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Provider Opinion about Guidance Provided by a Prostate Cancer Screening Educational Pamphlet

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Executive Summary

Problem

Provider Opinion about Guidance Provided by a Prostate Cancer Screening Educational Pamphlet, a quality improvement initiative, addresses the non evidence-based practice of uninformed prostate cancer screening at the Denver Veteran Affairs Medical Center (VAMC). The population of interest is primary care providers (PCPs) in two Denver VAMC primary care clinics, Firm A Clinic and Saturday Intake Clinic. The intervention is the detailed prostate cancer screening educational pamphlet and corresponding discussions. The comparison is the frequency of prostate cancer screening informed decision making in Firm B, another Denver VAMC primary care clinic, without the guidance of the pamphlet. The outcome of interest is PCPs opinion about the pamphlet offering guidance with prostate cancer informed decision making.

Purpose

Patients will continue to request prostate specific antigen (PSA) tests until providers educate them about the pros and cons of screening. The mission of this project is to ensure that Denver VAMC PCP's are fully aware of the latest research and guidelines regarding prostate cancer screening in order to provide accurate information to male veterans in deciding about PSA testing by having them review the educational pamphlet that reflects current evidence- based practice.

Goals

Denver VAMC PCPs must meet the following goals in order for the mission to occur: (a) to be knowledgeable about the latest prostate cancer screening research and guidelines; (b) to explain the risk of prostate cancer to male veterans;(c) to explain the risks, benefit, alternatives, and uncertainties of PSA screening to veterans; (d) to consider the male veteran's values in deciding about PSA screening; and (e) to engage the male veteran in decision making at the desired level.

Objectives

The outcome objectives are the means by which Denver VAMC PCPs will engage in the type of shared decision making that practice guidelines recommend. The measurable project objectives include (a) design and print a prostate cancer screening educational pamphlet using the latest evidence based practice, (b) educate providers in Firm A Clinic and Saturday Clinic about the practice issue, and (c) measure perceptions of PCPs regarding use of the detailed prostate cancer screening pamphlet via a survey. A comparison group, PCPs in Firm B Clinic, provides a link to current practices.

Plan, Outcomes and Results

Outlook email messages were sent to all PCPS. The detailed pamphlet was tested by three PCPs in Firm A Clinic and five PCPs in Saturday Clinic. The eight completed surveys indicated that the brochure did offer Denver PCPs guidance in informing patients about prostate cancer screening. All eight PCPs found the detailed pamphlet informative, with appropriate graphics, and a user friendly format. Some physicians in Firm B do not routinely order PSAs because it is no longer a clinical reminder, but other PCPs order PSAs because of fear of liability.

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The following proposal is a quality improvement initiative, or small scale intervention, linked to Denver Veteran Affairs Medical Center (VAMC) primary care providers' (PCPs) assessment of a prostate cancer screening educational pamphlet (Cassarett, Karlawish, & Sugarman, 2000). Prostate Cancer Informed Decision Making, the original Capstone Project, was changed to Informed Decision Making with the Guidance of Two Prostate Cancer Screening Educational Pamphlets, and changed again, to Provider Opinion about Guidance Provided by a Prostate Cancer Screening Educational Pamphlet. Each revision resulted in simplification, with less data needing to be collected and analyzed, including excluding the need for private information. In other words, measuring the two patient categorical outcomes of informed versus not informed, and prostate specific antigen (PSA) drawn versus PSA not drawn, was replaced by measuring the two provider categorical outcomes of basic or detailed pamphlet preference (see Appendices B and C), and guidance offered versus guidance not offered, by the two prostate cancer screening educational pamphlets. The final revision resulted in measuring PCPs' assessment of the detailed pamphlet, an ordinal level of measurement ranking the responses to survey questions. In retrospect, the change makes good sense because in order for patient's behavior to change, provider's behavior must change first. Patients will continue to request PSA screens until providers educate them about the pros and cons of screening; therefore, educating providers is the logical place to start the implementation of the evidence-based practice of prostate cancer screening informed decision making.

Problem Recognition and Definition

Statement of Purpose

The obligation of a Doctorate of Nursing Practice (DNP) is to change patient care practices that do not promote health and well-being. This challenge is particularly relevant to the practice of prostate cancer screening with a PSA blood test. Providing a detailed prostate cancer screening educational pamphlet to PCPs in two Denver VAMC Clinics is one way to ensure that PCPs will inform Denver male veterans about the pros and cons of prostate cancer screening before PSA testing is offered. The outcome of interest is PCPs' opinion on whether the detailed pamphlet offered guidance regarding prostate cancer informed decision making.

Attempting to identify individuals in a broad segment of the population for latent conditions is a double edged sword because some may benefit while others may be diagnosed and treated for cancer unnecessarily (Schwartz, Woloshin, Fowler, & Welch, 2004). This approach to healthcare is particularly true for cancer screening, especially prostate cancer screening (Schwartz et al.). The healthcare profession has developed a culture that believes searching for cancer is prudent preventative care, and consequently, prostate cancer screening continues without good evidence (Adami, Baron, & Rothman, 1994). Searching for indolent cancer does not promote health and well-being (Perez- Stable, 2009). One way to reverse this practice is to inform men about the pros and cons of screening before offering a PSA test (Krist, Woolf, Johnson, & Kerns, 2007). This project proposes that providers need to learn about the pros and cons of prostate cancer screening, including the recommendation for informed decision

making, in order for screening behaviors to change (Partin et al., 2004). The impact of this evidence-based practice is to decrease the identification of latent prostate cancers and the corresponding treatments, resulting in increased morbidity and decreased quality of life for male veterans.

Problem Statement

Cancer is a heterogeneous disease caused by the development of abnormal cells that divide (Encarta, n.d.). Some cancers are life threatening while others are clinically dormant (Paul & Kunz, 2010). Distinguishing between aggressive and latent cancers is not initially easy; therefore, patients are often diagnosed with a cancer which may have regressed, grown slowly, or not spread (Paul & Kunz). For instance, prostate cancer is the second most common cancer in men besides skin cancer, but the lifetime risk of dying from it is only 2.9% (Hallberg, 2011). Enthusiasm for cancer screening in the United States, promoted by the press and various treatment centers, leads many patients to opt for screening despite false-positive test results and the possibility of unnecessary treatments (Schwartz et al., 2004).

Secondary prevention by screening for prostate cancer with a prostate specific antigen (PSA) test is not evidence-based practice. The goal of secondary prevention is to decrease morbidity and mortality by detecting prevalent, clinically significant cancers before they become symptomatic (Fitzgerald, 2005). Diagnosing and treating preclinical and clinically dormant prostate cancers does not meet the criterion for screening because the benefit of testing does not outweigh the harm (Perez- Stable, 2009). In other words, the benefit of saving a one life does not balance the harm of needless treatment of 48 men (Schroeder, Hugosson, Roobol, M. et al., 2009).

The PSA test was originally used to monitor the response to treatment in patients with prostate cancer (Albin, 2010). Mass population PSA testing was initiated in the late 1980's without well conducted trials to support the benefit of screening (Adami, Baron, & Rothman, 1994). The PSA test was touted as having high sensitivity and specificity, when in fact its ability to identify correctly those who have the disease (sensitivity) is overestimated, and its ability to identify correctly those who do not have the disease (specificity) is underestimated (Hoffman, Fletcher & Rind, 2010). The PSA test, the outcome measure, cannot discriminate between individuals with and without prostate cancer, the outcome evaluated; thus, the PSA test has a poor predictive value.

The lack of definitive data on prostate cancer screening outcomes and the risk of overdiagnosis and treatment have made prostate cancer screening a controversial issue (Hoffman, et al., 2010). The vast majority of prostate cancers currently detected in the United States are asymptomatic, found on routine PSA testing, and are clinically localized (U.S. Department of Health &Human Services, 2008). The modest absolute reduction in mortality from prostate cancer over time comes at the cost of diagnosing and aggressively treating nonprogressive cancers (Pignone, 2009). Additionally, the harms of screening start immediately; whereas, the potential benefits are not realized for years to come (Pignone). For example, many men diagnosed with prostate cancer as a result of screening will not experience clinical problems for years, even without treatment (Hoffman, Fetcher, O' Leary, & Rind, 2011). However, undergoing curative radical prostatectomy and radiation therapies for localized, low-risk disease can lead to immediate complications including long-time life risks such as impotence and incontinence (Goldhagen, 2011). These risks are devastating, especially for those destined to die with, instead of from, prostate cancer.

The American Urologic Association (AUA), American Cancer Society (ACS), U.S. Preventative Services Task Force (USPSTF), and other major medical organizations recommend that providers discuss the risks and benefits of prostate cancer screening before PSA testing is performed by way of shared or informed decision making (Woolf & Krist, 2009). According to Krist et al. (2007), per the USPSTF, "A decision is shared when the patient (1) understands the risk of the disease to be prevented; (2) understands the preventive service, including risk, benefit, alternatives, and uncertainties; (3) weighs his values regarding the decision; and (4) is engaged in the decision at the desired level" (p. 112-113). Recent data shows that few providers are doing this (Gaster et al., 2010). The problem then is that prostate cancer screening is routinely done without informed decision making, and this is not in line with evidenced based practice.

PICO

Evidence-based practice studies often detail the specifics of the study using a patient/population, intervention, comparison, outcome of interest (PICO) format (Houser & Oman, 2011). The question is, does the detailed prostate cancer screening pamphlet guide providers with informed decision making regarding PSA testing?

P: The population of interest is PCPs in the Saturday Intake Clinic and Firm A Primary Care Clinic.

I: The intervention is the detailed prostate cancer screening educational pamphlet and corresponding discussions.

C: The comparison is the frequency of prostate cancer screening informed decision making in Denver VAMC Firm B Primary Care Clinic without the guide of the pamphlet.

O: The outcome of interest is PCPs opinion about the pamphlet offering guidance with prostate cancer informed decision making.

Project Significance, Scope, and Rationale

The USPSTF states that the evidence is insufficient to recommend for or against prostate cancer screening; men age 75 years or older should not be screened, and shared decision making should include discussion of potential risks (Lin, Lipsitz, Miller, & Janakiraman, 2007). In October of 2011, the USPSTF revised their guidelines recommending against screening for prostate cancer with a PSA test, regardless of age, race, or family history (Hoffman et al., 2011). Despite the recommendations, shared decision making is not routine practice because the patient requests the test, the provider favors testing, the PSA is simply added to a requisition for other blood tests, or a PSA is ordered without the patient understanding its purpose and consequences (Woolf & Krist, 2009). Provider reasons for not discussing the risks and benefits of screening include lack of time and competing demands, forgetfulness, limited patient health literacy, and fear of liability (Guerra, Jacobs, Holmes, & Shea, 2007).

Since the emerging role of the DNP is to ensure integration and application of evidence-based practice to patient care, a nurse-sensitive outcome area is to ensure informed decision making about prostate cancer screening at the Denver VAMC. In order for screening behaviors to change, health care provider's behaviors need to change, and that requires education. Providers need to know that the existing evidence from randomized control trials does not support the routine use of screening for prostate cancer with prostate specific antigen, with or without digital rectal exam (Djulbegovic et al., 2010). The detailed prostate cancer screening

pamphlet will educate providers about the limitations of prostate cancer screening with the ultimate goal of patient informed decision making resulting in decreased interest in PSA testing with subsequent improved health outcomes (Casserett, Karlawish, & Sugarman, 2000).

Theoretical Foundation for Project and Change

A DNP is educated to improve health care by looking at the whole picture through empiric science, personal knowing, ethics, and aesthetics. Emancipatory knowing integrates the four fundamental patterns of knowing. Praxis, the process of emancipatory knowing, involves instituting healthcare changes designed to provide the highest level of care (Chinn & Kramer, 2008). Prostate cancer screening and treatment was born out of empiric knowledge. This practice leads to nearsighted care because the other forms of knowing were omitted. Adami (2010) sums up the practice of prostate cancer screening well, "Although cancer screening is intuitively appealing, the logistic complexities, ethical dilemmas and potential harms of intervention in healthy populations are often underestimated" (p.300). Therefore, patients need to be asked if they would be willing to accept a high risk of side effects from treatment in return for a small chance of living longer, along with other personal knowing, ethical, and aesthetic questions. For example, does the patient want to know if he has prostate cancer, even if the cancer might never do him any harm, or, how important is sex in his life? (Hoffman et al., 2011).

A conceptual model outlines the Capstone Project starting with the initial model and two revisions (see Appendices D, E, and F). The final model was started with the outcome, provider's opinion about guidance provided by the pamphlet. The population was further defined by concepts borrowed from the Health Belief Model, a model developed by Rosenstock in 1966, and furthered by Becker and colleagues in the 1970s and 1980s, to explain preventative

behaviors (Kane & Radosevich, 2011). The intervention, prostate cancer screening educational pamphlet, was appropriately given a less impressive spot than the perceived threat of prostate cancer, depicted in the large oval. The perceived threat of prostate cancer, propagated by the mass media and other cancer screening enthusiasts, results in misinformed decision making (Ablin, 2010).

The Health Belief Model suggests that an individual's perception about the seriousness and susceptibility of prostate cancer is the driving force behind screening. The perceived threat of prostate cancer is modified by age, education level, social class, personality, mass media, knowing a prostate cancer victim, philosophy of life, and advice from family, friends, and other health care providers. A belief in the efficacy of prostate cancer treatment leads to screening (Kane & Radosevich, 2011). In fact, most Americans believe that finding cancer early saves lives, and 56% of those surveyed want screening for clinically irrelevant cancers (Perez-Stable, 2009). On the other hand, studies of prostate cancer screening decision aides consistently show that enhanced knowledge is associated with decreased interest in screening (Hoffman et al., 2009). For example, one study randomly assigned 176 men to usual care, a face-to-face discussion of PSA testing, a videotape, or a combination of videotape and discussion. PSA testing was selected by 98 percent of men assigned to usual care compared to 50 percent of men that were assigned to combined discussion and videotape intervention (Frosch, Kaplan, & Felitti, 2001).

The concept of causal inferences in epidemiology is similar to the exploration of benefits and harms of treatment in outcomes research (Kane & Radosevich, 2011). One or more of nine guidelines can be used for judging whether an association is causal; however, a temporal relationship is the most important because it clarifies the order between exposure and disease and

the length of interval between the two (Gordis, 2009). The temporal relationship of prostate cancer diagnosis and disease specific morbidity or mortality is important not only for clarifying the order in which the two occur but also in regard to the length of the interval between diagnosis and disease specific morbidity or mortality (Gordis). In other words, a positive PSA test leading to a positive prostate biopsy is not temporally related to morbidity or mortality because some prostate cancers grow so slowly they wound never have caused symptoms (Lin et al., 2008).

The causal guidelines inferences were modified in 1986 to include categorization of the evidence by the quality of its source (Gordis, 2009). The USPSTF uses an eight step analytic plan to evaluate the evidence for a screening program by reviewing relevant randomized trials. By assessing the strength of evidence the USPSTF moves from causal inferences to policy recommendations (Gordis). Since 2002, the USPSTF has maintained that the evidence is insufficient to recommend for or against screening; since 2008, the USPSFT has maintained that the evidence is sufficient to recommend against screening for men 75 years and older (Lin et al., 2008), and since October, 2011, the USPSTF has recommended that the evidence is sufficient to recommend against screening healthy men (Bankhead, 2011).

Only a small part of the causal chain was depicted while constructing this conceptual model with the outcome of provider's opinion about guidance provided by the prostate cancer educational pamphlet. Unfortunately, an educational pamphlet is not enough to end the continued practice of prostate cancer screening in asymptomatic men because there are multideterminants of health preference which comprise the entire causal process (Earp & Ennett, 1991). One major determinant of health preference is a person's belief, including a commitment to prostate cancer screening, despite false-positive test results or the possibility that testing could lead to unnecessary treatment (Schwartz, Woloshin, Fowler, & Welch, 2004).

Literature Selection/ Systematic Process Supports Problem

Prostate cancer diagnosis and treatment is a therapy/harm clinical question. In order to prove or disprove prostate cancer screening efficacy, a systematic review of randomized controlled trial was searched for in the health sciences databases (Houser & Oman, 2011). The trials revealed that there is no strong evidence that PSA testing decreases mortality; there is no evidence about the best treatment for clinically localized prostate cancer (Clements et al., 2007), and patient/provider treatment preferences reflect geography and perceptions more than evidence-based recommendations (U.S. Department of Health & Human Services, 2008).

In 2009, two ongoing randomized trials of PSA screening provided the first quantitative estimates of the survival benefits due to early detection (primary empirical resources). The prostate arm of the National Cancer Institute-sponsored Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial found no survival benefits from annual PSA screening combined with digital rectal exam (Andriole et al., 2009). A larger similar trial, the European Randomized Study of Screening for Prostate Cancer (ERSPC), initiated in the early 1990s, with men aged 50 to 74 years, found a 20% reduction in prostate cancer screening every four years (Schroder et al., 2009). This finding means that 1410 men needed to be screened, and 48 men needed to receive early treatment, in order to prevent one cancer death at ten years (Adami, 2010).

The Cochrane Collaboration updated their 2006 S*creening for prostate cancer (Review*) in 2010 (secondary empirical resource). The database included electronic searches of the PROSTATE registrar, MEDLINE, EMBASE, CANCERLIT, NHSEED and hand searching of five prominent urology and cancer journals. Inclusion criteria included comparing mass screening for prostate cancer to no screening and exclusion criteria included not being a randomized controlled trial. A meta-analysis of five randomized controlled trials, selected from a

review of 205 potentially relevant articles, concluded that prostate cancer screening did not significantly decrease prostate cancer-specific mortality. Only the European trial reported a reduction in mortality as outlined above (Ilic, O'Connor, Green, & Wilt, 2010).

A high level of evidence is needed when making clinical treatment decisions that involve a high risk-benefit ratio, such as a potential cancer diagnosis leading to controversial treatment, therefore it is imperative to have solid evidence supporting clinical practice guidelines (Houser & Oman, 2011). The USPSTF, responsible for developing clinical practice guidelines for prevention and screening, ranks studies by their quality and evidence, followed by estimates of the balance of benefits and harms. Critical gaps in the 2002 USPSTF review prompted the 2007 evidence update (secondary empirical resource). Articles in PubMed and the Cochrane Library from January, 2002 to July, 2007 were searched for evidence on health outcomes associated with PSA screening , harms of screening for prostate cancer, and the natural history of PSA-detected, nonpalpable localized prostate cancer. Three hundred ninety, 420, and 91 potentially relevant articles were identified to address the three respective areas of concern. Sixty eight articles were obtained for full text review and ten articles met inclusion criteria. The USPSTF concluded that PSA screening is associated with psychological harms and its potential benefits remain uncertain (Lin, et al., 2008, p.194).

Prostate cancer data in the U.S. is retrieved from individual state population-based or central cancer registries designed to provide outcome data to help improve patient care (Garvin, 2007). The Surveillance, Epidemiology, and End Results (SEER) Program was established after the National Cancer Act of 1971 mandated systematic collection of cancer data for use in the prevention, diagnosis, and treatment of cancer (Garvin). The SEER program collects cancer incidence and survival data from nine states, five metropolitan areas, and the Alaska Tumor

Registry encompassing about 26 percent of the U.S. population. Patient demographics, primary tumor site, stage at diagnosis, first course of treatment, and follow-up for vital statistics are the data collected (NCI, February 2010).

Stephenson et al. (1996) hypothesized that when an increase in incidence is observed following the introduction of a screening test, a subsequent decrease in incidence is bound to happen as prevalent cases are removed from the population and screening intensity decreases, a phenomenon they called a cull effect. The method used to test their hypothesis involved comparing prostate cancer rates from the SEER national registry to the age-adjusted prostate carcinoma trends which they tracked from the population-based Utah Cancer Registry. The authors concluded that the Utah Cancer Registry Data from 1993 and 1994 indicates that the incidence of prostate carcinoma is rapidly decreasing after similarly rapid increases. The rapid and highly correlated rise in prostate cancer incidence observed in both SEER and the Utah incidence rates between 1988 and 1991 raised concerns about the diagnosis and treatment of clinically insignificant cancers and increased invasive prostate cancer treatment without good evidence (Stephenson et al.).

The exhaustive medical literature review was halted after the same patterns and references kept recurring. The repeating themes correlate with the key points identified by England's National Health Service Prostate Cancer Risk Management Programme (PCRMP) for men to be aware of prior to taking a PSA test:

- The PSA test facilitates the early detection of prostate cancer at a stage when potentially curative treatments can be offered.
- There is currently no strong evidence that PSA testing reduces mortality from prostate cancer.

