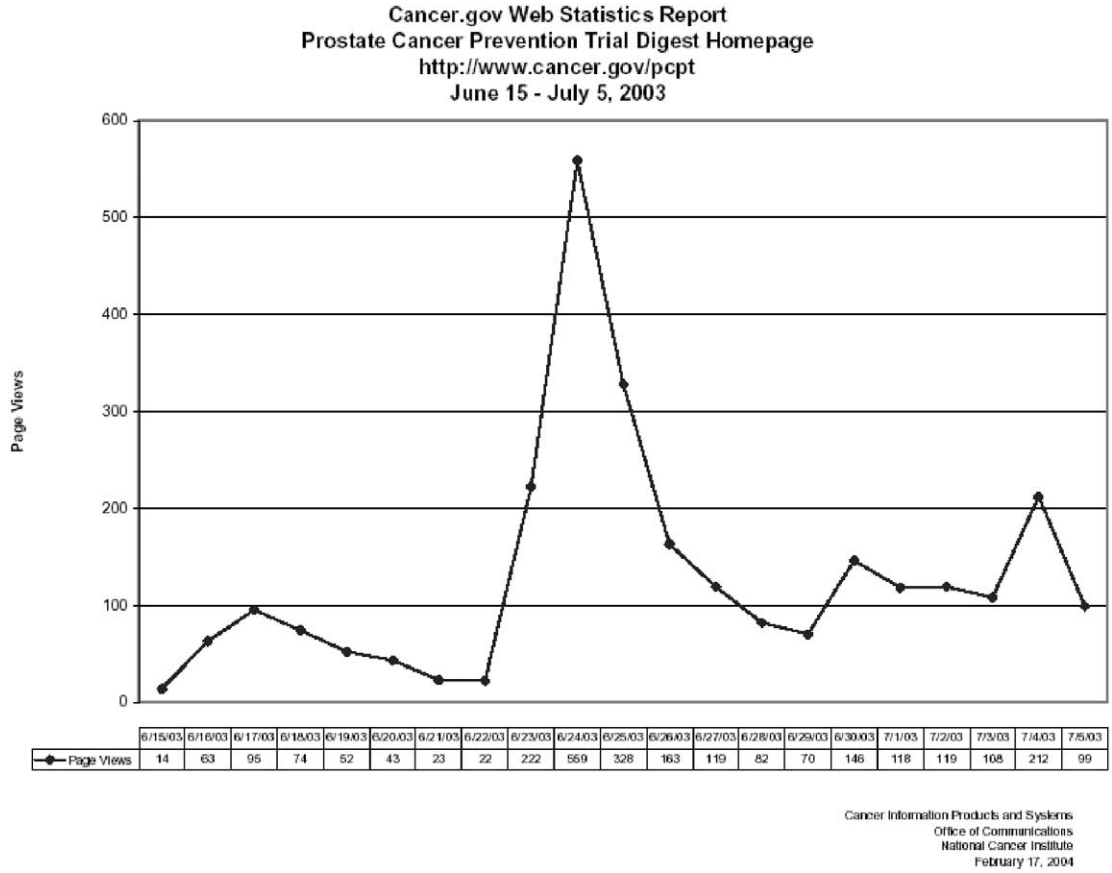

Fig. 6. Cancer.gov web statistics report. This chart shows the increase in Internet traffic to the NCI web page (http://cancer.gov/pcpt) immediately after the release of PCPT results. The web page was promoted in all of NCI's media materials about the trial.

Telemundo, and Univision. Additionally, results were broadcast on CNBC Live as well as on the ABC Radio Network.

Using coded VNR footage, 387 television stations broadcasted 745 news stories on the trial, reaching an estimated audience of more than 69 million [15]. These numbers do not reflect television news stories that did not use the actual VNR footage.

Based on reporting from the Lexis Nexis database and the Factiva database for June and July 2003, PCPT results appeared in 65 original daily news articles, 18 of which were written for publications that also have news distribution services [16,17]. These 18 included the Washington Post, Associated Press (AP), Wall Street Journal, Reuters, New York Times, Los Angeles Times, United Press International (UPI), and others, including business news services. Such syndicated news articles appear in multiple publications both in print and online, but were only counted once here.

The main PCPT web page (http://cancer.gov/pcpt) was viewed 1,495 times the week of June 22–28, 2003, more than four times the amount from the previous week (n = 341). Visitor activity peaked on June 24, the day after the public announcement, when the page was viewed 559 times (Fig. 6).

Subjective measures

Tracking the success of a communications project often relies in part on subjective measurements of success. For instance, the SWOG received virtually no complaints from participants about the letter containing the overall PCPT results. Because the letter was from the principal investigators at the SWOG, instead of from local investigators, the anticipation was that complaints would reach the cooperative group if they were serious (S. Carlin, personal communication, February 2004). Similarly, NCI did not receive complaints from intermediaries who were contacted about receipt of this information. This is telling, given that key constituents who disagree with NCI's actions or interpretations of research frequently provide feedback to the Institute.

Content of a majority of news articles reflected the main concerns identified by NCI: Conveying the scientific excitement of the findings, mentioning the known and potential side effects, discussing the risk/benefit trade off of this intervention, emphasizing that the decision to start or stop taking the drug was not an acute one, and having the message expressed in an understandable way. In addition, the media did not follow up the original story with additional reports of men taking or abandoning the drug in their

confusion with the results, as was the case when results of the Women's Health Initiative showed that combined hormone therapy increased the risk for breast cancer.

The week the results were released, late-night talk show host, Jay Leno, used the findings as part of his monologue, stating: "Researchers have discovered that a drug used to prevent baldness can prevent prostate cancer. The only problem is that there is a side effect. It causes a hairy prostate. Imagine the discussion between a man and his wife."

The media draws parallels to Propecia: 5 mg vs 1 mg dose

Although NCI materials clearly explained that the PCPT results were based on the 5-mg dose of finasteride used to treat BPH and marketed as Proscar, a majority of news outlets described the drug as one used "to treat baldness," drawing a certain parallel with Propecia. This is somewhat understandable because of the popularity of the drug for this common condition but unfortunate because PCPT results cannot be extrapolated to the Propecia dose, which is 1 mg daily.

Conclusion

The multifaceted approach used by NCI to distribute information about findings from the PCPT was successful in raising awareness of the results of the trial. This initial dissemination of results went as well as could be planned, given that clinical trials seeking answers often raise as many new questions with their completion as answers. Using objective measures, media coverage for the story was widespread, including use of materials prepared by NCI and the SWOG, such as the video news release and NCI web page. Subjective review of the news stories and other feedback showed the strategies used were successful in conveying the importance of the finding and the uncertainty of the apparent increase in high-grade disease, the causes of which are being explored in ongoing research.

Commentary

The decision to initiate prevention therapy is an individual one, involving a complex evaluation of potential benefit and risk. The decision is also not an acute one because prostate cancer development is a long process occurring over decades. However, more needs to be done to familiarize the population with the concept of cancer prevention and to better identify individuals at increased risk for developing the disease. It is only through public understanding of the process of carcinogenesis, coupled with interventions that truly stop or reverse the process, that cancer prevention will become as widely accepted as disease prevention in other chronic illnesses.

Acknowledgments

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