- Not all men with raised PSA will have prostate cancer/the PSA test will not detect all prostate cancers.
- Prostate cancer is diagnosed through a prostate biopsy which can be uncomfortable or painful.
- Prostate biopsies will not detect all prostate cancers.
- Prostate cancers range from aggressive to slow growing forms – slow growing tumors may not result in symptoms or shorten life expectancy.
- There is no evidence about the optimum treatment for localized prostate cancer.
- Some treatments for prostate cancer can have significant side effects (Clements et al., 2007, Table 1).

Establishing prostate cancer screening efficacy and safety involves both clinical and epidemiological research. Distinguishing causation from association, establishing validity of outcome measures, estimating lead time, and studying the natural history of disease are epidemiological studies relevant to prostate cancer screening. Epidemiologists unanimously use the PSA as an example of a test with poor validity and consistently insinuate that it was irresponsible to introduce prostate cancer screening without well-conducted randomized trials because now it is virtually impossible to conduct those studies (Gordis, 2009).

Three epidemiologists from the University of Washington and the Fred Hutchinson Cancer Research Center in Seattle estimated lead time and overdiagnosis associated with PSA screening (primary qualitative descriptive epidemiologic study). These researchers conceptualized the observed incidence of prostate cancer as the sum of secular trends (incidence without PSA testing) and the excess incidence over and above the secular trend (incidence based on screening and unknown lead times). The authors developed two likelihood models to estimate

mean lead time under specified distributional assumptions and with a smooth secular trend. This novel likelihood approach allowed the authors to make formal inferences about the lead time and overdiagnosis associated with PSA screening in the U.S. and provided a first glimpse of a secular trend in disease incidence (Telesca, Etzioni, & Gulaiti, 2007).

Telesca et al. (2007) contend that one of the main costs associated with the PSA test is that it markedly increases overdiagnosis by detecting cancers that would not otherwise have been diagnosed within the patient's life. The cost is related to the lead time, or the time by which screening advances diagnosis, resulting in overdiagnosis, because death from other causes precedes the date of symptomatic disease and/or occurs during the lead time. The authors also provided some provocative insights about racial disparities in prostate cancer with estimated lead times of 4.50 years for whites and 6.43 years for blacks. In addition to black men's aggressive clinically detected cancers, blacks may be subject to a higher frequency of latent disease because the higher incidence of aggressive prostate cancer in blacks was based on data from symptomatic disease cases prior to the PSA era (Telesca et al., p.15).

Prevalence is the proportion of the population affected by a disease at a moment in time; it is not a measure of risk since it does not take into account the duration of the disease. Incidence is a measure of risk because it is the number of new cases of a disease that occur during a specified period of time (Gordis, 2009). Another relevant epidemiologic article studied these concepts using a novel highly technical method to estimate the asymptomatic incidence and duration of prostate cancer; according to Etzioni, Cha, Feuer, and Davidov (1998), "Prostate cancer is known as a disease with extremely high prevalence relative to its clinical incidence in the population" (p. 775). It is precisely this combination of asymptomatic incidence and duration that is of interest to researchers trying to explain the natural history of prostate cancer and how it

can lead to effective screening strategies. Comparison of the lifetime risks of preclinical and clinical disease confirmed that prostate cancer is a slow growing disease and approximately 50 to 75 percent of new cases are likely to remain asymptomatic (Etzioni et al., p. 784).

Adami (2009), a Harvard epidemiologist and former surgeon, who currently researches various cancers, predicts that historians may consider the prostate cancer pseudo-epidemic "a disaster of contemporary medicine" (p. 298). In 1994, Adami questioned the ethics of a prostate cancer screening trial, "To intervene in healthy people is not ethical without the widespread evidence of a net benefit- the evidence for which, in our opinion, is still uncertain" (p. 959). He works closely with Swedish researchers and concurs with the growing number of health agencies that advise against prostate cancer screening with a PSA (Adami).

The next step in the prostate cancer screening review was to explore the literature on informed decision making. The previously mentioned article by Clements et al. (2007) from the United Kingdom (UK) is an open access article, which means it can be reproduced and distributed as long as it is correctly cited. The National Screening Committee in the UK recommends against prostate cancer screening but the public concern about prostate cancer led the Department of Health to introduce the PCRMP in 2001. The program recommends that the PSA be available to interested men provided they are aware of the pros and cons. This qualitative study used semi-structured interviews with 21 general practitioners (GPs) from 18 GP practices in Oxfordshire to explore GPs' reports of consultations with asymptomatic men. The study concluded that despite GPs' understanding of the importance of informed decision making, the information provided was inconsistent because of provider preferences and their need to counter most men's positive opinion about screening. The authors contend that written information and a return visit would provide a more balanced picture, and they discussed how providing

information to patients about clinical issues that are not evidence based is problematic (Clements et al., Discussion section, para. 3).

The National Survey of Medical Decisions (DECISIONS Study), an original investigation by Hoffman et al. (2009), evaluated the medical decision–making process for PSA testing. The study design was a random-digit-dial survey of a national probability sample of 3010 English-speaking adults 40 years and older. A telephone survey of a subsample of 375 men who had either undergone PSA testing or discussed prostate cancer screening with a provider in the past two years was reported. This study was the first to systematically use the same survey methodology to assess one of nine common medical decisions ranging from initiating antihypertensive to screening for prostate, colorectal, or breast cancer. The conclusion of these authors was that health care provider's opinions strongly influenced screening decisions and shared decision making was lacking because subjects had limited knowledge, did not receive both sides of the story, and their preferences were not routinely considered (Hoffman et al.).

Another study by Partin et al. (2004), about informed decision making, was a randomized trial examining the effect of two prostate cancer screening educational interventions done at four Midwestern Veteran Affairs medical facilities (University of Minnesota). One thousand, one hundred fifty-two male veterans age 50 and older with primary care appointments were randomized to usual care, pamphlets, or a video. Two weeks prior to their primary care appointment, subjects received a mailed pamphlet, video, or no educational interventions. One week after their appointment, subjects completed a phone survey to assess knowledge, preferences, and decision making participation. VA utilization databases were used to assess PSA testing rates two weeks and one year post target appointment. The Social Cognitive Theory

was the conceptual model employed. Based on the results, pamphlet subjects were more likely than controls to discuss screening with their provider but video subjects were not. Video and pamphlet subjects were less likely to intend to have a PSA, relative to controls. PSA testing rates did not differ significantly across groups at one year. Possible confounding variables include PSA tests being drawn without patient knowledge, provider enthusiasm for screening, and a wash between those that were affected by the education, resulting in decreased screening for some and increased screening for others. Providers need to receive the intervention as well as the patients in order for screening behaviors to change (Partin et al.).

Market/Risk Analysis

Project Strengths, Weaknesses, Opportunities, Threats

The timing is this Capstone Project's strength because the latest studies and USPSTF clinical practice guidelines are finally confirming and recommending what has been researched and gently recommended for twenty years; namely, prostate cancer screening is not supported by randomized clinical trials (Andriole et al., 2009; Djulbegovic et al., 2010; Ilic et al., 2010) and "healthy men do not need prostate cancer screening with PSA because the test does not save lives and often leads to unnecessary testing, interventions, and treatment" (Bankhead, 2011, para. 1). The prostate cancer screening educational pamphlet will arrive just in time to educate providers, patients, and families about the confirmed futility of wide-spread prostate cancer screening among asymptomatic men (Adami, 2010).

The Project's weakness is the lack of enthusiasm among physician stakeholders. The Assistant to the Chief of Staff delegated the Project to the Chief of Ambulatory Care, and both

physicians warned not to proceed with the Project without their approval, including review by Urology. Unfortunately, the Chief of Ambulatory Care backed out of the Project because he believes in prostate cancer screening, and the Chief of Urology was indifferent. Curb-side advice from two VAMC oncologists was that PSA screening saves lives (T. Braun & E. Pajon, personal communication, July, 2011).

Driving /Restraining Forces

The driving force to the Project is the continuation of wide-spread PSA testing among asymptomatic men despite limited evidence of benefit and overwhelming evidence of harm (Adami, 2010). Providing information to patients about prostate cancer screening, when there is no established evidence base, is problematic (Clements et al., 2007). Asking a patient to decide if he wants PSA testing after the personal recommendation of a "highly qualified" television talk show host is absurd when thousands of doctors cannot settle the dispute (Suss, 2008). The restraining force to the Project is the flip side of the driving force, which is the United States commitment to cancer screening (Schwartz et al., 2004). Even though PSA testing cannot detect prostate cancer and, more importantly, it cannot distinguish between lethal and latent cancers (Ablin, 2010), the organizational culture still fosters wide-spread testing for PSA among asymptomatic men.

Zaccagnini and White state (2011), "As the lines between quality improvement activities and research blur, the tendency for these projects to undergo review by IRBs is stronger than in the past" (p. 456). The Capstone Project, a quality improvement initiative or small scale intervention linked to the assessment of a prostate cancer screening educational pamphlet, required approval by three institutions, including two internal review boards ; therefore, restraining forces to the project included the time required to complete the Regis, VA, and

Colorado Multiple Institutional Review Board (COMIRB) training followed by Regis IRB, VA, and COMIRB applications and approvals (see Appendices O,P,Q , R, and S). Training included four Collaborative Institutional Training Initiatives (CITI) and VA privacy training (see Appendices N and O). Finally, approval by the VA Research and Development (R & D) Committee was required after IRB approval (see Appendix T).

Barriers to providers' discussions of prostate cancer screening fell under the category of patient, provider, or system. The barriers included health literacy, cognitive dysfunction, and mental illness, forgetfulness or provider's belief about screening, and lack of time, lack of consensus within the medical profession, and fear of litigation (Guerra et al., 2007). Fear of liability is a valid concern because the structure of the U.S. legal system supports local screening practices and not ordering a PSA test can be considered a malpractice error of omission (Guerra et al., 2007). For example, in July 2003, a Virginia jury found a family practice guilty of malpractice when a patient decided against PSA screening, after informed decision making, and subsequently was found to have a high PSA and terminal prostate cancer (Merenstein, 2004).

Need, Resources, and Sustainability

There is a need for prostate cancer screening informed decision making at the Denver VAMC because random PSA blood tests are currently done without standard education on the pros and cons of screening. According to the latest guidelines, patients should receive education about the pros and cons of prostate screening before proceeding or not proceeding with testing (Woolf & Krist, 2009). In order for screening behaviors to change, providers need to learn about the pros and cons of prostate cancer screening, including the recommendation for informed decision making (Partin, M. et al., 2004). A detailed prostate cancer screening educational pamphlet will help educate and guide providers.

The Denver VAMC is part of the Eastern Colorado Health Care System (ECHCS), which is part of the VA, the largest integrated health-care system in the country (DeYoe, 2011). There are 319 providers in the ECHCS including physicians, dentists, nurse practitioners, and other licensed independent practitioners. All enrolled veterans are eligible for preventative care services, ambulatory diagnostic and treatment services, hospital inpatient diagnostic and treatment services, and prescription drugs prescribed by a VA provider. Prevention includes immunizations, physical examinations (including eye and hearing exams), health care assessments, screening tests, and health education programs. Medical, surgical, mental health and substance abuse are provided as outpatient and inpatient services (Hughes, 2011; U.S. Department of VA, 2011). It is clear to see from the preceding description that the VA plays a major role in prostate cancer screening.

The population that needs to be informed is Denver VAMC male patients starting at age 45 years old for high risk patients and 50 years old for all others. High risk patients are first-degree family relatives with prostate cancer because heritable factors account for 42% of the risk (Gordis, 2009, p. 279), and race because blacks have the highest risk (Perez-Stable, 2009, Prostate Cancer section, para 2). The setting is Denver VAMC primary care, with overlap into other clinics where prostate specific antigen (PSA) blood tests could potentially be ordered, such as specialty clinics (Hughes, 2011).

The corporate workload database for the VA is located nationally in the Austin Computerized Data Center. Statistics for the Denver VAMC are incorporated within the ECHCS. There are 400,664 veterans in the ECHCS primary service area (DeYoe, 2011, p. 39); from October 1, 2009 to September 30, 2010, a total of 67, 832 veterans were seen as outpatients (eligibility categories help explain why less than one fifth of the veterans utilize the ECHCS).

The number 67,832 reflects all patients, not all visits, since each patient may be seen multiple times; the number includes 6,976 females, 60,854 males, and two unknowns. The Denver VAMC cared for 57, 330 patients, including 51,250 males and 6,080 females. The average age for all Denver VAMC patients is 58 years with following breakdown: age 24 or less, 873 ; age 25 to 34, 5,456 ; age 35 to 44, 5,335; age 45 to 54, 8,834 ; age 55 to 64, 17,942 ; age 65 to 74, 10,257 ; age 75 to 84, 6,038 ; age 85 to 94, 2,527 ; and, age 94+, 68 (A. Carver, personal communication, March 30, 2011).

Most prostate cancers detected in the U.S. are asymptomatic, clinically localized, and found on routine PSA testing (U.S. Department of Health & Human Services, 2008); this correlates with the new cases of prostate cancer at the Denver VA. Prostate cancer data for 2008 to 2010 was obtained from the ECHCS Tumor Registry. There were 209 cases of prostate cancer diagnosed since 2008 except for new patients arriving with the diagnosis. At least 75% of the cases were clinically localized. The largest groups of men to receive the diagnosis (76%) were in their fifties and sixties (N. Jones, personal communication, April, 20, 2011; Hughes, 2011).

The project is sustainable because the above population description illustrates the greatest number of veterans falling within the group that providers need to educate, namely male veterans from age 45 years and above. Providers undoubtedly will be bombarded with questions about why PSA screening is no longer recommended in healthy men (Hallberg, 2011). The pamphlet will provide providers with the tool to explain the reasons behind the latest recommendations. The ultimate goal is to have the pamphlet distributed though-out the clinics with yearly updates.

Stakeholders and Project Team

The group with an investment in the Project includes the patients, providers, and system. The Project was initiated to protect patients against unnecessary invasive diagnostics and treatments. Educating providers about the latest research and guidelines will ensure patient protection through informed decision making. The system includes Project approval by the Regis University, the Denver VAMC, and the University of Colorado Denver IRBs. Completion of CITI courses in the Protection of Human Research Subjects and Health Insurance Portability and Accountability Act (HIPPA) is required by the three institutions; the VAMC also requires completion of a security course on the VA Talent Management System.

The project team includes eight Denver VAMC PCPs, including four providers in the Saturday Intake Clinic and four providers in the Firm A Clinic. The ECHCS Medical Media Program Manager is responsible for the pamphlet design and production. The author is involved with distributing the pamphlets and informing the providers about the Project. The data collection and interpretation is carried out by the author with oversight by a PhD-prepared RN mentor.

Cost Benefit Analysis

The Food and Drug Administration approved the PSA test for prostate cancer screening in 1994 (Albin, 2010). Each year approximately 30 million American men undergo PSA screening with an annual bill of at least three billion dollars, much of it paid by Medicare and the VA (Albin, 2010, para 1, 3). The cost of prostate cancer screening is overdiagnosis, or the detection of disease through screening that would not otherwise have been detected within the patient's lifetime (Telesca et al., 2007). The USPSTF cites a false positive test rate of up to 80% which can lead to unnecessary biopsies and therapies with possible adverse side effects of incontinence and impotence (Schepman, 2011, para 4). The cost of making and distributing the

educational pamphlet and asking selected PCPs about their opinion on guidance provided by the pamphlet is miniscule; the benefit is less interest in prostate cancer with subsequent positive health and financial outcomes.

Project Objectives

Mission/Vision/Goals

A population needs assessment revealed that there is a need for a change in screening practices at the Denver VAMC (Jacobsen & O'Connor, 1999). In other words, the time has come to close the gap between what is, and what should be, in performing, prostate cancer screening at the Denver VAMC (Hughes, 2011). The preceding analysis identified Denver VAMC's current prostate cancer screening practices; the mission, vision and goals provide directions to where the Denver VAMC should be regarding prostate cancer screening practices (Kruschke & Stoeckel, 2011).

The mission statement asks what the Denver VA PCPS do, who they do it for, and why they do it (Kruschke & Stoeckel, 2011). The mission of this project is to ensure that Denver VAMC PCPs are fully aware of the latest research and guidelines regarding prostate cancer screening in order to provide accurate information to male veterans starting at age 50 years, or 45 years for high risk patients. The vision statement provides an inspirational image of the future (Kruschke & Stoeckel). The vision of this Project is for PCPs to practice health care ethically by rejecting unproven prostate screening behaviors in favor of scientific evidence. Denver VAMC PCPs must meet the following goals in order for the mission and vision to occur:

- To be knowledgeable about the latest prostate cancer screening research and guidelines.

- To explain the risk of prostate cancer to male veterans.
- To explain PSA screening to male veterans, including the risks, benefit, alternatives, and uncertainties.
- To consider the male veteran's values in deciding about PSA screening.
- To engage the male veteran in decision making at the desired level (Krist et al., 2007).

The preceding goals are simply the steps of shared decision making recommended by the USPSTF (Krist et al.)

Process/Outcomes Objectives

Objectives are the means by which goals are met; according to Kruschke & Stoeckel (2011), they are "specific, measurable, achievable action items that are realistic and time-bound" (p. 17). Outcome objectives state a specific time frame for achievement of the intended outcome; whereas, process objectives clearly outline the steps needed to achieve the outcomes objectives (Zaccagnini and White, 2011). The Project findings and results are organized by objective; therefore, measurable objectives are needed to form data collection. The outcome objectives for Provider Opinion about Guidance Provided by a Prostate Cancer Screening Educational Pamphlet are the means by which Denver PCPs will use the steps of shared decision making recommended by the USPSTF. The measurable Project objectives include:

1. Design and print a prostate cancer screening educational pamphlet using data from a systematic review of randomized controlled trials of prostate cancer screening efficacy. Include the first quantitative estimates of the survival benefits due to early detection provided by the two large ongoing randomized clinical trials of PSA testing, the ERSPC study and the prostate arm of

the National Cancer Institute-sponsored PLCO Cancer Screening Trial (Andriole et al., 2009; Schroeder, Hugosson, Roobol et al., 2009).

2. Educate providers in Firm A Clinic and Saturday Intake Clinic about the prostate cancer screening practice issue by sending weekly messages about the latest USPSTF guidelines, major medical organization's recommendations and attached relevant articles via *Office Outlook.*

3. Measure participating PCPs perceptions of guidance provided by the detailed prostate cancer screening pamphlet using the eight question survey.

The Time Table of Accomplishments (see Appendix L) clearly outlines the process by which the outcome objectives were achieved. It is clear to see from the list of accomplishments that the process needed to achieve the Capstone Project outcomes objectives entails one step forward, and two steps back, but constant movement toward meeting the mission of ensuring that Denver VAMC PCPs are fully aware of the latest research and guidelines regarding prostate cancer screening in order to provide accurate information to male veterans.

Evaluation Plan

A logic model illustrates how and why a project will work (Kellogg, 2004). The initial Prostate Cancer Screening Informed Decision Making Logic Model (see Appendix G) was simplified after VA IRB pre-review on September 14, 2011 and simplified again after the oral presentation in the DNP Capstone Project class NR 706B. The Logic Models (see Appendix H and I) provide clarity and focus on specifics. "If…then…" statements connect the program's parts depicted in rows under the columns of Resources/Inputs, Activities, Outputs, Outcomes, and Impacts (Kellogg). Reading the Model from left to right starts with the first two columns, the planned work, and ends with the intended results, the last three columns (Kellogg).

The outputs, outcomes, and impacts of PCPs in two VA clinics utilizing the prostate cancer screening educational brochure to help guide prostate cancer screening informed decision making, followed by all Denver VAMC PCPs using the brochure, are the most important components to monitor because they gauge the success of the Project. The ultimate success of this Project will be when the vision for PCPs to practice health care ethically, by rejecting unproven prostate screening behaviors in favor of scientific evidence, is realized. In reality, proving that the proposed change took place is easier said than done because life is complicated with influences and forces beyond one's control. Therefore, demonstrating progress toward the ultimate impact of less interest in PSA screening, leading to less incidence of prostate cancer, and leading to improved quality of life is more about documenting this Project's contribution, rather than documenting that the change actually occurred in a given time period (Kellogg, 2004).

Population/Sampling Parameters/Setting

A convenience sample of VAMC PCPs in the Saturday Intake Clinic and PCPs in Firm A Clinic comprise the study group. The comparison data is the incidence of prostate cancer screening informed decision making with PCPs in Firm B Clinic, the comparison group, without the guide of the pamphlet. The outcome of interest to be quantified are the providers' opinions measured on an interval scale of yes, somewhat or maybe, or no about whether the detailed prostate cancer screening educational pamphlet offered guidance for informed decision making. The outcomes of interest to be qualified are PCPs' discussions about their current prostate cancer screening practices as well as the responses from PCPs in the comparison group. There will be no inclusion or exclusion criteria to control for the extraneous variable of the providers' initial belief prior to the intervention. The PCPs will be fully informed of the project via *Microsoft*

Office Outlook e-mail and will receive the detailed prostate cancer screening education pamphlets to review before their primary care clinics (see Appendix C).

Evidence-Based Practice Methodology and Measurement

A quantitative pilot study design will be used to answer the PICO question. The variables, reiterated in statistical terms, include the dependent variable of provider opinion on whether the pamphlets offered guidance regarding prostate cancer informed decision making. The independent variable is the prostate cancer screening educational pamphlets and corresponding discussions. The extraneous variable is provider health belief. The survey (see Appendix J) used to measure provider opinion about guidance provided by the pamphlet is discussed in pages 31 to 33.

The Capstone Project is a quality improvement initiative with no defined research question; it is a small-scale intervention linked to assessment of a prostate cancer screening pamphlet. The quantitative data collected measures provider opinion about guidance provided by the pamphlet. Anecdotal information received from provider e-mails describes Firm B PCPs' screening practices without the pamphlet, the comparison data. The statistical method for evaluation of the quantitative data collected in the survey is limited to frequencies. This analytic option is appropriate because the purpose of data collection for this process improvement Project is to implement evidence-based practice into primary care rather than to evaluate a research project. In other words, the collected data and Project findings are used to measure a change in practice rather than collecting data to make the project reproducible (Zaccagnini & White, 2011). The Project's ultimate goal is prostate cancer screening informed decision making resulting in improved health outcomes for Denver VAMC male patients (Cassarett, Karlawish, & Sugarman, 2000).

Protection of Human Rights Procedure Complete

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research was developed in 1976 after four days of intensive discussions between members of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The statement includes a distinction between research and practice; a discussion of the three basic ethical principles of respect for persons, beneficence , and justice; and remarks about applications of these principles through informed consent, assessment of risks and benefits , and selection of subjects (Ryan et al., 1976). Some of these principles can be applied to the dilemma of uninformed prostate cancer screening and the subsequent outcome of using the detailed prostate cancer educational pamphlet. The ultimate impact is to stop the intrusion into asymptomatic unsuspecting men's lives with a harmful screening practice disguised as preventative care.

Mass population PSA testing was initiated in the late 1980s without a persuasive randomized trial or other compelling scientific evidence (Adami, Baron, & Rothman, 1994). The novel screening practice resulted in an unprecedented cancer incidence increase from 1988 to 1992 followed by a steep and then modest decline (Adami, 2010). Because of cultural cancer screening enthusiasm, the practice of prostate cancer screening preceded research. In October, 2011, the USPSTF upgraded their recommendation not to screen healthy men with a PSA blood test because the test does not save lives and often leads to unnecessary testing, interventions, and treatment (Bankhead, 2011).

Research and practice often occur together and according to the Belmont Report (Ryan et al., 1976), "This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity

shoulder undergo review for the protection of human rights" (p.3). The blurred distinction between research and practice has resulted in a trial of prostate cancer screening in the western world since 1988 without review for the protection of human rights (Adami et al., 1994).

The Capstone Project is about doing what is "Right" and "Proper" and about what the evidence-based practice recommends. The moral and ethical principle of respect for persons includes autonomy, or one's right to choose, and protection for those with diminished autonomy (Ryan, et el, 1976). Providing PCPs with a prostate cancer screening educational pamphlet will result in patient informed decision making, a prerequisite for autonomy. Patient preference, or autonomy, is the guiding principle here, and if a man wants to be screened, knowing the negative consequences, that is his prerogative. On the other hand, health illiteracy and cognitive impairment precludes autonomy, making the patient vulnerable. The truth of the matter is almost all patients are vulnerable because, according to Suss (2008), "If thousands of doctors can't agree on whether PSA screening results in any benefit, then it makes no sense to ask the patient to settle the dispute" (p. 1288). In other words, many patients may make foresighted decisions not understanding that the ability to detect a disease by screening does not always equate to a benefit to those screened (Gordis, 2009).

The principle of beneficence is about the balance of good versus harm. Offering asymptomatic men a diagnostic intervention associated with increased cancer diagnosis, modest mortality reduction, and substantial morbidity constitutes harm (Adami, 2010). The modest absolute reduction in prostate cancer over time comes at the cost of diagnosing and treating clinically irrelevant cancers (Pignone, 2009). Additionally, the harms of screening start immediately; whereas, the potential benefits are not realized for years to come (Pignone, 2009). The harms of treatment may include erectile dysfunction and urinary incontinence after radical

prostatectomy, defecation problems following radiation therapy, and hot flashes/feminization with hormone therapy (Hoffman, Fletcher, & Rind, 2010). Informed decision making is no license to subject patients to harmful interventions (Adami et al., 1994); thus, prostate cancer screening is not beneficent.

Justice is fair and moral treatment of people includes not basing treatment decisions on demographics. Unfortunately, prostate cancer is not an equal opportunity disease, with older age, race (black), and family history the only well-established risk factors (Jemal et al., 2011). The introduction of the PSA test has led to a large percentage of African American males undergoing aggressive treatments for cancers that may well be indolent. For example, increased screening in active-duty air force personnel between 2005 and 2008 resulted in a three times higher rate of prostate cancer among white servicemen, and eleven times higher rate for black servicemen, compared to rates between 1991-1994 (Goldhagen, 2011,para 4). Of those with low risk disease, significantly more active duty servicemen elected curative surgery than retirees (93% vs. 53%) (Goldhagen, para 6).

Telesca et al. (2007) estimated lead time and overdiagnosis associated with PSA screening from prostate cancer incidence trends with lead times of 4.50 years for whites and 6.43 years for blacks (p.15). The finding of a longer lead time among blacks is surprising because of the known higher incidence and poorer survival in blacks. The authors conclude that, in addition to black men's aggressive clinically detected cancers, they also may be subject to higher frequency of latent disease because the higher incidence of aggressive prostate cancer in blacks was based on data from symptomatic disease cases prior to the PSA era (Telesca et al.).

Information, comprehension, and voluntariness are part of the informed consent process. The detailed prostate cancer screening educational pamphlet will satisfy the three elements of

informed consent. The often perfunctory shared decision making will become more detailed with the risks and benefits of prostate cancer screening clearly spelled out in the pamphlet. Hopefully, vulnerable male veterans will be better equipped to make a systematic assessment of the risks and benefits of screening.

Instrumentation Reliability/Validity and Intended Stats

Choosing the appropriate statistical test is necessary to answer the Project's questions about provider opinion about guidance offered. Surveying the providers will be the method of data collection. The data gathered from each of the eight providers in the sample will describe the guidance provided by the pamphlet, thus descriptive rather than inferential statistics is appropriate. Providers' opinions on guidance offered by the pamphlet are ordinal level measurements of outcome data that can be ranked. The responses to the survey questions will have verbal labels of yes, somewhat or maybe, and no with corresponding codes of 1, 2, and 3(see Appendix J). The numerical codes cannot be rearranged; therefore, the numbers are not arbitrary. Since it is not meaningful to measure averages with variables measured on nominal and ordinal scales, the analytic option for this Project is limited to frequencies (Polit, 2010). Finally, generalizability of the outcomes will be limited, and clear conclusions about cause and effect will not be possible because there is no randomization and no control group.

The survey (see Appendix J) was easily developed because the questions are intuitive. An eighth question was added to assess the format of the pamphlet after Project implementation. The eight survey questions are simple, direct, short, concrete, and single concept questions. The survey is valid because it actually measured what was intended to be measured; provider opinion on guidance offered by the pamphlet including format. Finally, completion of the survey by the eight Project participants will avoid nonresponce bias (Zatz, 2011).

A frequency distribution will be constructed from the ordinal data measuring provider opinion about guidance offered by the pamphlets. The data will be reported as percentages. A bar graph will be constructed to display frequency information with the categories listed on the horizontal axis and the frequencies or percentages on the vertical axis (Polit, 2010).

Comparison of the PCPs' screening practices without the pamphlet and other observations made during project implementation and application will be used to change prostate cancer screening practices at the Denver VAMC including the Eastern Colorado CBOCs. The treatment that will be done with the data collected includes continued reinforcement about the requirement for informed prostate cancer screening, continued education about the USPSTF recommendations not to screen healthy men with a PSA blood test, and continued pamphlet production and distribution. In other words, completion of the Capstone Project will be the beginning of prostate cancer screening evidence-based practice within the ECHCS.

Timeframe, Budget, and Resources

The goal of assessing informed decision making with the guidance of a prostate cancer screening educational pamphlet is to improve the process, outcomes, and efficiency of prostate cancer screening practices at the Denver VA (Cassarett, et al., 2000). The timeframe for this Project is outlined in Appendix K followed by a chronological list of accomplishments in Appendix L. There needs to be ten minutes of PCPs time to inform patients about the pros and cons of screening using the detailed prostate cancer educational pamphlet; the design and pamphlet production will be done by the ECHCS Medical Media Program Manager; and weekly *Microsoft Office* e-mail messages/discussions will be sent to educate providers. These are the three main resources needed for implementation and application of the evidence-based practice

Project. The budget is the hypothetical amount of money needed for the Project including pamphlet production (see Appendix M).

Project Findings and Results

The first objective, to design and print a prostate cancer screening educational pamphlet using the latest evidence-based practice began with the writing of the detailed pamphlet. The mentor thought the detailed pamphlet was too long; therefore, the basic pamphlet was created for patients, with four pre and post questions. The ECHCS Medical Media Program Manager discussed the design and production of the prostate cancer screening educational pamphlets with the author. The *UpToDate* Journal and Right's manager was contacted for approval to use their graphics, which he subsequently edited and approved. A fifth question was added to the basic pamphlet to avoid bias because the Project mentor thought the pamphlet was slanted against prostate cancer screening. Finally, the written portion of the pamphlets was complete, use of *UpToDate* graphics was approved, and a picture of a can of worms representing the dilemma caused by screening was added. The ECHCS Medical Media Program Manager created the detailed pamphlet for COMIRB review using the can of worms picture for the cover and the *UpToDate* graphics inside the folded pamphlet.

Two hundred detailed pamphlets were printed for the Project implementation. The pamphlets went fast the first week because PCPs were sending patients home with them. On January 7, 2012 a request was made for 500 to 1000 more pamphlets, but the request was put on hold by the Project's new mentor, a PhD-prepared RN, the Denver VAMC Patient Safety Specialist. The mentor advised against distributing the pamphlets to the patients because the purpose of the Project is to assess the pamphlet. The question, "Is the format of the pamphlet user

friendly" was added to the survey (see Appendix J) to address the issue of pamphlet font and format per the Project mentor's advice. The survey now included assessment of the brochure format in addition to measuring provider's opinions about guidance provided by the detailed pamphlet.

Sending a patient home with the detailed pamphlet is an ideal method to inform the patient and his family about the often indolent natural history of prostate cancer, the limitations of PSA testing, and the inconsistent evidence thus far from major prostate cancer screening trials (Hoffman, 2011). According to Hoffman, "Decisions about prostate-cancer screening should be based on the preferences of an informed patient" (p. 2017); therefore, public approval and distribution of the pamphlet is imperative to ensure that evidence-based practice is the basis of clinical care at the Denver VA.

The second outcome objective, to educate providers in Firm A Clinic and Saturday Intake Clinic about the practice issue, began by sending the following *Office Outlook* e-mail message to Denver VA PCPs:

> Subject**:** Quality Improvement Project
>
> In October, 2011 the United States Preventative Service Task Force recommended against screening health men with a prostate specific antigen (PSA) blood test. Other major medical organizations recommend informed or shared decision making prior to offering PSA testing. A quality improvement initiative project will be done to assess prostate cancer screening guidance provided by an educational pamphlet (see attachment). Four volunteer primary care providers (PCPS) from Firm A, and four volunteer PCPs from the Saturday Intake Clinic, are needed to assess the pamphlet. The comparison group will be an assessment of the guidance provided from four volunteer PCPs in Firm B without the uses of the educational pamphlet. Thank-you for your help in implementing this evidenced based practice at the Denver VAMC (P. Hughes, personal communication, December 22, 2011).

Replies to the above message started the following day including one physician and four nurse practitioners (NP)volunteering to test the pamphlet with age appropriate men during primary care clinic visits.

The design of the Project was to have four PCPs in Firm A Clinic and four PCPs in the Saturday Intake Clinic test the detailed prostate cancer screening educational pamphlet followed by completing the eight question survey. Instead, only three PCPs in Firm A Clinic and five PCPs in Saturday Clinic tested the pamphlet. The three study PCPs in Firm A included one physician and NPs. The one participating Firm A physician personally responded to the email request and the two participating Firm A NPs were personally recruited. The five study PCPs in the Saturday Intake Clinic are NPS.

The Evidenced-Based Clinical Practice Guidelines/Clinical Quality Program Specialist NP working for the VA Office of Quality & Safety participated in the email discussions. He was the only provider to respond to the request for suggestions on the detailed pamphlet before it was sent to public affairs for approval to distribute to patients and families. After the suggested grammatical errors were corrected the pamphlet was sent to public affairs and was subsequently approved for public use.

Each participating provider received copies of the detailed pamphlet, the latest *NEJM* article on screening for prostate cancer (Hoffman, 2011), the VA R&D Approval Letter, and weekly *Office Outlook* email messages about the Project including prostate cancer screening guidelines, dilemmas, and discussions. The messages and informative articles were also sent to all Denver VAMC PCPs, the Chief of Ambulatory Care, the Chief of Urology, and the Nurse Practitioner Supervisor. Unbeknownst to the author, providers in the ECHCS CBOCs received

many of the email messages, leading to requests for posters and pamphlets from PCPs in Colorado Springs and Pueblo.

Coincidently, the Deputy Chief of Staff's poster on the Principles of Shared Decision Making was displayed at the Denver VAMC in early February, just a few weeks after the Project started. The Deputy Chief of Staff was familiar with the Project because of a former meeting in April, 2011 when a return visit for informed consent prior to PSA screening was vetoed and the Chief of Ambulatory Care was assigned as the initial Project mentor. It was timely and advantageous that the poster was displayed at the same time as the Project; therefore, the following message was sent to providers:

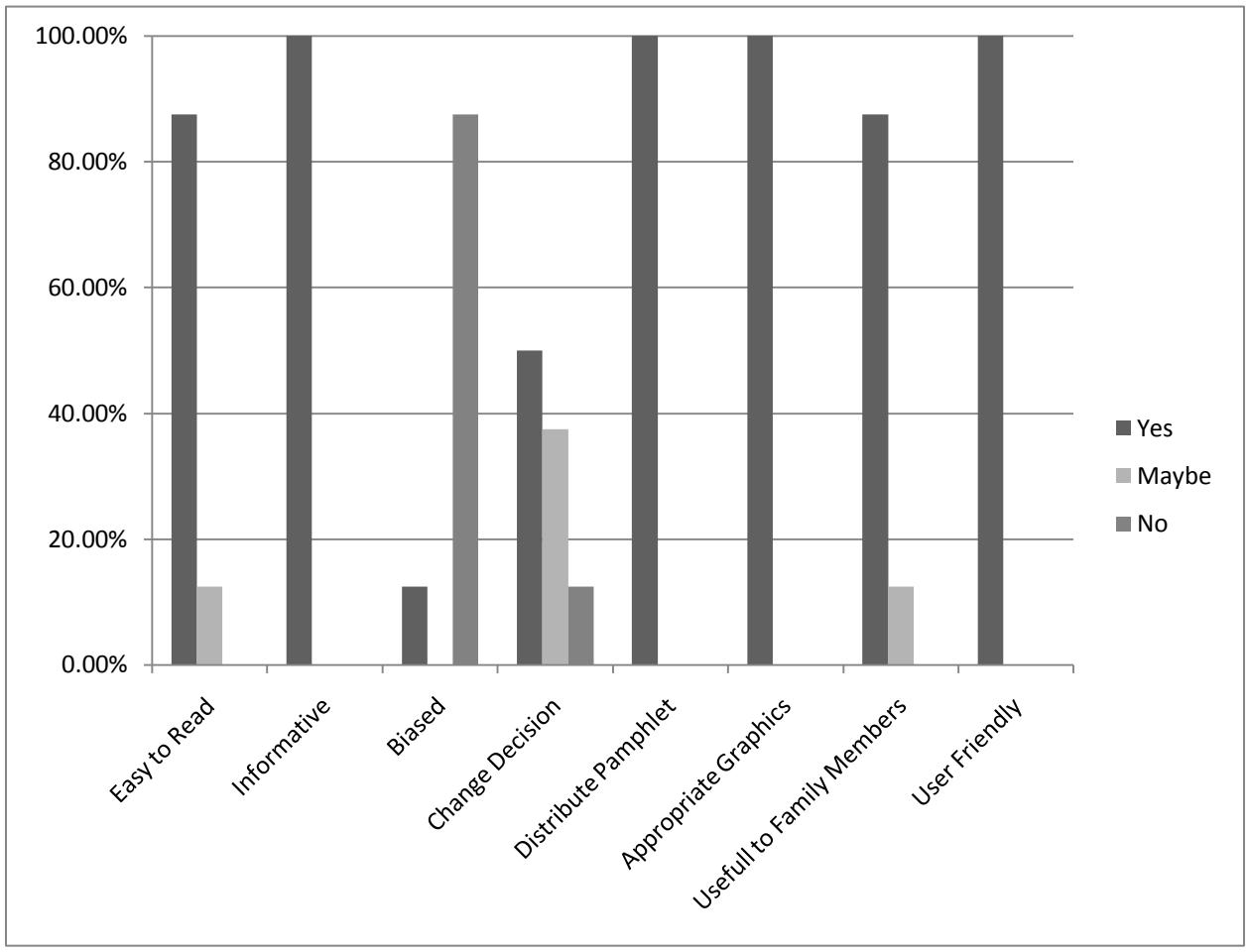
> Dr. Lithium Lin's poster on the Principles of Shared Decision Making is displayed in the prosthetic hallway. Plan of care, participation, perception, pros & cons, and preferences surround patient centered shared decision making. The 6 P's (principles) of shared decision making can be used for patients that request prostate cancer screening.
>
> The American Urologic Association, American Cancer Society, U.S. Preventative Services Task Force, and other major medical organizations recommend that providers discuss the risks and benefits of prostate cancer screening before PSA testing is performed by way of shared or informed decision making (Woolf & Krist, 2009). According to Krist et al. (2007), per the US Preventative Services Task Force (USPSTF), "A decision is shared when the patient (1) understands the risk of the disease to be prevented; (2) understands the preventive service, including risk, benefit, alternatives, and uncertainties; (3) weighs his values regarding the decision; and (4) is engaged in the decision at the desired level" (p. 112-113).
>
> References:
>
> Krist, A., Woolf, S., Johnson, R., and Kerns, W. (2007). Patient education on prostate cancer screening and involvement in decision making. *Annals of Family Medicine. 5:112-119 (*P. Hughes, personal communication, February 16, 2012).

Having the Deputy Chief of Staff on board is critical to the implementation of the evidence-based practice of informed prostate cancer screening because he is responsible for communications with ECHCS medical staff and assisting with changes in medical practice (Houser & Oman, 2011).

Statistical Data

The third outcome objective, to measure participating PCP's perception of guidance provided by use of the detailed prostate cancer screening pamphlet with male veterans aged 50-75 , was accomplished using an eight question survey (quantitative data) (see Appendix J). The eight completed surveys indicated that the pamphlet did offer Denver PCPs guidance in informing patients about prostate cancer screening. The survey also specified that the detailed pamphlet format is appropriate (Figure 1). Eight (100 percent) PCPs found the detailed prostate cancer screening pamphlet informative, with appropriate graphics and a user friendly format. Seven (87.5%) PCPs found the pamphlet useful for family members; whereas, one (12.5%) provider found the pamphlet somewhat, or maybe, useful for family members. Seven (87.5 percent) PCPs said the pamphlet was easy to read; whereas, one (12.5%) provider said the pamphlet was somewhat, or maybe, easy to read. Seven (87.5 percent) PCPs found the pamphlet to be unbiased; whereas, one (12.5%) provider found it biased. Half of the PCPs (*n*=4) thought the brochure would change decisions of vets to get a PSA; whereas, three (37.5 percent) PCPs though the brochure would somewhat, or maybe, change decisions of vets, and one PCP (12.5 percent) though the brochure would not change the decision of vets to get a PSA.

Figure 1: Survey Results



Reliability of Findings

Reliability refers to how consistently an instrument measures the attribute it is designed to measure (Polit, 2010). The eight question survey (see Appendix J) is the instrument designed to measure the attribute of guidance provided to PCPs by the pamphlet. Since the survey was filled out by PCPs in close proximity to the time they used the pamphlet there was absolutely no recall bias. Since the positive answer to question four is "no" the error of measurement which occurs when a survey is filled out haphazardly did not occur (Polit, 2010). In other words, the seven PCPs that found the pamphlet helpful answered "no" appropriately when asked if the pamphlet is biased instead of haphazardly answering "yes". Likewise, the one provider that holds a strong

belief in the benefits of prostate cancer screening answered “yes”, the pamphlet is biased, instead of haphazardly answering “no”. A provider’s health belief is a subjective bias which decreases the reliability of prostate cancer screening brochure survey; for example, the provider that though the pamphlet is biased also answered “no” the pamphlet would not change decisions of vets to get a PSA.

The comparison data was received serendipitously when an e-mail message was sent, asking for four volunteer PCPs in Firm B to discuss their prostate cancer screening practices without the guidance of the attached pamphlet. The request was preceded by a detailed paragraph describing the current prostate cancer screening dilemma and ended with an inaccurate statement, “For example, today a PCP in Firm C told me that PSAs are routinely ordered on all male patients over 50” (P. Hughes, personal communication, February 6, 2012). The incorrect statement resulted in email rebuttals by two physicians followed by a discussion about the Project at the physicians monthly Journal Club. Apparently none of the physicians routinely order PSAs because it no longer is a clinical reminder. Some physicians are concerned about the potential legal implications of not even talking about PSA screening and having the patient getting it done somewhere else and being diagnosed with prostate cancer (and bringing a lawsuit against the VA for not diagnosing it); therefore, some physicians will routinely have the discussion. A highly respected physician recommends doing the right thing by following the USPSTF recommendation not to screen healthy men. The ten Journal Club physicians are aware of the latest USPSTF guidelines.

In retrospect, the incorrect statement was a godsend because it caused indifferent physicians to respond defensively. In fact, the above two physician responses were the only responses received from the multiple providers on Firm B. Despite the response from only two providers, instead of the requested four, the Capstone Project was unexpectedly the topic of discussion at the physicians' Journal Club on February 7, 2012. Since there were ten physicians at the monthly Journal Club, and one physician stated that "None of the physicians routinely order PSAs"; it is safe to assume that at least four Firm B Clinic physician providers do not routinely order PSA tests on healthy veterans.

The potential legal implication of not discussing prostate cancer screening with patients is a valid concern, resulting in some providers routinely ordering PSAs. For instance, in a study aimed at identifying factors that facilitate or prevent prostate cancer screening discussions, three physicians stated they will default to ordering a PSA due to medical-legal concerns if they are unable to have a discussion with the patient (Guerra et al., 2007). Patient barriers that prevent physicians from discussing prostate cancer screening include comorbidities, limited education/health literacy, competing preventative health discussions, mental illness, and the patients already deciding they want PSA screening (Guerra et al). Interestingly, being well educated does not preclude problems with health literacy (Hoffman, 2009). The preceding findings correlate with Denver VAMC providers' reasons for ordering PSA tests without a patient discussion.

The Chief of Ambulatory Care informed the Health Promotion Disease Prevention (HPDP) Program Manager about the Project because the HPDP's project was concurrently taking place to reduce PSA screenings in men over 75 years. The first short meeting took place

on February 28, 2012, followed by emails and phone communication. The HPDP Program Manager was included in email messages about the Capstone project from then on.

In 2012, The HPDP Program Committee chose to address the potential over utilization of PSA screening within the ECHCS because there was speculation that PSAs were routinely being ordered in men over 75 years despite the VHA Clinical Recommendations against screening for this population. Two physicians, a urologist, and a PCP worked with the HPDP Program Manger to study the issue and develop interventions, if necessary. Data from the Veterans Integrated Service Network (VISN) 19 Data Warehouse included ECHCS VA patients ≥ 75 years who had a PSA drawn November, 2010 to November, 2011. One thousand seven hundred sixty nine patients≥ 75 years had a PSA done within the 12 month time frame. Five hundred and three patients with a history of prostate cancer were eliminated from the denominator, assuming the PSA was used for monitoring not screening, leaving 1266 patients having a PSA drawn for unknown reasons. A random sample of 50 patients from the 1266 was indentified for chart review to look for reasons for PSAs being ordered; three were eliminated because they were found to have prostate cancer. Eighty-seven percent (*n*=41) of PSAs done in men ≥ 75 was for routine screening which is not in line with the VHA and USPSTF guidelines. The planned interventions are to send out a MEMO to ECHCS providers about the recommendations not to routinely screen men≥ 75 years and to create a flag in the CPRS lab package that would appear when a PSA is ordered for men ≥ 75 years without a diagnosis of prostate cancer (L.Shainline, personal communication, March 6, 2012).

Results Discussed According to Evidence-Based Practice

The results of the preceding QI project correlate with clinical observations made over the past 15 years. In other words, the vast majority of PSAs done at the VA ECHCS are randomly

drawn, including being ordered on men too old to ever benefit from screening. The USPSTF has recommended against screening men age 75 years or older for years (Lin et al., 2008), yet the preceding project shows that screening in this group is quite routine. Despite the response from the Journal Club physicians that PSAs are not routinely ordered, the evidence reveals quite the opposite. Therefore, the Capstone QI Project is here just in time to educate providers about the recommendations for prostate cancer screening informed decision making for men ≤ 75 who request to be screened. The Project will facilitate evidence -based practice by providing a detailed pamphlet to guide providers and educate patients. The HPDP Program QI Project is here just in time to ensure evidence -based practice at the ECHCS by educating providers not to order PSAs on veterans ≥ 75 years, including flagging PSA orders placed for male veterans ≥ 75 years.

The Capstone Project helped improve the process of prostate cancer screening at the Denver VAMC. The pamphlet, and corresponding discussions, educated providers about the USPSTF recommendations not to screen healthy men, and provided a guide for providers to inform patients who request to be screened (Bankhead, 2011; Lin et al., 2008). Public approval of the pamphlet, followed by mass production and distribution in the ECHCS primary care clinics, will ensure that the standard of care for prostate cancer screening is based on scientific evidence. In other words, by using data from the two large ongoing randomized clinical trials of PSA screening, the pamphlet will help bridge the gap between evidence and practice. Additionally, public approval of the pamphlet will help ensure that male veteran patients do not undergo PSA testing without the type of shared decision making that practice guidelines recommend (Woolf & Krist, 2009).

Limitations, Recommendations, Implications for Change

Limitations

The limitations to the project are the small number of participants, particularly physician participants. Recruiting Firm A Clinic physician volunteers to test the pamphlet and engaging Firm B Clinic physicians in discussions about their prostate screening practices without the pamphlet was difficult. The small number of PCPs and patient encounters may have prevented new themes from emerging from the data (Guerra et al., 2007). In other words, since there were only eight participants, there may be a wide range of experiences not captured (Clements et al 2007). Furthermore, VA providers care for patients who are mostly low income and/or service connected; therefore, the findings are less generalizable to providers who care for a more affluent and/or heterogeneous population.

The value of the qualitative findings obtained from providers' discussions, and lack thereof, increased the depth of understanding about prostate cancer screening practices at the Denver VAMC. A common theme from PCP's direct and indirect discussions is that routine PSAs are not done at the Denver VA, although clinical experience and the VA HPDP Program QI project reveal quite the opposite. Additionally, Denver VA medical specialist's opinions about PSA screening are far more optimistic than some of their PCP cohorts. For example, two VA oncologists stated that PSA screening saves lives (T. Braun & E. Pajon, personal communication, July, 2011), and the Chief of Urology agrees that PSAs should not be done on men $\geq$ 75 years (E. Park, personal communication, August, 2011). The Chief of Urology's recommendation, through the HPDP Program QI Project, to stop PSA screening in men $\geq$ 75 years seems to be too little, too late. In other words, the USPSTF has recommended against screening men $\geq$ 75 years for years (Lin et al., 2008) and now recommends against prostate

cancer screening with a PSA test, regardless of age, race, or family history (Hoffman et al., 2011).

Recommendations and Implications for Change

Improved healthcare outcomes depend on inter-professional collaboration in developing uniform standards of care (Regis University Loretto Heights School of Nursing, 2010). The lack of consensus about the utility of PSA screening among medical specialties leads to inconsistent practice guidelines with the recommendation for shared decision making between patient and clinician as the only standard of care (Hoffman et al., 2011). For example, the AUA recommends offering PSA screening at age 40; the ACS recommends offering PSA screening at age 50; and the USPSTF recommends not screening healthy men with a PSA because the test does not save lives and often leads to downstream consequences of PSA testing (Hoffman, 2011; Bankhead, 2011) . Major medical organizations need to come up with one standard prostate cancer screening guideline instead of asking the patients to decide if they want to undergo PSA testing. As Suss (2008) stated, "I don't think it is a good idea for experts to ask their clients or patients to make choices about means. If thousands of doctors can't agree on whether PSA screening results in any benefit, then it makes no sense to ask the patient to settle the dispute" (p.1288); therefore, shared decision making is somewhat of a misnomer.

The USPSTF recommends against PSA testing in healthy men (Bankhead, 2011; Hoffman, 2011). The AUA and the ACS recommend shared decision making about PSA screening starting at age 40 and 50 respectively (Hoffman, 2011) . Medical specialists who perform prostate surgeries and treat cancer are less skeptical about PSA testing than the USPSTF, an independent committee of experts, supported by the U.S. Government. The independent committee of experts undergoes a rigorous process to ensure that evidence is used

for developing clinical practice guidelines for prevention and screening. The Task Force grades its recommendations based on the strength of evidence from randomized clinical trials and the magnitude of net benefit (benefits minus harms). Members include experts in primary care, prevention, evidenced-based medicine, research methods, public health, and health policy (Gordis, 2009). Therefore, it makes good sense to use the USPSTF recommendations as the gold standard of care, rather than recommendations from medical organizations that stand to profit from PSA screening.

Prostate cancer screening efficacy and safety involves both clinical and epidemiological research. Distinguishing causation from association, establishing validity of outcome measures, estimating lead time, and studying the natural history of prostate cancer are epidemiological studies which can be used to critically appraise current practice, develop practice guidelines, and drive organizational change in order to improve healthcare outcomes (Regis University Loretta Heights School of Nursing, 2010). Based on cancer epidemiology data (Etzioni et al., 1998; Telesca et al), prostate cancer screening with a PSA should be abandoned because as Gordis (2009) puts it, "Even the best of intentions and passionate evangelism cannot substitute for rigorous evidence that supports or does not support the benefit of screening" (p.331). As of October 2011, the rigorous evidence does not support the benefit of screening for prostate cancer with a PSA blood test (Bankhead, 2011).

Evidence-based practice is based on clinical expertise, patient choice, and valid research evidence (Tymkow, 2011). Cancer screening enthusiasm often leads to patient choice conflicting with scientific evidence; such is the case for people committed to cancer screening regardless of its implications. Addressing the social problem of cancer screening enthusiasm requires assuming a leadership role to ensure accountability for quality, safe, evidenced based

patient care (Regis University Loretta Heights School of Nursing, 2010). Health care marketing must stop portraying screening as an obligation in order to reduce the public risk of over testing and over treating (Schwartz et al., 2004). In other words, according to Woolf & Krist (2009), "What is ultimately required is a deeper change in culture among providers and consumers of health care to delay dissemination, resist the assumption that newer is better, wait for evidence, tolerate observation over intervention, and accept uncertainty" (p. 1559).

Finally, changing health care policy will help reverse one of the major reasons behind PSA screening, fear of liability. The change will result in cultural and organizational changes which decrease or eliminate legal consequences for failing to diagnose cancer through screening. The VAMC has already has made the change by excluding PSA screening from their computerized view alerts. In other words, in order to encourage patients to participate in screening decision making, the VAMC's electronic medical record has built in physician reminders and checklists related to preventative care and counseling. Since PSA screening is no longer a clinical reminder, not ordering a PSA test should not be considered a malpractice error of omission. Unfortunately, the community standard of care may not coincide with the VAMC's national standard of care.

The legal standard of health care is not defined uniformly through-out the United States because state statutes define it. For states with no relevant statute, case law governs the standard of care for providers in the state. Twenty-nine states and Washington D.C. use a national standard of care and twenty-one states or jurisdictions use some version of the locality rule (Lewis, Gohagan, & Merenstein, 2007). The 1880 locality rule protected rural physician based on the premise that they did not have the same opportunities as their colleagues in the big cities;

therefore, they were no held to the same standard of care. Even though many states abandoned the locality rule by the 1970s, the rule is still invoked in medical malpractice case (Lewis, et al.).

The persistence of the locality rule has serious implications for providers and may serve to promote the practice of substandard health care (Lewis, Gohagan, & Merenstein, 2007). The "community standard" or "locality rule" has traditionally been a problem between plaintiffs and defendants in medical malpractice cases leading to dozens of reported decisions from the appellate courts (Ford, 2011). In a medical malpractice lawsuit, it is necessary for the plaintiff to prove that the physician did not follow the necessary standard of care; however, the standard of care can be different depending on where the provider works (Truglio et al., 2011). The courts have never applied a consistent set of standards for the locality rule; in fact, a military lawyer assigned to defend the veterans' administration against malpractice claims, arising under state law, gave up trying to decipher the inconsistent cases on the locality rule (Ford). Depending on the jurisdiction, expert witnesses (health care providers) base their support or criticism of the case on either the national or community standard. Since the author practices in Colorado and Colorado still adheres to some form of the locality rule, it is necessary to be knowledgeable about Colorado's applicable standard of care.

According to Longest (2010), "Public policies do not exist in isolation" (p. 204); therefore, analysis of the public policy environment is part of the larger external environment which health care organizations need to evaluate to determine the externally imposed threats and opportunities to their performance (Longest). Health care providers' performance of the national evidenced- based practice standard of prostate cancer screening informed decision is threatened by the antiquated locality rule. Colorado's version of the locality rule holds general practitioners to a community standard; whereas, specialists are held to a national standard (Lewis, et al.,

2007). Colorado's locality rule and other states that adhere to some form of the locality rule must be amended to national standards of care for all providers which will result in uniformity and state wide evidence-based practice.

Prostate cancer screening is not evidence-based practice but customary care. Current guidelines recommend against prostate cancer screening in healthy men (USPSTF, 2011) or informed/shared decision making for those who want to be screened (Woolf & Krist, 2009). Fear of litigation is one of the reasons providers continue with uninformed prostate cancer screening. Fear of litigation is a valid concern because the structure of the United States legal system supports local screening practices, and not ordering a PSA test can be considered a malpractice error of omission (Guerra et al., 2007). According to Keene (as cited in Sorrel, 2010), "medical standards should drive legal standards, not the other way around" (para, last). Therefore, since it is the state's responsibility to act as guardians of the public's health and regulators of the healthcare system and pursuit of health (Longest, 2010), it is time for the Colorado Assembly to modify the locality rule to national standards.

Conclusion

In 2009, the first quantitative estimates of the survival benefit due to early detection of prostate cancer have not been shown to have a significant impact on mortality (Adami, 2010). Existing evidence from randomized controlled trials reveals that early detection of prostate cancer through PSA screening comes at the price of additional testing, unnecessary invasive treatments, and impaired quality of life yet to be quantified (Djulbegovic et al., 2010). However, since the triad of evidence-based practice includes best scientific evidence, clinical experience,

and patient preferences (Houser & Oman,2011) individual patients' values are key factors in deciding whether to offer screening(Djulbegovic et al.).

The success of evidence based practice depends on paying close attention to the synergy of time and circumstance, critically analyzing results of studies which could improve patient care, and then acting at the right time to change the organizational culture which supports antiquated practices. Current guidelines recommend that PCPs discuss the advantages and disadvantages of prostate cancer screening prior to testing, but this is not routine. Time, effort, resources, fear of litigation, and cultural enthusiasm for cancer screening are some of the reasons informed decision making is often not done (Woolf & Krist, 2009). The challenges in implementing the required practice change of informed prostate cancer screening with the guidance of the detailed pamphlet includes fostering commitment among those involved such as patients, providers, and policy makers. Despite the challenges, the onus and moral obligation of VAMC health care providers are to educate patients about the risks and benefits of screening before undergoing PSA testing.

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Appendix A

Systematic Literature Review Table

	Article 18	Article 2	Article 27	Article 10
Article Title and Journal	Medical Ethics: Ethics of a prostate cancer screening trial. *The Lancet*.	Mortality Results from a Randomized Prostate Cancer Screening Trial The *New England Journal of Medicine*	The PSA testing dilemma: GP's reports of consultations with asymptomatic men: a qualitative study. *BMC Family Practice.*	PSA testing: What is the use? *Lancet*
Author / Year	Adami, H., Baron, J., Rothman, K. (1994).	Andriole, G., Crawford, D., Grubb, R., Buys, S., Chia.D, Church, T., …Berg, C.(2009)	Clements, A., Watson, E., Tanvi, R, Bukach, C., Shine, B., Austoker, J. (2007).	Crawford .(2005)
Database and Keywords	Keywords used to search for the article include prostate cancer, cancer screening, prostate specific antigen (PSA), and clinical guidelines. The data bases included *UpToDate, Cochrane Database of Systematic Reviews, CINHL, MEDLINE,* and *Google Scholar* The article includes 31 references.	Keywords used to search for the article include prostate cancer, cancer screening, and prostate specific antigen (PSA). Database: CINHL with Full Text. The article includes 31 references.	Keywords used to search for the article include prostate cancer screening and decision making. Database: Google Scholar The article includes 18 references.	Keywords used to search for the article include prostate cancer, cancer screening, prostate specific antigen (PSA), and clinical guidelines. Database:CINHL with Full Text The article includes 11 references.

Research Design	Medical ethics, opinion of authority	Randomized controlled trial across 10 study centers in the USA. Each study center used recruitment sources and strategies appropriate to the local situation. Participants were randomized 1:1.	Semi-structured telephone interviews with 21 general practitioners (GPs) from 18 GP practices in Oxfordshire.	This article is an opinion of a Urologist.
Level of Evidence	Level 7: Opinions of authorities, experts.	Level 2:RCTs	Level 6: Qualitative interview study.	Level 7: Opinions of authorities/ experts
Study Aim / Purpose	Discusses the ethics of a prostate cancer screening trial.	The effect of screening with prostate-specific-antigen testing and digital rectal examination on the rate of death from prostate cancer is unknown. This is the first report from the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial on prostate-cancer mortality.	This study aimed to elicit GPs accounts of their discussions with asymptomatic men who consult with concerns about prostate cancer in order to identify the degree to which the National Health Service Prostate Cancer Risk Management Programme (PCRMP) guidance was reflected in these consultations. The PCRMP has recommended that screening for prostate cancer is available for asymptomatic men, on the understanding that they have	The author attempts to answer what is the best approach to dealing with the number one cancer in men and the second leading cause of male cancer deaths. Screening, PSA as a marker, and what to tell patients are the issues of focus.

			been provided with full and balanced information about the advantages and limitations of the PSA test. Guidance has been distributed to all GPs in England and Wales to assist in the provision of information to men.	
Population Studied / Sample Size / Criteria / Power	Not applicable	Participants were males aged 55 to 74 years. Men with a history of prostate, lung or colorectal cancer were excluded, along with participants currently receiving cancer treatments. In 1995, men who had undertaken more than one PSA blood test in the previous three years were also excluded. Screening group 38,343; control group 38,350.	A purposive sample of GPs was identified through first PSA test requests made for patients, of any age, to the Department of Clinical Biochemistry, John Radcliffe Hospital, Oxford. As part of a separate study, questionnaires had been sent to the requesting GPs. Of the 173 GPs who returned a questionnaire, 94 indicated that they would be willing to take part in a	Not applicable

			telephone interview. Consecutive GPs were invited to take part in this study. 21 GPs, from 18 surgeries, were interviewed within the time frame of the study.	
Methods / Study Appraisal / Synthesis Methods	Discusses the ethics of a prostate cancer screening trial by comparing screening for prostate cancer with screening for breast cancer. Points out that cytological screening for cervical cancer was introduced 20 years ago without a persuasive randomized trial or other compelling scientific foundation.	Compared mass screening for prostate cancer to no screening: 1993-2001, 76,693 men at 10 U.S. study centers randomly assigned for annual screening or usual care as the control. Screening group was offered annual PSA testing for 6 years and digital rectal examination for 4 years. Numbers of all cancers and deaths and causes of death ascertained.	Semi-structured telephone interviews to elicit i) the content of discussions GPs have with asymptomatic men who consult with concerns about prostate cancer/PSA testing and ii) the attitudes of GPs toward the PSA test. Data analysis included identification of the key issues within the data. A transparent coding scheme and regular discussions between the researchers helped to ensure	Opinion of a Urologist about the usefulness of the PSA blood test.

			the credibility and trustworthiness of the findings.	
Primary Outcome Measures and Results	Discusses adverse treatment effects of prostate cancer treatment. Authors comment that if a screening tool with inadequate sensitivity and specificity is used to detect cancers with an unknown, often benign, natural course, and as a result patients are subjected to an experimental treatment with substantial side effects, the net effect of screening could be harmful.	Primary outcome was prostate cancer mortality at 7 and 10 years follow up; number of prostate cancers diagnosed reported. After 7-10 years of follow- up the rate of death from prostate cancer was very low; did not differ significantly between the two groups.	All GPs reported undertaking some discussions with asymptomatic men about the PSA test. They described focusing most of the discussion on the false-positive and false-negative rates of the test, and the risks associated with a prostate biopsy. They reported less discussion of the potential for diagnosing indolent cancers, the dilemmas regarding treatment options for localized prostate cancer and the potential benefit of testing. Considerable variation existed between GPs in	The author notes a correlation between PSA, cancer, and benign prostatic hypertrophy and notes that a rapid rise in PSA is associated with more aggressive cancers. He then goes on to state "we" recommend decreasing the PSA threshold for biopsy from 4ng/ml to 2ng/ml because it SEEMS to detect more localized cancers.

			their accounts of the degree of detail given, and GP's presentation of information appeared to be affected by their personal views of the PSA test.	

Author Conclusions/ Implications of Key Findings	No prevention trial is ethically acceptable if the purpose is simply to provide evidence of net harm. To intervene in healthy people is not ethical without the widespread perception of a net benefit. As of yet the ethical justification for prostate cancer screening trial has yet to be heard.	After 7-10 years of follow- up the rate of death from prostate cancer was very low and did not differ significantly between the two study groups.	The GPs in this study appear to recognize the importance of discussions regarding PSA testing; however, a full and balanced picture of the associated advantages and limitations does not seem to be consistently conveyed. Factors specific to PSA testing which appeared to have an impact on the GPs discussion were the GPs personal opinions of the PSA test, and the need to counter men's primarily positive views of the benefits of PSA testing. Awareness of their views on the consultations may help GPs give men a more balanced presentation of the benefits and limitations of the PSA test.	The author acknowledges that the price of detecting cancers early comes at the expense of more biopsies, treatment-related morbidity, and overtreatment of some men but then endorses doing more biopsies. He concludes until a better test comes along PSA is here to stay.

Strengths/ Limitations	Strengths are the high qualifications of the authors. Limitation is this is an opinion.	According to the 2010 Cochrane Screening for Prostate Cancer (Review) there was adequate sequence generation; adequate allocation concealment; intervention and data on diagnosed cancers and mortality not blinded; incomplete outcome data was not addressed; it was free of selective reporting and free of other bias.	This study is the first to address the discussions about PSA testing that takes place during GP consultations with asymptomatic men concerned about prostate cancer, and as such provides a valuable insight into the extent to which the implications of undergoing a PSA test are discussed. The value of qualitative research lies in the depth of understanding gained from detailed descriptions of specific experiences; therefore the number of participants in a qualitative study is necessarily small. The small number of participants may mean that there were a range of experiences that were not captured. Interviews reliant on recall of events can suffer from recall bias.	This opinion of a practicing urologist is biased with the author talking out of both sides of his mouth.

			A further limitation is that GPs for this study were recruited from one regional area.	
Funding Source	No funding source mentioned.	Supported by contracts from the National Cancer Institute. GlaxoSmith Kline, Aeterna Zentaris, Antigenics, Ferring Pharmaceuticals, Veridex, AstraZeneca, Momenta Pharmaceuticals, Genentech, and Roche provided lecture fees, grant support, and research support to individual	GPs were paid 50 pounds as reimbursement for the time spent in the telephone interview. The work was funded by Cancer Research UK and the NHS cancer Screening Programmes (grant number C73/A2983).	The author declares no conflict of interest.

		researchers.		
Comments	Hans-Olov Adami is highly qualified to give expert opinion. He has a long background as a practicing surgeon with a focus on oncology. He conducts clinical and epidemiologic research in parallel. His clinical research includes randomized trials, prognostic studies, and studies of clinical issues using an observational study design. His focus is on cancer epidemiology and is currently working on prostate cancer with research ranging from genetic association studies to randomized trials of radical surgical treatment, and prediction of outcome using	Excellent large randomized control study with low risk of bias. One of two (European trial) ongoing randomized trials of PSA screening, to provide the first quantitative estimate of the survival benefit due to early detection of prostate cancer. This USA trial found no survival benefit from annual PSA screening combined with digital rectal exam.	This article identified barriers faced by GPs in providing PSA screening education including time constraints and personal opinions. GPs were less likely to discuss the potential for diagnosing indolent cancers and the lack of evidence for the effectiveness for prostate cancer treatments. An interview study is pending which looks at consultations prior to PSA testing from men's perspective.	This article is an opinion of a Urologist and was written in 2005 when PSAs were given more credence than today.

	molecular and genetic markers.			

	Article 24	Article 12	Article 22	Article 9
Article Title and Journal	Asymptomatic incidence and duration of prostate cancer. *American Journal of Epidemiology.*	Patient-Centered Discussion about Prostate Cancer Screening: A Real-World Approach. *Annals of Internal Medicine*	Are physicians discussing prostate cancer screening with their patients and why or why not? A pilot study. *Journal of General Internal Medicine.*	The prostate cancer pseudo-epidemic. *Acta Oncologica*
Author / Year	Etzioni, R., Cha, R., Feurer, R., Davidov, O. (1998).	Gaster, B., Edwards, K., Brown Trinidad, S., Gallagher, T., Braddock, C. (2010)	Guerra, C., Jacobs, S., Holmes, J., Shea, J. (2007).	Adami, Hans-Olov(2010)
Database and Keywords	Database:CINHL with Full Text Keywords in the article include disease progression; natural history; prevalence; prostatic neoplasms; SEER program. Article includes 19 references.	Database:CINHL with Full Text Keywords used to search for the article included prostate cancer screening, clinical guidelines, shared decision making. Article includes 52 references	Database:CINHL with Full Text Key words in the article include prostate-specific antigen; prostate cancer screening; mass screening; physician practice patterns; physician-patient relations; communication barriers; informed decision making. Article includes 39 references	Database:CINHL with Full Text Key words (Major subjects) include early intervention, health screening, incidence, PSA, prostatic neoplasms Article includes 26 references and six tables/charts displaying statistics.

Research Design	Single descriptive study	Ideas and opinions	Qualitative pilot study involving in-depth, semistructured interviews with 18 purposively sampled, academic and community-based primary care physicians.	This article is a lecture by Dr. Adami, presented at SOF meeting in Uppsala, Sweden, March 18-20, 2009. It is a review of studies of the natural history and treatment impact of prostate cancer carried out in Sweden and other Nordic countries during the last two decades.
Level of Evidence	Level 6: Single descriptive study.	Level 7 : Opinions of authorities/experts	Level 6: Single descriptive or qualitative study	Level 1: Systematic review
Study Aim / Purpose	The goal of this paper is to estimate the length of the asymptomatic period in prostate cancer, that is, the time of onset of the disease until the appearance of symptoms leading to its diagnosis. Also estimate the duration of the preclinical period, which the authors define as the time from onset of the disease until its clinical diagnosis, whether due to symptoms or not.	Recent data suggest that few providers are discussing prostate cancer screening with their patients despite national guidelines that recommend it. The authors propose a process-approach (Ask-Tell-Ask) that promotes tailored conversations and value-based recommendations.	This study aimed to identify factors that facilitate or prevent prostate cancer screening discussion.	To present indirect evidence, incidence and mortality trends, and summarize studies of the natural history and treatment impact of prostate cancer.

Population Studied / Sample Size / Criteria / Power	Estimate the age-specific incidence of new (stage A1) prostate cancers using preclinical prevalence data from autopsy studies performed between 1941 and 1964 and clinical incidence data for the years 1960-1986 from the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute.	Not applicable	18 participating physicians	The information in this article is extracted from multiple studies: One study of the natural history of early prostate cancer involved watchful waiting of 223 symptomatic patients in Orebro County in Sweden before the PSA era (1977-1984);Another study of survival benefit of radical local treatment includes a multi-center randomized controlled trail of 695 men newly diagnosed with a clinically localized prostate cancer, and with a PSA value less than 50 PG/nl and no evidence of metastases randomized to radical prostatectomy or watchful waiting. In 2009, the European and USA ongoing randomized trials of PSA screening were mentioned with 162,387 men from seven countries followed for an average of 9 years

				in the European trial and 76 693 men in the USA trial.
Methods / Study Appraisal / Synthesis Methods	Begin by estimating the number of new cases of asymptomatic disease in any given age interval from the incidence data above. Then, the preclinical prevalence estimates are divided by the derived preclinical incidence	Provides a time-efficient model which emphasizes the provider's role as an interactive guide rather than a one-way supplier of information in discussing the pros and cons of prostate cancer screening.	Barriers and facilitators of prostate cancer screening discussions were ascertained using both interviews and chart-stimulated recall-a technique utilizing patient charts to probe recall and provide context to physician decision-making during clinic	Extrapolated findings from multiple studies and incidence and mortality trends. Prostate cancer is an extreme example of autopsy-detected tumors. The prevalence of such lesions is about 20% already among men aged 45 years and increases with

	estimates to yield estimates of the average duration of asymptomatic disease.		encounters. Analysis was performed using consensus conferences based on grounded theory techniques.	age; these lesions detected at autopsy did not cause symptoms or contribute to death.
Primary Outcome Measures and Results	The estimated mean duration among white men is between 11 and 12 years and appears to be approximately 1 year shorter for blacks than for whites. Comparison of the lifetime risks of preclinical and clinical disease suggests that approximately 75% of prostate cancers will never become diagnosed if clinical incidence remains at levels observed in 1984-1986, prior to the introduction of PSA screening in the population.	Ask-Tell-Ask approach will improve the quality of care by encouraging more informed decisions about prostate cancer screening.	All 18 participating physicians reported that they generally discussed prostate cancer screening (PCS) with patients, though 6 reported sometimes ordering PSA tests without discussion. A PCS discussion occurred in only 16(36%) of the 44 patient-physician encounters when patients were due for PCS that also met criteria for chart-stimulated recall. Barriers to PCS discussion were patient comorbidity, limited education/health literacy, prior refusal of care, physician forgetfulness, acute-care visits,	Orebro study with continued follow up beyond 20 years; as of 2001, 9% of men still alive, only 16% had died from prostate cancer, whereas 75% had died from other causes. Multi-center trial of 695 men at 12 years follow-up, 47 (12.5%) of the surgery group and 68(17.9% of the watchful waiting group had died of prostate cancer yielding a relative risk of 0.65 comparing watchful waiting to radical prostatectomy. The absolute risk reduction at 12 years was 5.4 % which translates into 19 patients needing to be treated with radical

			and lack of time. Facilitators of PCS discussion included patient-requested screening, highly educated patients, family history of prostate cancer, African American race, visits for routine physicals, review of previous PSA results, extra time during encounters, and reminder systems.	prostatectomy in order to avert one prostate cancer death. The absolute risk difference in the European trial was 0.71 cancer deaths/1000 men screened, meaning that 1410 men must be screened and 48 cases of prostate cancer treated to avert one death. At 10 years in the US trial there were 92 prostate cancer deaths among 38343 men randomized to screening but only 82 among 38350 men randomized to no screening; the difference was not statistically significant.

Author Conclusions / Implications of Key Findings	The asymptomatic incidence and sojourn time estimates are biologically plausible and are consistent with the literature on PSA growth in prostate cancer cases. They confirm what has already been suspected for some time, namely, that prostate cancer is a relatively slow-growing neoplasm, and they suggest that among whites, 50-75 percent of new cases are unlikely to surface clinically. The estimates should be useful to researchers studying the natural history of the disease and designing effective and cost-effective screening programs.	Shared decision making about prostate cancer screening is crucial, given the continued uncertainty about its risks and benefits.	Prostate cancer screening discussions sometimes do not occur. Important barriers to discussion are inadequate time for health maintenance, physician forgetfulness, and patient characteristics. Future research should explore using educational and decision support interventions to involve more patients in PCS decisions.	The prostate cancer mortality rate has varied little over 40 years, but the detection of clinically insignificant cancers through PSA testing has entailed a drastic increase in the recorded incidence. For ethical and scientific reasoning--reinforced by recommendations from respected authorities-careless PSA testing among men who are poorly informed or ignorant that PSA is analyzed in their blood sample must come to an end.

Strengths/ Limitations	Limitations: The mathematical relation, average duration equals prevalence divided by incidence, has a long history in the epidemiologic literature. An implicit assumption is that the condition of interest is progressive in the sense that it will terminate unless prevented, for example by competing mortality. Therefore, this approach is not valid for non-progressive diseases or for diseases that can regress. Given the possibility that prostate cancer cases may exist in whom the tumor might remain indolent no matter how long they lived (infinitely indolent), this is a limitation of the approach.	This model is based on emerging theory and evidence in the field of patient communication with the goal of engaging patients and addressing their concerns.	Strengths of this study include the open- ended interview and chart-stimulated recall which allowed for the identification of many important barriers to PCS discussion. Chart-stimulated recall is an innovative method by which to achieve triangulation in qualitative research when conducting physician interviews and increases the validity of data obtained by physician interview. Also helps address the discrepancy between physicians ' perceived and actual behavior related to recommending cancer screening tests as well as recording bias inherent in methods based on chart abstractions. The study is limited because of the small number of physicians and patient encounters which may have prevented the	In this groundbreaking article, the author, Professor, Department of Epidemiology, Harvard School of Public Health, former practicing surgeon with a focus on oncology, states that future historians may indeed consider the prostate cancer pseudo-epidemic a disaster of modern medicine. There are no limitations to this study.

			authors from reaching thematic saturation, the point at which no new themes emerged from the data. The study was conducted in 1 large health system with a predominantly urban and suburban sample of physicians therefore the results are not generalizable.	
Funding Source	Research was supported by National Institutes of Health grant R29 CA 70227(R. Etzioni), by contract NCI NO1CN-05230 from the National Cancer Institute (R. Etzioni and R. Cha), and by National Research Service Award 5 F32 Ca 71133002(O.Davidov).	Grant support in part by the CDC and the National Cancer Institute through the Cancer Prevention and Control Research Network, a network within the CDC's Prevention Research Centers Program.	Grant support from the National Institutes of Health Center for Population Health and Health Disparities at the University of Pennsylvania. Also the National Cancer Institute and the Robert Wood Johnson Foundation provided grant support.	The author reports no conflicts of interest. The author alone is responsible for the content and writing of the paper.

Comments	Epidemiologist have a much better handle on the true nature of screening including lead time bias, false positive and negatives, and the prevalence of indolent disease. Epidemiologists try to understand the natural history of a disease in order to develop efficient screening strategies.	Much needed educational tool which encourages evidence based practice.	This study confirms the fact that prostate cancer screening education is sporadic and random and therefore evidence based practice is not occurring.	The author is highly qualified since he is working predominantly on prostate cancer with research ranging from genetic association studies to randomized trials of radical surgical treatment, and prediction of outcome using molecular and genetic markings

	Article 26	Article 6	Article 17	Article 16
Article Title and Journal	Health care reform: Prostate cancer screening decisions: Results from the national survey of medical decisions (DECISIONS Study). *Archives of INTERNAL MEDICINE.*	Screening for prostate cancer (Review) *The Cochrane Collaboration*	Global cancer statistics. *http://caonline.amcancersoc.org/cgi/content/full/caac.20107v1. CA Cancer J Clin 2011 doi: 10.3322/caac.20107*	Natural history of early, localized prostate cancer. *Journal of American Medical Association.*
Author / Year	Hoffman, R., Couper, M., Zikmund-Fisher, B., Levin, C., McNaughton-Collins, M., Helitzer, D., VanHoewyk. Barry, M. (2009).	Ilic D., O'Connor, D., Green S., Wilt,TJ.(2010)	Jamal, A., Bray, F., Center, M., Ferlay, M., Ward, E., Forman, D.(2011).	Johansson, J., Andren, O., Andersson, S., Dickman, P., Holmberg, L., Magnuson, A., Adami, H. (2004).
Database and Keywords	Database: CINHL with Full Text. Keywords used to search for the article include prostate cancer screening and decision making. Article includes 33 references.	Database: CINHL with Full Text. The authors did electronic searches of the PROSTATE registrar (made available by the Cochrane Prostatic Diseases and Urologic Cancers Group and the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CANCERLIT and NHS EED. Hand searching of five prominent urology journals	Incidence data (the number of newly diagnosed cases each year) are derived from population based cancer registries. Although the quality of information from most of the developing countries might be considered, in relative terms, of limited quality, it often remains the only source of information available on the profile of cancer and as such provides valuable information. The total number of cancer deaths by	. Database: CINHL with Full Text. Keywords used to search for the article include prostate cancer, prostate cancer mortality Article includes 26 references.

		and Cancer journal. Keywords not mentioned. Keywords used to search for the article include prostate cancer screening and systematic review.	country is made available by the World Health Organization. Incidence and mortality rates (number of cases or deaths per 100,000 persons per year) were estimated in GLOBOCAN by country, using the most recently available data collected at the International Agency for Research on Cancer or available in routine reports from the registries themselves. 168 references.	
Research Design	A randomly selected national sample of 3010 English-speaking US adults 40 years and older. Included in the survey were 375 men who had either undergone or discussed (with health care providers) PSA testing in the previous 2 years.	Systematic review of 205 potentially relevant articles with 5 RCTs meeting the inclusion criteria for meta-analysis.	Description of global cancer statistics with incidence data derived from population-based cancer registries.	Population-based, cohort study with a mean observation period of 21 years.
Level of Evidence	Level 6: Single descriptive or qualitative study.	Level 1: Systematic reviews/meta-analysis of all RCTs	Level 6: Single descriptive or qualitative study	Level 4: Cohort study.

Study Aim / Purpose	Objectives were to characterize the decision-making process and evaluate factors associated with discussing screening before a making a PSA testing decision and undergoing PSA testing following a discussion.	To determine whether screening for prostate cancer reduces prostate cancer-specific mortality, all-cause mortality, and its impact on quality of life, including adverse events.	Provide an overview of the global cancer burden, including the estimated number of new cancer cases and deaths in 2008 and the incidence and mortality rates by region for selected cancer sites.	To examine the long-term natural history of untreated, early stage prostate cancer.
Population Studied / Sample Size / Criteria / Power	A randomly selected national sample of 3010 English-speaking US adults 40 years and older. Included in the survey were 375 men who had either undergone or discussed (with health care providers) PSA testing in the previous 2 years.	Five RCTs with a total of 341,351 participants were included in this review. All involved PSA testing, though the interval and threshold for further evaluation varied across trials. The age of participants ranged from 50 to 74 years and duration of follow up from 7 to 15 years.	Global cancer statistics: About 12.7 million cancer cases and 7.6 million cancer deaths are estimated to have occurred worldwide with 56% of the cases and 64% of the deaths in the economically developing world.	A consecutive sample of 223 patients (98% of all eligible) with early-stage (TO-T2 NX MO classification), initially untreated prostatic cancer. Patients with tumor progression were hormonally treated (either by orchiectomy or estrogens) if they had symptoms.
Methods / Study Appraisal / Synthesis Methods	The DECISIONS study consisted of a random-digit-dial telephone survey of a national probability sample of English-speaking US adults 40 years and older. Participants completed a set of screening questions and	This updated version of the 2006 review identified 106 potentially relevant articles for full text review in addition to the 99 in 2006 resulting in review of 205 articles. Two RCTs in 2006 and three more in 2010 met the	National incidence rates were estimated using one of several methods, dependant on the availability and quality of data, in the following order of priority:1) National Incidence data, 2)National mortality data	Setting: Regionally well-defined catchman area in central Sweden (recruitment March 1977 through February 1984). The TNM system and the World Health Organization classification of malignant diseases were

	were then eligible for decision-specific question modules if they had taken a medical action or discussed taking that action with health care providers for 1 of 9 common medical decisions within the past 2 years. Modules covered decisions related to cancer screening tests for prostate, colorectal, or breast cancer as well as other topics.	inclusion criteria. Data from the trials were independently extracted by two authors. The methodological quality of three of the studies had a high risk of bias.	and local registry data, 3)Regional incidence data from one or more cancer registries but no mortality data, 4) Frequency data, 5) No data available. Country-specific incidence and mortality rates were prepared for 27 types of cancer, by sex and 10 age groups. A full description of the data and methods used for each county are available in GLOBOCAN 2008.	used. PSA was not available when the cohort was recruited. A total of 654 cases of prostate cancer were diagnosed and 223 patients were ultimately included in the cohort study and followed up from diagnosis until death of the end of the observation period. Scheduled tests were performed to follow the progression of disease and the medical records of all diseased patients were reviewed. Progression and survival rates were determined and multivariable analyses were used to quantify the independent effects of follow-up time, age at diagnosis, grade, and stage.

Primary Outcome Measures and Results	Overall, 69.9% of subjects discussed screening before making a testing decision, including 14.4% who were not tested. Health care providers most often (64.4%) raised the idea of screening, and 73.4% recommended PSA testing. Health care providers emphasized the pros of testing n 71.4% of discussion but infrequently addressed the cons (32.0%). Although 58.0% of subjects felt well-informed about PSA testing, 47.8% failed to correctly answer any of the 3 knowledge questions. Only 54.8% of subjects reported being asked for their screening preferences. A health care provider recommendation (odds ratio, 2.67; 95% confidence interval, 1.08-6.58) was the	Primary outcomes prostate specific and all-cause mortality. Secondary outcomes: incident prostate cancers by stage and grade at diagnosis; metastatic disease at follow up; quality of life; harms of screening; and costs associated with screening programs. No statistically significant reduction in prostate cancer-specific or all-cause mortality among the whole population of men randomized to screening versus controls.	Breast cancer in females and lung cancer in males are the most frequently diagnosed cancer deaths for each sex in both economically developed and developing countries, except lung cancer is preceded by prostate cancer as the most frequent cancer among men in economically developed countries. The increased incidence of breast cancer in developed countries is due in part to postmenapausal therapy or oral contraceptives. Prostate cancer incidence rates vary by more that 25-fold worldwide, with the highest rates recorded primarily in the developed countries of Oceania, Europe, and North America largely because of PSA screening which detects clinically important tumors	After complete follow-up, 39 (17%) of all patients experienced generalized disease. Most cancers had an indolent course during the first 10-15 years. Follow-up from 15(when 49 patients were still alive) to 20 years revealed a substantial decrease in cumulative progression-free survival (45.0% to 36.0%), survival without metastases (from 76.9% to 51.2%), and prostate cancer-specific survival (from 78.7% to 54.4%). The prostate cancer mortality rate increased from 15 per 1000 person-years during the first 15 years to 44 per 1000 person-years beyond 15 years of follow-up.

	only discussion characteristic associated with testing Valuing HCP information was also associated with testing (odds ratio, 1.26; 95% confidence interval, 1.04-1.54).		as well as other slow-growing tumors which might otherwise escape diagnosis. In contrast, males of African descent in the Carribean have the highest cancer mortality rates in the world.	

Author Conclusions / Implications of Key Findings	Recommendations and information from health care providers strongly influenced testing decisions. However, most prostate cancer screening decisions did not meet criteria for shared decision making because subjects did not receive balanced discussions of decision consequences, had limited knowledge, and were not routinely asked for their preferences.	Prostate cancer screening did not significantly decrease prostate cancer-specific mortality in a combined meta-analysis of five RCTs. Only one study (ERSPC) reported a benefit in a subgroup of men aged 55 to 69. Within this subgroup it was determined that 1410 men needed to be invited to screening and 48 additional men subsequently diagnosed with prostate cancer needed to receive early intervention to prevent one additional prostate cancer death at 10 years. Any benefits from prostate cancer screening may take up to 10 years to accrue; therefore, men who have a life expectancy less than 10 t0 15 years should be informed that screening for prostate cancer is unlikely to be beneficial.	The global burden of cancer continues to increase largely because of the aging and growth of the world population and an increasing adoption of cancer-causing behaviors, particularly smoking, within economically developing countries. A significant proportion of the worldwide burden of cancer could be prevented through the application of existing cancer control knowledge, implementing programs for tobacco control, vaccination(for liver and cervical cancers), and early detection and treatment, as well as public health campaigns promoting physical activity and healthier dietary patterns. Much needs to be learned about the causes of several major cancers including prostate	Although most prostate cancers diagnosed at an early stage have an indolent course, local tumor progression and aggressive metastatic disease may develop in the long term. These findings would support early radical treatment, notably among patients with an estimated life expectancy exceeding 15 years.

			and colorectal cancers.	

Strengths/ Limitations	The study had several important limitations. The results were susceptible to recall bias because authors relied on patient self-report to characterize the testing process and there could be up to a 2-year lag time from the discussing screening to being surveyed. Another limitation was the lack of assessment of health literacy, defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" . Patients with health literacy deficits have greater difficulty understanding and recalling complex medical information and are less likely to actively participate in the decision-making process.	Excellent comprehensive systemic review. The methodological quality of three of the studies had a high risk of bias.	Limitations: The global and region-specific estimates are built for 182 countries or territories, together with a set of methods based on the availability of cancer incidence and mortality data at the country or regional level. Therefore the estimates presented in GLOBOCAN 2008 are variable in accuracy, depending on the extend and the validity of available data by country, ranging from real and valid counts of cases and deaths, to estimates based on samples, through to those based on neighboring rates. Strengths include provision by the World Health Organization of country specific cancer mortality estimates by sex and age group for 2008, based on broad cause-of-death models. These data were	Strengths: High internal validity of this population based study because there was complete follow-up and standardized procedures were used for clinical examination, ascertainment of disease progression, and classification of death. The slight difference between cause-specific and relative survival times were largely consistent over time. Limitation: Difficult to validate survival data in any new cohort study of watchful waiting since aggressive treatment of prostate cancer has become more routine than 25 years ago when the cohort was assembled.

	Strengths include addressing an important timely topic with recommendations to provide alternate strategies, such as decision aids, to ensure a process that engages patients in decision making, provides them with information about alternative strategies, and facilitates the incorporation of their preferences and values into the medical plan.		used in estimating the overall burden of cancer is several countries were no or very limited information was available.	
Funding Source	The study was supported by the not-for-profit FIMDM, Boston, Massachusetts, and by the New Mexico VA Health Care System, Albuquerque. Dr. Zikmund-Fisher is supported by a career development award from the American Cancer Society (MRSG-	No known declarations of interest	Funding not mentioned. The authors report no conflicts of interest.	The study was supported by grants from the Orebro County Council Research Committee, the Orebro University Hospital Research Foundation, Obrebro, Sweden, and the Swedish Cancer Society.

	06-130-01-CPPB).			
Comments	The DECISIONS study reaffirms that men are not receiving adequate information and their provider's opinion is often the deciding factor.	Excellent updated systematic review of all randomized controlled trials of screening versus no screening was eligible for inclusion in this review. This article is an update of the 2006 Cochrane review which identified insufficient evidence to either support, or refutes the use of routine mass, selective or opportunistic screening for prostate cancer.	The roles of PSA testing in the reduction of the prostate cancer mortality rates at the population level have been difficult to quantify. Older age, race (black), and family history remain the only well-established risk factors and there are not established preventable risk factors for prostate cancer. Much remains to be learned about the cause of prostate cancer.	This study advocates for aggressive cancer treatment but this was prior to PSA testing, and no screening for activities for prostate cancer took place during the period when this cohort was recruited.

	Article 5	Article 20	Article 4	Article 19
Article Title and Journal	15-Year follow up of a population based prostate cancer screening study. *The Journal of Urology*	Patient education on prostate cancer screening and involvement in decision making. *Annals of Family Medicine.*	Screening decreases prostate cancer death: first analysis of the 1988 Quebec prospective randomized controlled trial. *Prostate*	Clinical Guidelines: Benefits and harms of prostate-specific antigen screening for prostate cancer: An evidence update for the U.S. Preventative Task Force. *Annals of Internal Medicine.*
Author / Year	Kjellman, A., Akre, O., Norming, U., Tornblom, M., Gustafsson, O.(2009)	Krist, A, Woolf, S., Johnson., Kerns, W. (2007).	Labie F., Candas B., Dupont A., Cusan L., Gomez J., Suburu, R. et al.(1999)	Lin, K., Lipsitz, R., Miller, T., Janakiraman, S. (2008).

Database and Keywords	Database: Cochrane Library Keywords in the article are prostate; prostatic neoplasm; mortality; outcome assessment (healthcare), mass screening. Article includes 17 references	Database: Cochrane Library Keywords: Prostatic neoplasm; decision making; patient education/methods; guideline adherence/statistics & numerical data; prostate-specific antigen/blood; mass screening/methods; prevention/cancer; information management. Article includes includes 39 references	Database: PubMed Keywords in the article are prostate cancer; screening; PSA; hormonal therapy. Article includes 49 references	Data Sources in the identified in the article: PubMed and the Cochrane Library (search dates, January 2002 to July 2007), referenced lists of retrieved articles, and expert suggestions. Keywords for three topics. 1) Evidence on health outcomes associated with PSA screening: prostate neoplasm, screening, prostate-specific antigen, early diagnosis, PSA velocity, PSA doubling time, prostate specific antigen doubling. 2) Evidence on the harms of screening for prostate cancer: prostate neoplasm, screening, false positive reactions, adverse effects, mass screening/adverse effects, mass screening/psychology, anxiety, quality of life, health

				knowledge, attitudes, practice. 3) Evidence on natural history of PSA-detected, nonpalpable, localized prostate cancer: prostatic neoplasms, natural history, epidemiology, disease progression, survival analysis, watchful waiting, active surveillance, population surveillance, expectant management, conservative management.
Research Design	Randomized controlled trial in Stockholm, Sweden. Male participants were identified through census records. The study reports on a 15 year follow -up of participants on prostate cancer outcome.	Randomized controlled study comparing paper-based and Web-based decision aids vs. no previsit education as a control.	Randomized controlled trial in Quebec, Canada. Participants were men identified from electoral roles and allocated 2:1 in favor of screening. The study reports on an 11-year follow-up of participants on prostate cancer outcome. Men age 45-80 years	Data extraction: Studies were reviewed, abstracted, and rated for quality by using predefined U.S. Preventative Services Task Force criteria.

			with screening group 31,133 and control group 15,353.	
Level of Evidence	Level 2:RCTs	Level 2: Evidence from one or more RCTs.	Level 2:RCTs	Level 1: Systematic reviews/meta-analysis of randomized controlled trials.
Study Aim / Purpose	Report on a 15-year follow up of participants on prostate cancer outcome; evaluating the long-term survival in attendees and nonattendees of a onetime screening for prostate cancer.	Many clinicians lack resources to engage patients in shared decision making for prostate cancer screening. This study evaluated whether previsit educational decision aids facilitate shared decision making.	Evaluate the impact of prostate cancer screening on cancer-specific mortality	To examine new evidence on benefits and harms of screening asymptomatic men for prostate cancer with PSA.
Population Studied / Sample Size / Criteria / Power	Participants were all men aged between 55-70 years living in the catchment area of Stockhom South Hospital. Men with an earlier diagnosis of prostate cancer were excluded from the study. Numbers include screening group-2374 and control group 24,772	A total of 497 men participated (75 control, 196 brochures, 226 Web site).	46,486 men aged 45-80 years registered in the electoral roll of the Quebec city area were randomized in 1988 between screening and no screening. Screening included measurement of serum PSA using 3.0ng/ml as upper limit of normal	Systemic Review of articles addressing three questions: 1) Health outcomes associated with PSA screening, 390 potentially relevant articles, 2) Harms of prostate cancer screening, 421 potentially relevant articles, 3) Natural history of PSA-detected

			and digital rectal examination (DRE) at first visit. At follow-up visits, serum PSA only was used.	prostate cancer, 91 potentially relevant articles.
Methods / Study Appraisal / Synthesis Methods	Compare mass screening for prostate cancer to no screening: Interventions were one time screening versus control (not invited for screening). The screening consisted of DRE, PSA test and TRUS. TRUS guided biopsies were performed if abnormal findings occurred during the DRE and/or TRUS. A repeat TRUS was performed if the PSA was greater than 7ng/nl.	Men aged 50 to 70 years undergoing a health maintenance examination at a large family practice were enrolled.	Compared mass screening for prostate cancer to no screening: Interventions were annual screening versus control (not invited for screening). TRUS biopsy was only performed if PSA was above 3.0ng/ml for the first time or increased by more than 20% from last measurement.	Randomized, controlled trials and meta-analysis of PSA screening and cross-sectional and cohort studies of screening harms and of the natural history of screening-detected cancer were selected to answer the three aforementioned questions.
Primary Outcome Measures and Results	Incidence rate ratios were calculated using Poisson regression models. Increased risk of death in nonattendees and	The primary outcome was patient-reported level of control over the decision to be screened. Secondary outcomes	Primary outcome was prostate cancer mortality at 11 years follow-up. Also reported was prostate cancer death incidence	No good-quality randomized, controlled trials of screening for prostate cancer have been completed. In one cross-sectional

	decreased mortality in screening attendees. The difference mortality rate was attributable to death from causes other than prostate cancer.	included frequency of screening, patient knowledge, decisional conflict, and time spent discussing screening. Patients exposed to either aid were no more likely than control patients to report collaborative decision. 36% of patients in each group reported equally sharing decision responsibility. Exposure to either decision ad increased patients' involvement in decision making compared with the control condition (Web site, P=.03; brochure, P= .03). Only 46% of control patients reported an active decision-making role, compared with 56% of Web site and 54% of brochure patients. Patients exposed to a decision aid answered a greater percentage of knowledge questions correctly(54%	rates in screened versus unscreened cohorts, and clinical stage and choice of therapy in men diagnosed with prostate cancer.	and two prospective cohort studies of fair to good quality, false-positive PSA screening results caused psychological adverse effects for up to one year after the test. The natural history of PSA-detected prostate cancer is poorly understood.

		control vs 69% Web site, P < .001, and vs. 69% brochure, P < .001) and were less likely to be screened (94% control vs. 86% Web site, P = .06, and vs. 85% brochure, P= .04).		
Author Conclusions / Implications of Key Findings	No evidence was found of a beneficial effect of the screening procedure. Significant lower life expectancy in non-attendees in a population based prostate cancer screening study.	Patients in the decision aid groups were more informed and more engaged in the screening decision than their control counterparts. Exposure did not promote shared decision-making control, however. Whether shared decision making is the ideal model and how to measure its occurrence are subjects for further research.	Strong support for early diagnosis and treatment. Early diagnosis combined with treatment of localized disease decreased death from prostate cancer by 62%.	Prostate-specific antigen screening is associated with psychological harms, and its potential benefits remain uncertain

Strengths/ Limitations	According to the Cochrane Screening for prostate cancer (Review) adequate sequence generation was unclear; no allocation concealment; blinding is not possible to the screening intervention ; incomplete outcome data was addressed; unclear if free of selective reporting; free of bias and data was analyzed according to the intention-to-screen -	Limitations: 1) Outcomes measured by patient and physician questionnaires as opposed to direct observation or interview, 2) A well-educated, computor-savvy patient population was studied , 3) In July 2003, the study practice lost a well-publicized malpractice case involving shared decision making and prostate cancer screening, 4) 46% of the control patients reported that they viewed educational material before the office visit, 5) Study was underpowered to detect differences between the brochure and Web site groups.	According to the Cochrane Screening for prostate cancer(Review) unclear adequate sequence generation; no mention of allocation concealment; not possible to blind intervention; incomplete data was addressed; unclear if free of selective reporting; not free of bias, data was not analyzed according to the intention-to-screen principle	Limitations: Few eligible studies were identified. Long-term adverse effects of false-positive PSA screening test results are unknown. Strengths: Nonrandomized studies of PSA screening excluded.
Funding Source	Supported by the Stockholm County Council and the Thure and Brita Grafstrom Foundation. Grant from Odd Fellows and Karolinska Institute.	Funding support: This work was funded by the American Academy of Family Physicians Foundation under the Joint Grant Awards Program.	Funding not mentioned	Potential financial conflicts of interest: None disclosed.

Comments	Contradictory results	Simple paper and Web-based decision-making aides were equally effective at promoting patient activation in the decision-making process. Further research can be done to define and measures shared decision making and usefulness of aids.	According to the 2010 Cochrane Screening for prostate cancer (Review) crossover and contamination were issues; From a total of 31,133 men randomized to the screening group only 7348(23.6%) were actually screened and of the 15,353 randomized to the control group, 1122(7.3%) were screened for prostate cancer.	The USPSTF recommendation for prostate cancer screening has consistently been a grade I; The evidence is insufficient to recommend for or against routinely providing (the service). Evidence that (the service) is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. It is fascinating that wide-spread testing for PSA among asymptomatic men continues when the USPSTF has consistently given prostate cancer screening, the service, such a low recommendation.

	Article 7	Article 23	Article 13	Article 29
Article Title and Journal	Prostate-specific antigen: friend or foe. *Urologic Nursing*	Randomized trial examining the effect of two prostate cancer screening educational interventions on patient knowledge, preferences, and behaviors. *Journal of General Internal Medicine.*	Cancer part 1: Prevention and screening Cancer screening 2009: Setting evidence-based priorities. *Audio-Digest Internal Medicine*	Editorial: Health care reform: Weighing the benefits and downsides of prostate-specific antigen screening. *Arch Intern Med*
Author / Year	Linn, M., Ball, R., Maradigiegue,A.(2007) .	Partin, M., Nelson, D., Radosevich, D., Nugent, S., Flood, A., Dillon, N., Holtzman, J., Haas, M., Wilt, T.(2004).	Perez-Stable. (2009)	Pignone,M. (2009)
Database and Keywords	Database: CINHL with Full Text Author's database includes systematic review of 52 references from 1991-2007 using Evidence-Based Medicine Reviews, Medline, and CINAHL. Author's keywords are prostate-specific antigen, PSA, prostate cancer, prostatectomy, prostatic hyperplasia, prostate cancer screening, and prostate cancer costs.	Database: CINHL with Full Text Author's keywords are prostate neoplasm; prostate-specific antigen; mass screening; decision-making; patient education.	From the 37th Annual Advances in Internal Medicine, presented by the University of California, San Francisco, and School of Medicine. No mention of key words.	Database: Google Scholar Keywords to find article PSA screening Article includes 17 references s

Research Design	A review of the medical evidence and controversy related to PSA screening. A search of Evidence Based Medicine Reviews, Medline, and CINHL along with government statistics and research material is the methodology employed. Included are CEU, exam questions, review, tables/charts	Randomized controlled trial.	Lecture	Editorial
Level of Evidence	Level 4: Case study	Level 2: Evidence from one or more RCTs	Level 7: Opinions of authorities/ experts	Level 7: Opinion of expert/authority
Study Aim / Purpose	The purpose of this article is to review the medical evidence and controversy surrounding PSA screening	To assess the effect of video and pamphlet interventions on patient prostate cancer screening knowledge, decision-making participation, preferences, and behaviors.	Setting evidence-based priorities for cancer screening in 2009.	To weigh the benefits and downsides of prostate-specific antigen screening
Population Studied / Sample Size / Criteria / Power	This is a review article and did not study a population	One thousand, one hundred fifty-two male veterans age 50 and older with primary care appointments at participating facilities were randomized and 893 completed follow-up. Setting four Midwestern Veterans	Examined criteria for cancer screening including evidence based recommendations for colon, breast, lung, and prostate cancer screening.	This is an editorial but a table was presented with outcomes for 2 cohorts of 1000 men aged 60 years and at average risk to demonstrate the balance of benefit versus harm of PSA screening.

		Affairs medical facilities.		
Methods / Study Appraisal / Synthesis Methods	In addition to reviewing relevant literature this article is a comprehensive review of PSA screening history and background to include: PSA history; Screening recommendations; Epidemiology;PSA screening movements Cochrane Review screening Controversies; Financial considerations; and Case study of medico-legal considerations.	Interventions: Patients were randomized to mailed pamphlet, mailed video or usual care/control. Outcomes assessed by phone survey 2 weeks postinterventio n included a 10-iten knowledge index; correct responses to question on prostate cancer natural history, treatment efficacy, the PSA's predictive value, and expert disagreement about the PSA; whether screening was discussed with provider; screening preference; and PSA testing rates.	Lecture	Editorial.

Primary Outcome Measures and Results	This is a review article and did not have primary outcome measures and results.	Mean knowledge index scores were higher for video and pamphlet, subjects versus controls. Video and pamphlet subjects reported significantly higher percentages of correct responses relative to controls to questions on prostate cancer natural history, treatment efficacy, and expert disagreement, but not PSA accuracy. Pamphlet subjects were more likely that controls to discuss screening with their provider but video subjects were not. Video and pamphlet subjects were less likely to intend to have a PSA, relative to controls. PSA testing rates did not differ significantly across groups.	Approximately 80% of men between 50 and 80 year of age have had PSA test. Approximately 15% lifetime risk; approximately 30% of men have prostate cancer at autopsy. Studies show similar survival associated with watchful waiting and active therapy.	Table of 1000 cohorts compared diagnosed as having prostate cancer: screening (53) versus (23) not screened; biopsies required (39) versus (23) ; adverse effects (impotence, incontinence or both) (26) versus (12) ; prostate cancer deaths (3)versus (4); other deaths(113) versus(113) .

Author Conclusions / Implications of Key Findings	Although PSA testing has become a primary screening method for prostate cancer in the US, this test has come under scrutiny. PSA screening lacks a high level of specificity due to frequent false-positive results. Additionally, major health organizations differ in their screening recommendations for use of the PSA test. The medical community and patients must understand the benefits and possible detriments of this screening test. Providers should approach each man individually when recommending a PSA test, noting that many risk factors must be considered in a screening protocol for prostate cancer.	Mailed interventions enhance patient knowledge and self-reported participation in decision making, and alter screening preferences. The pamphlet and video interventions evaluated are comparable in effectiveness. The lower-cost pamphlet approach is an attractive option for clinics with limited resources.	Public opinion about screening is that finding cancer early usually or always saves lives; 56% of those surveyed want screening, even for clinically irrelevant cancers.	The decisions about whether to be screened for men aged 50 to 75 years hinges on whether the known downsides of overdiagnosis and treatment-related adverse effects are counterbalanced by a sufficiently large chance that screening will result in a reduction in the risk of death from prostate cancer. Two recently reported randomized trials conclude that, at best, prostate cancer screening leads to a modest absolute reduction in prostate cancer mortality overtime. However, this benefit comes at a large cost in terms of increasing the diagnosis and treatment of cancers that would not have gone on to cause any

				problems. Moreover, the harms of screening begin to accrue immediately, whereas the potential benefits are realized only many years later.
Strengths/ Limitations	This systematic review of 52 references from 1991-2007 is comprehensive, reliable and objective.	Strengths include providers blinded to the fact that their patients were participating in a trial. Follow-up interviewers were blinded from intervention assignment, but the statisticians conducting the analysis were not. All authors were involved in the development of the pamphlet but none were	Interesting informative nonbiased lecture.	Strength is a succinct summary of harms and benefits with an illustrative table of cohort of 1000 men. Limitation is level 7 evidence.

		involved in the development of the video. Limititations include the generalizability to the population since this involved VA patients who are usually low income and/or service connected.		
Funding Source	Urologic Nursing Editorial Board Statements of Disclosure: Bradway, PhD, RN is on the Consulting Board for Boehringer Ingelheim Pharmaceuticals; Gaines, MS, ARNP,CUNP is on the Speakers' Bureau for Pfizer, Inc., and Novertis Oncology; Russell, MN, CMSRN is on the Advisory Board for Roche/Abbott Labs	Funded by VA Health Services Research and Development Service grant # 11R 99 277-1 to the Center for Chronic Disease Outcomes Research, Veterans Affairs Medical Center, Minneapolis Minn.	Faculty disclosure: In adherence to ACCME Standards for Commercial Support, Audio-Digest requires all faculty and members of the planning committee to disclose relevant financial relationships within the past 12 months that might create any personal conflicts of interest. For this program, the faculty and planning committee reported nothing to disclose.	Dr. Pignone is supported by Established Investigator Award 5K05 CA129166 from the National Cancer Institute and by the Foundation for Informed Medical Decision Making.

Comments	This systematic review of 52 referenced from 1991-2007 is comprehensive, reliable and objective. Informative article that traces the origins of the PSA and lists the inconsistent recommendations for prostate cancer screening among nine major health care organizations.	This study hit close to home because it took place at four Midwestern Veterans Affairs medical facilities. A low-cost pamphlet is an attractive option because it is easy to implement.	This informative lecture about setting evidence-based priorities is in line with promoting evidence based practice.	Excellent editorial which simplifies the issue.

	Article 3	Article 1	Article 25	Article 28
Article Title and Journal	Clinical consequences of screening for prostate cancer: 15 years follow-up of a randomized controlled trial in Sweden *European Urology*	Screening and Prostate-Cancer Mortality in a Randomized European Study *The New England Journal of Medicine*	Enthusiasm for cancer screening in the United States. *JAMA*.	Risk profiles and treatment patterns among men diagnosed as having prostate cancer and a prostate-specific antigen level below 4.0 ng/ml. *Arch Intern Medicine.*
Author / Year	Sandblom,G., Varenhorst, E., Lofman, O., Rosell,J., Carlson, P. (2004)	Schroder, F., Hugosson, J., Roobol, M., Tammela, T., Ciatto, S., Nelen, V.,…Auvinen,A.(2009).	Schwartz, L., Woloshin, S., Fowler, F., Welch, G. (2004).	Shao, Y., Albertson, P., Roberts, C., Yong, L., Mehta, A., Stein, M., DiPaola, R., Lu-Yao, G. (2010).
Database and Keywords	Database searched: Cochrane Library Keywords in the article are prostate cancer; screening; survival; tumour stage; treatment; digital rectal examination; prostate-specific antigen Article includes 17 references and two editorial comments.	Database searched:CINHL and Cochrane Library Keywords used to search include: prostate cancer, cancer screening, prostate specific antigen (PSA), and clinical guideline. The article includes 31 references.	Database searched: CINHL with Full Text. Keywords used to search: Cancer screening.	Database searched: CINHL with Full Text. Keywords used to search include: prostate cancer, cancer screening, prostate specific antigen (PSA), and clinical guideline The article includes 26 references.

Research Design	From the total population of men aged 50-69 years in Norrkoping (n=9026) every sixth man (n=1494) was randomly selected to be screened for prostate cancer every third year over a 12-year period. The remaining 7532 men were treated as controls .In 1987 and 1990 only DRE was performed, in 1993 and 1996 DRE was combined with a test for PSA.	Randomized ,multicenter trial of screening for prostate cancer, with the rate for death from prostate cancer as the primary outcome	Survey using a national telephone interview of adults selected by random digit dialing, conducted from December 2001 through July 2002.	Data from the Surveillance, Epidemiology, and End Results system were used to describe patient characteristics and treatment patterns in men with newly diagnosed prostate cancer.
Level of Evidence	Level 2: RCTs	Level 2 : randomized controlled trials(RCTs)	Level 6: Single descriptive or qualitative study.	Level 6: Single descriptive or qualitative study.
Study Aim / Purpose	To characterize prostate cancers detected in a population-based screening programme and to evaluate the effectiveness of screening with three-year intervals.	The European Randomized Study of Screening for Prostate Cancer was initiated in the early 1990s to evaluate the effect of screening with prostate-specific-antigen (PSA) testing on death rates from prostate cancer.	To determine the public's enthusiasm for early cancer detection.	To determine the risk profile and treatment patterns among men diagnosed as having prostate cancer and a prostate-specific antigen level below 4.0 ng/ml.

Population Studied / Sample Size / Criteria / Power	Participants were Norrkoping males aged 50-69 years of age. The screened cohort diminished from 1492 men at the start of the study to 1118 in 1996 due to migration and death. Data on survival was complete for the whole cohort including those who migrated.	A total of 162,387 men in the core age group underwent randomization; of these men 72,952 were assigned to the screening group and 89,435 to the control group. A total of 62 men in the screening group and 82 men in the control group died between identification and randomization.	Five hundred individuals participated (woman aged >/= 40 years and men aged >/= 50 years; without a history of cancer).	123934 men identified from the SEERS system with newly diagnosed prostate cancer from 2004 to 2006.
Methods / Study Appraisal / Synthesis Methods	Compared mass screening for prostate cancer to no screening; RCT in Norrkoping, Sweden. Interventions were screening every 3 years versus control (not invited for screening). The 1st and 2nd rounds of screening were DRE; the 3rd and 4th rounds were DRE and PSA test. Transurethral ultrasound biopsy was performed if DRE abnormal or PSA > 4.0ng/ml.	Compared mass screening for prostate cancer to no screening: The researchers identified 182,000 men between the ages of 50 and 74 years through registries in seven European countries for inclusion in the study. The men were randomly assigned to a group that offered PSA screening at an average of once every 4 years or to a control group that did not receive the screening.	Responses to a survey with 5 modules: a general screening module (e.g., value of early detection, total - body computed tomography); and 4 screening test modules: Papanicolaou test; mammography; PSA test; and sigmoidoscopy or colonoscopy.	Age-standardized treatment rates were calculated in 5-year age strata. Logistic regression was used to quantify the odds ratio of men with low- and high- risk disease and the use of radical prostatectomy or radiation therapy.

Primary Outcome Measures and Results	Primary outcome was prostate cancer mortality at 15 years follow-up. Also reported was clinical stage and choice of therapy in men diagnosed with prostate cancer across both screened and control groups, and number of prostate cancers diagnosed. There was no significant difference in total or prostate cancer-specific survival between the groups.	Primary outcome was prostate cancer mortality and number of prostate cancers diagnosed. Rate ratio for death from prostate cancer in the screening group, compared with the control 0.80. The absolute risk difference 0.71 death per 1000 men. 1410 men would need to be screened, 48 additional cases of prostate cancer need to be treated to prevent one death from prostate cancer.	Most adults (87%) believe routine cancer screening is almost always a good idea and that finding cancer early saves lives(74% said most or all the time). Less than one third believe that there will be a time when they will stop undergoing routine screening. Thirty-eight percent of respondents had experienced at least 1 false-positive screening test; more than 40% characterized that experience as "very scary" or the "scariest time of my life". Yet, looking back, 98% were glad they had the initial screening test. Most had a strong desire to know about the presence of cancer regardless of its implications: and 56% said they would want to be tested for pseudodiseases. Seventy-three percent would	Men with a PSA level of 4.0 ng/ml or lower represent 14% of incident prostate cancer cases. Fifty-four percent of men diagnosed as having prostate cancer and PSA levels lower than 4.0 ng/ml harbor low-risk disease, but over 75% of them received radical prostatectomy or radiation therapy. Men with screen-detected prostate cancer and PSA values lower than 4 ng/ml were 1.49 and 1.39 times more likely to receive RP and RT, respectively, and were less likely to have high-grade disease than men who had non-screen-detected prostate cancer.

			prefer to receive a total-body cat scan instead of $1000 in cash.	
Author Conclusions / Implications of Key Findings	Although PSA had not been introduced in the clinical practice at the start of the study, still able to show that possible to perform a long-term population-based randomized controlled study with standardized management and that screening in general practice is an efficient way of detecting localized prostate cancer.	PSA-based screening reduced the rate of death from prostate cancer by 20% but was associated with a high risk of overdiagnosis.	The public is enthusiastic about cancer screening. This commitment is not dampened by false-positive test results or the possibility that testing could lead to unnecessary treatment. This enthusiasm creates an environment ripe for the premature diffusion of technologies such as total-body CAT scans, placing the public at risk of over testing and	Most men diagnosed as having prostate cancer with a PSA threshold below 4.0ng/ml had low-risk disease but underwent aggressive local therapy. Lowering the biopsy threshold but retaining our inability to distinguish indolent from aggressive cancers might increase the risk of overdiagnosis and

			overtreatment.	overtreatment.

Strengths/ Limitations	According to the 2010 Cochrane Screening for prostate cancer (Review) there was no adequate sequence generation; no allocation concealment; not blinded to the screening intervention; unclear incomplete outcome data addressed; unclear if free of selective reporting	According to the 2010 Cochrane Screening for prostate cancer (Review) there was adequate sequence generation; allocation concealment unclear; intervention not blinded but causes of death evaluated in a blinded manner; incomplete outcome data was addressed; it was free of selective reporting but unclear if the study was free of other bias.	Potential limitations: 5% of adults living in households without phones were not represented. Although response rate was good, 72% among individuals known to be eligible and 51% among those estimated to be eligible, systematic bias between respondents and nonrespondents is still possible. Findings about false-positive PSA tests results are based on only 10 men and should be interpreted cautiously.	The analysis was limited by the nature of the data source. The SEER system collects information from all patients in 16 registries. The Gleason scores and PSA values recorded by the SEER system reflect the information that was used to make clinical decisions. The SEER system does not record information such as percentage of free PSA or the number of positive scores found on biopsy analysis. The major strength is the large sample size that is population based and includes patients from defined geographic areas in all clinical settings rather than selected institutes.

Funding Source	A grant for the study was received from the Research Council in the South-East Region of Sweden. Supported also by the Swedish Cancer Foundation and the County Council of Ostergotland.	Supported by grants from Europe Against Cancer and the fifth and sixth framework program of the European Union, by grants from agencies and health authorities in the participating countries, and by unconditional grants from Beckman Coulter. The studies in each national center were funded by numerous local grants.	Drs Woloshin and Schwartz are supported by the Veterans Affairs Career Development Awards in Health Services Research and Development and by Robert Wood Johnson Generalist Faculty Scholar Awards. This study was supported by grant DAMD17-96-MM-6712 from the Department of Defense Breast Cancer Research Program, grant CA91052-01 from the National Cancer Institute, and a Research Enhancement Award from the Department of Veterans Affairs to investigate the harm from excessive medical care.	This study was supported by National Cancer Institute grant ROI CA 116399, Cancer Institute of New Jersey core grant NCI CA-72720-10, and Robert Wood Johnson Foundation grant 60624.

Comments	Excellent large randomized control study with complete follow up data at 15 years but high risk of bias. This study shows it is possible to perform a randomized controlled study of prostate cancer screening, with a registration allowing for unbiased comparisons between the screened group and control group. This is the first published population-based randomized controlled trial on prostate cancer screening with complete data on tumor stage, tumor grade and treatment for the control group as well as the intervention group.	Excellent large randomized control study with low risk of bias. To prevent 1 death from prostate cancer 1410 men would need to be screened and 48 additional cases of prostate cancer would need to be treated; that seems like a high price to pay.	The public's enthusiasm about cancer screening is short sighted and is driven in part by a paternalistic health care system. Medicine and health care needs to get out of the business of prediction, including tampering with Mother Nature, and back into the business of healing. The increased breast cancer incidence observed in many Western countries in the late 1980s and 1990s was due in part to use of postmenopausal hormone therapy. Oral contraceptive use is associated with increased breast cancer incidence. Prostate cancer is a hormone driven disease, yet some men are treated with testosterone. The counterintuitive	By doing biopsies on patients with PSA values in the "normal" range the sensitivity and specificity of the PSA test can be determined. Usually patients with low PSA levels are not brought back for sequential and/or simultaneous testing because prostate biopsies and transrectal ultrasounds are no fun, expensive, and invasive. Data will now be available in 4 cells which is precisely what is needed to determine the validity of the PSA test.

			practice of treating normal physiologic states, such as fertility, painful periods, menopause, and andropause with hormones know to cause cancer is what the public should be enthusiastic about stopping.	

	Article 15	Article 11	Article 8	Article 14
Article Title and Journal	Urinary and sexual function after radical prostatectomy for clinically localized prostate cancer. The prostate cancer outcomes study. *Journal of the American Medical Association.*	The Fall in Incidence of Prostate Carcinoma: On the Down Side of a Prostate Specific Antigen Induced Peak in Incidence--Data from the Utah Cancer Registry. *Cancer*	Reflection: The problem with choice: What my mechanic taught me about PSA screening. *Canadian Family Physician*	Estimating lead time and overdiagnosis associated with PSA screening from prostate cancer incidence trends. *The International Biometric Society*
Author / Year	Stanford, J., Feng, Z., Hamilton, A., Gilliland, Stephenson, R., Eley, J., Potosky, A. (2000).	Stephenson. Smart, C., Mineau, G., James, B., Janerich, D., & Dribble, R. (1995).	Suss,R.(2008)	Telesca, D., Etzioni, R., Gulati, R.(2008).
Database and Keywords	Database searched: CINAHL with Full Text. Keywords: Prostate cancer treatment , side effects Author's database includes population-based cancer registries in six geographic areas of the United States. The article includes 20 references.	Database searched: Google Scholar Author's database includes Utah Cancer Registry, and Surveillance, Epidemiology, and End Results (SEER) national registry. Keywords include prostate carcinoma, screening, incidence, mortality, and prostate specific antigen. The article includes 50 references	Database searched: CINAHL with Full Text. Keywords: decision making, health screening, PSA, prostatic neoplasms The article includes 2 references.	Database searched: MEDLINE Author's database includes prostate cancer incidence trends derived from the Surveillance, Epidemiology and End Results (SEER) registry of the National Cancer Institute Key words include Additive models; Cancer screening; Convolution models; Lead time Distribution; Penalized likelihood.

				The article includes 23 references
Research Design	The Prostate Cancer Outcomes Study, a population-based longitudinal cohort study with up to 24 months of follow up.	Tracked age-adjusted prostate carcinoma incidence trends from the population-based Utah Cancer Registry and compared them with rates from the Surveillance, Epidemiology, and End Results (SEER) Program.	The journal article is a letter by Dr. Suss, a Canadian Family Practice Doctor and Assistant Professor in the Department of Family Medicine at the University of Manitoba in Winnipeg	Research design: Conceptualized observed incidence as the sum of the secular trend in incidence, which reflects incidence in the absence of PSA, and the excess incidence over and above the secular trend, which is a function of population screening patterns and unknown lead time.
Level of Evidence	Level 4: Cohort study.	Level 6:Single descriptive study	Level 7: Opinions of authorities/ experts	Level 6: Single descriptive or qualitative study
Study Aim / Purpose	To measure changes in urinary and sexual function in men who have undergone radical prostatectomy for clinically localized prostate cancer.	The Utah Cancer Registry data were examined for a decrease in prostate cancer incidence.	The author questions whether it is right to ask patients to decide if they want to be screened for prostate cancer.	The primary goal is to estimate the lead time distribution associated with PSA screening utilizing population screening and disease incidence trends to make inferences.

Population Studied / Sample Size / Criteria / Power	A total of 1291 black, white, and Hispanic men aged 39 to 79 years diagnosed as having primary prostate cancer between October 1, 1994, and October 31, 1995, and who underwent radical prostatectomy within six months of diagnosis for clinically localized disease.	Conservatively estimated Utah prostate carcinoma incidence for 1994. The state of Utah had a current population of 1,907,936 with 167,840 men older than age 50 years.	Not applicable	Not applicable
Methods / Study Appraisal / Synthesis Methods	Men diagnosed as having primary prostate cancer between 10/1/1994 and 10/31/1994 who were residents of areas covered by 6 population based SEERs registries. A total of 11137 eligible cases were identified, and 5672 were randomly sampled for PCOS. Of the sampled cases, 4736(83.5%) were contacted and invited to participate, and 3533(62.3%) completed a 6- and/or 12-month survey. Medical record abstracts were completed for 3486 (98.7%)	Rapid case ascertainment methods used to estimate Utah prostate carcinoma incidence for 1994.	Reflection	The present analysis includes men aged 50-64, whereas the previous study considered only men aged 65 and above. After conceptualizing observed incidences two likelihood models were developed: likelihood model for the excess incidence given the secular trend and used it to estimate the mean lead time under specified distributional assumptions and a likelihood model for observed incidence and use it to simultaneously estimate the mean

	of the sampled, participating cases. For analysis of surgery, all PCOS patients aged 39 to 79 years with histologically confirmed, clinically localized prostate cancer who underwent radical prostatectomy as primary treatment within 6 months of diagnosis date and who had both survey and medical records data(n=1301).			lead time together with a smooth secular trend. Variances and confidence intervals are estimated using via a parametric bootstrap.
Primary Outcome Measures and Results	Primary outcome measures are distribution of and change in urinary and sexual function measures reported by patients at baseline and 6, 12, and 24 months after diagnosis. At 18 or more months following radical prostatectomy, 84.4 % of men were incontinent and 59.9% were	A rapid and highly correlated rise in prostate carcinoma incidence has been observed in both SEER and Utah incidence rates between 1988 and 1991, the last year for which SEER data are available. In 1992, Utah incidence rates peaked at 236.2 per 100,000. In 1993 and 1994, Utah incidence	Dr. Suss uses the analogy of his car mechanic asking him what type of fuel filter he wants. He knows nothing about fuel filters (the means), he knows he wants his car to run well at a reasonable price (the end). A healthy 50-year-old male wants to live as long as possible without incontinence and impotence (the	Outcome measures and results: Estimates correspond to overdiagnosis and frequencies of approximately 22.7% and 34.4% for screen-detected whites and blacks, respectively.

	impotent.	rates fell to 195.0, and an estimated 164.0 per 100,000 respectively.	end) so why ask him whether he wants a PSA screening test.	
Author Conclusions / Implications of Key Findings	Study suggests that radical prostatectomy is associated with significant erectile dysfunction and some decline in urinary function. These results may be particularly helpful to physicians and their patients with prostate cancer who face difficult treatment decisions.	Population-based data from the Utah Cancer Registry indicates the incidence of prostate carcinoma is decreasing rapidly after a similarly rapid increase. Documented increases in incidence for years prior to 1992, as well as projections for 1992 through 1995, raised concerns including economic impact, rising rate of treatment without documented therapeutic efficacy, treatment related morbidity, and screening leading to identification and treatment of clinically or biologically	The author contends we should leave the means to the experts, such as car mechanics and doctors, and the ends with individuals who are experts at what they want. It is difficult to do this though when the American Cancer Society recommends discussing the pros and cons with patients so they can make an informed decision about having a PSA screening test (means).	Likelihood-based approach allows authors to make formal inferences about the lead time and overdiagnosis associated with PSA screening in the United States. The model provided the first glimpse of a secular trend in disease incidence and finally the authors provided some provocative insights about racial disparities in prostate cancer.

		unimportant cancers.		
Strengths/ Limitations	This study provided the first description of outcomes experienced by a cohort of unselected, population-based patients who have undergone radical prostatectomy. In addition to its population based design, strength of the study is the large number of patients. Limitations include only 62.3% sampled men participating and a 24-month survey was not completed by 19.2% of those who had completed an earlier survey. Recall bias is	Quantitative data comparing prostate cancer rates from two reputable sources showing that the increase in prostate carcinoma incidence between 1984 - 1991 was largely attributed to the increased use of PSA in prostate carcinoma detection and screening including media coverage.	The author concludes that it is unreasonable to have patients make choices about means when thousands of doctor's can't agree if PSA screening results in any benefit.	Strengths and limitations: This article presented a novel method for making formal inferences about lead time and overdiagnosis from population incidence trends in the context of PSA screening. The model approach is based on the additive relationship between the excess incidence, which depends on the lead time, and the secular incidence trend; this provides a formal method for inferring a plausible secular trend. The limitations to the analysis are

	another potential limitation since baseline (prediagnosis) function was assessed on the 6-month survey.			uncertainty about the PSA screening frequencies and cancer detection rates thus the confidence intervals are narrow. A second limitation is the use of a specified parametric distribution for the lead time.
Funding Source	The study was supported by contracts from the National Cancer Institute in Bethesda, Maryland	1996 American Cancer Society. Presented at the 90th Annual Meeting of the American Urological Association, Las Vegas, April 26, 1995.	Competing interests: None declared	Funding source: The article was supported by the grants from Cancer Intervention and Surveillance Network (CISNET) and from the National Cancer Institute.

Comments	Informative population-based longitudinal study with up to 24 months of follow-up.	A screening phenomenon called a "cull effect" explains the shortcomings in prostate cancer incidence predictions starting in 1992. When a testing method is applied to a relatively static population of prevalent disease, an initial rapid rise in detection and hence incidence will be observed. As the cull effect removes individuals with prostate cancer from the population, the population becomes progressively depleted of detectable cases.	This journal reflection is very insightful and a delight to read.	Technical article with multiple graphs of incidence trends and statistical formulas through-out.

	Article 21	Article 30
Article Title and Journal	Trials of decision aids for prostate cancer screening: A systematic review. *American Journal of Preventative Medicine.*	Editorial: Health care reform: Shared decision making for prostate cancer screening: Do patients of clinicians have a choice? *Arch Intern Med*
Author / Year	Volk, R., Hawley, S, Kneuper, S., Holden, W., Stroud, L., Cooper, C., …Pavlik, V. (2007)	Woolf, S., Krist, A. (2009).
Database and Keywords	Medline was searched with key words "prostate cancer screening" and "decision making" for articles published through 2006. A 2003 Cochrane review, a 2002 evidence report by the Agency for Healthcare Research and Quality, and a review by Evans et al. were examined to identify studies on prostate cancer screening decision making. Reference lists from relevant articles were also reviewed. Finally, published abstracts and subsequent full papers from annual meetings of the Society for Medical Decision Making, the American Society of Preventive Oncology, and the Society of Behavioral Medicine were examined.	Database searched: CINAHL with Full Text. Keywords: decision making, health screening, PSA. Article has 20 references
Research Design	A systematic review	Editorial
Level of Evidence	Level 1: Systematic review	Level 7 :Opinion of expert/authority
Study Aim / Purpose	Patient decision aids are used to promote informed decision making. This review examines the methods and findings of studies that have evaluated the impact of prostate cancer screening decision aids on patient outcomes.	The uncertainty of PSA testing -and thus the logic for shared decision making (SDM)--persists, but there are questions about whether SDM occurs in practice, how well it is performed, and whether clinicians support SDM or find it feasible. This editorial aims to see if patients of clinicians have a choice.
Population Studied / Sample Size / Criteria / Power	Eighteen eligible trials, involving 6221 participants, were identified. Sixteen studies enrolled primary care patients, while the remaining two studies were community based.	This is an editorial. Discussed Hoffman et al's telephone survey of 375 men who had either undergone PSA testing or discussed prostate cancer screening with a clinician in the previous 2 years.

Methods / Study Appraisal / Synthesis Methods	MEDLINE, the Cochrane Registry, reference lists, and abstracts from professional meetings were searched through December 2006. Studies were included if a patient education intervention for prostate cancer screening had been evaluated against a control condition.	Editorial
Primary Outcome Measures and Results	Summary of outcome findings from 18 published controlled trials of patient decision aids for prostate cancer screening are listed on five horizontal pages. Knowledge of prostate cancer screening was the most common outcome, with 14 of 18 studies including such a measure. Intention to be screened was lower among decision-aid participants than control participants in six of the nine studies. The patient decision aides improved patient knowledge and made patients more confident about their decisions. The aids appeared to decrease interest in PSA testing and screening behavior among patients seeking routine care (relative risk=0.88, 95% confidence interval, p=0.008); the aides had no impact on the screening behavior of patients seeking screening services. Patients who received patient decision aids were more likely to prefer watchful waiting as a treatment option if they were found to have prostate cancer than were controls(RR=1.53, 95% CI=1.31-1.77, p <0.001)	According to Hoffman's study 70% recalled a discussion that preceded the testing decision, but only one-third remembered discussing any counterarguments to screening.
Author Conclusions/ Implications of Key Findings	Prostate cancer screening decision aids enhance patient knowledge, decrease decisional conflict, and promote greater involvement in decision making. The absence of outcome measures that reflect all elements of informed decision making continues to limit the field.	The larger cultural context helps explain the inertia of the health care system in implementing SDM. Making SDM feasible also requires changes in the practice environment, beginning with tort reforms that protect clinicians who give patients an informed choice about cancer screening , as well as reimbursement reform to facilitate the time investment for such counseling.

Strengths/ Limitations	This level one study had no apparent limitations. The strength relates to its in depth review with 18 trials, involving 6221 participants, and high quaility searches including Cochrane reviews.	Provocative editorial. Limitation is Level 7 evidence.
Funding Source	The project was funded in part by grants from the Centers for Disease Control and Prevention and the Agency for Healthcare Research and Quality.	No financial disclosure
Comments	Decision aids help patients take a more active role in making a decision about prostate cancer screening. There needs to be aids for patients with low health literacy.	Points out the problems implementing shared decision making.

Systematic Review Evidence Table Format (adapted with permission from Thompson, C. (2011). In J. Houser & K.S. Oman (Eds.), *Evidence-based practice: An implementation guide for healthcare organizations (*p.155). Sudbury, MA: Jones and Bartlett.

Reference:

Tymkow, C. (2011). Clinical scholarship and evidence-based practice. In M.E. Zaccagnini & K. W. White, K. W (2011). *The doctor of nursing practice essentials: A new model for advanced practice nursing (pp. 61-136).* Sudbury, MA: Jones and Bartlett.

Appendix B

Basic Prostate Cancer Screening Educational Pamphlet

Let's see what you know:

1) Can the PSA test help find prostate cancer early at a stage when potentially curative treatments can be offered?

Check Only One: Yes ☐ No ☐

2) Does prostate cancer usually lead to death?

Check Only One: Yes☐ No ☐

3) Does all prostate cancer cause harm?

Check Only One Yes ☐ No ☐

4) Is the prostate-specific antigen (PSA) blood test a good cancer screening test?

Check Only One: Yes☐ No ☐

5) What are the major side effects of prostate cancer treatments?

Check Only One: None☐ Impotence and Incontinence ☐ Bowel Problems ☐ Nausea☐

Screening for prostate cancer with a Prostate Specific Antigen (PSA) blood test starting at age 50, and age 45 for high risk men, means looking for cancer before it causes symptoms. Men with serious health problems, or age 75 or older, should not be offered screening. Prostate cancer screening can find cancers early when a cure may be possible but it often finds cancer which would never have caused problems. It is very important to know about the risks and benefits of screening before the decision to be screened or not is made.

The prostate gland is approximately the size of a walnut. It is located in front of the rectum, directly below the bladder, encircling the urethra, the tube which empties urine from the bladder (figure 1). The back of the prostate gland can be felt during a digital rectal exam (figure 2). The prostate gland helps control urine flow and normal sexual function. Prostate cancer treatment can lead to urinary incontinence and impotence, the inability to have sex.

Prostate cancer is the second leading cause of cancer death in U.S. males next to lung cancer. For an American male, the lifetime risk of developing prostate cancer is 16 men out of 100, but the risk of dying of prostate cancer is only 3 men out of 100.

(http://seer.cancer.gov/csr/1975_2004). Black men, and men with a first degree relative diagnosed with prostate cancer before age 65, are at increased risk.

The key points therefore to be aware of prior to undertaking a PSA test are the following:

- The PSA test facilitates the early detection of prostate cancer at a stage when potentially curative treatments can be offered.
- There is currently no strong evidence that PSA testing reduces death from prostate cancer.
- Not all men with raised PSA will have prostate cancer/the PSA test will not detect all prostate cancer.
- Prostate cancer is diagnosed through a prostate biopsy which can be uncomfortable or painful.
- Prostate biopsies will not detect all prostate cancers.
- Prostate cancers range from aggressive to slow growing forms-slow growing tumors may not result in symptoms or shorten life expectancy.
- There is no evidence about the optimum treatment for localized prostate cancer.
- Some treatments for prostate cancer can have significant side effects.

(Clements *et al. BMC Family Practice* 2007 8:35 doi: 10.1186/147-2296-8-35)

Ask yourself about how you feel about the possible benefits and harms of being screened:

- Do I want to know if I have prostate cancer, even if the cancer might never do me any harm?
- Would I be treated if I learned that I had prostate cancer?
- How do I feel about the risks of being treated for prostate cancer?
- How do I feel about the risks of getting a deadly or aggressive form of prostate cancer?
- Would I be willing to accept a high risk of side effects from treatment in return for a small chance of living longer?

(*Patient information: Prostate cancer screening (PSA tests) (The Basics)* 2011 **UpToDate**, www.uptodate.com)

Let's see what you now know:

1) Can the PSA test help find prostate cancer early at a stage when potentially curative treatments can be offered?

Check Only One: Yes ☐ No ☐

2) Does prostate cancer usually lead to death?

Check Only One Yes☐ No ☐

3) Does all prostate cancer cause harm?

Check Only One: Yes☐ No ☐

4) Is the prostate-specific antigen (PSA) blood test a good cancer screening test?

Check Only One: Yes☐ No☐

5) What are the major side effects of prostate cancer treatments?

Check Only One: None☐ Impotence and Incontinence ☐Bowel Problems ☐Nausea☐

Prostate gland

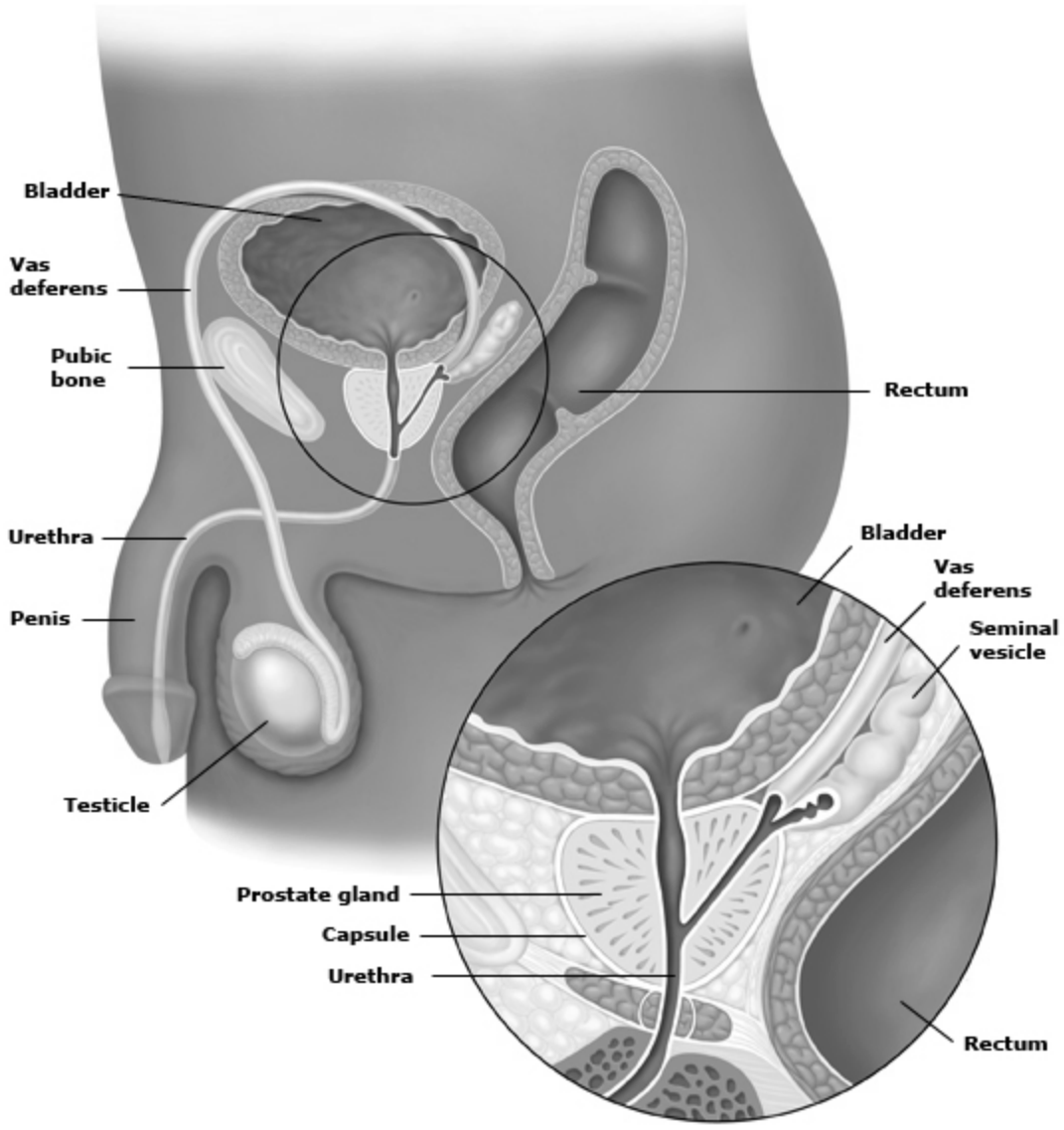

Figure B - 1: Prostate Gland

This drawing shows the male anatomy and a close-up of the prostate gland. Reproduced with permission from: Patient information: Prostate cancer screening (PSA tests) (The Basics). In: UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2011. Copyright © 2011 UpToDate, Inc. For more information visit www.uptodate.com.

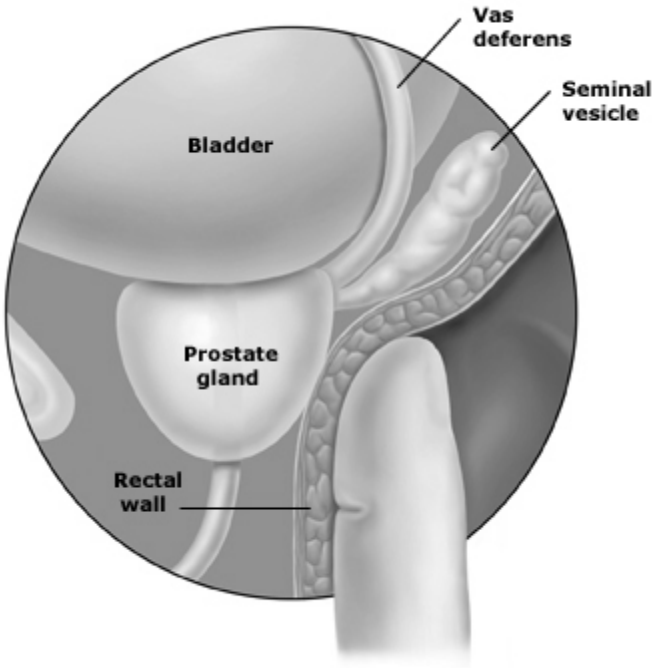

Figure B - 2: Rectal Exam

During a digital rectal exam, the doctor or nurse puts a finger inside your rectum and feels your prostate gland. That way he or she can see how big it is and whether it has bumps or dents or anything unusual. Reproduced with permission from: Patient information: Prostate cancer screening (PSA tests) (The Basics). In: UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2011. Copyright © 2011 UpToDate, Inc. For more information visit www.uptodate.com.

Appendix C

Detailed Prostate Cancer Screening Educational Pamphlet

Screening for prostate cancer with a Prostate Specific Antigen (PSA) blood test starting at age 50, and age 45 for high risk men, means looking for cancer before it causes symptoms. Prostate cancer screening leads to increased cancer diagnosis, modest mortality reduction (death), and substantial morbidity (illness). It is imperative therefore to be well informed about the risks and benefits of screening before the decision to be screened or not is made.

The prostate gland is approximately the size of a walnut. It is located in front of the rectum, directly below the bladder, encircling the urethra, the tube which empties urine from the bladder (see picture). The back of the prostate gland can be felt during a digital rectal exam. The prostate gland helps regulate bladder control and normal sexual function (erection and ejaculation), including storage and production of seminal fluid, a white milky substance which nourishes sperm.

The prostate gland is prone to problems. Prostatitis, inflammation of the gland, can cause painful urination and ejaculation. Benign Prostatic Hypertrophy (BPH), a condition common to aging men, is caused by the slowly enlarging prostate gland putting pressure on the urethra making it difficult to urinate. And finally, the prostate gland can develop cancer, ranging from a silent condition which does not spread and/or cause symptoms, to invasive disease spreading to nearby organs and bone, ultimately leading to death.

Prostate cancer is the second most frequently diagnosed cancer and the sixth global leading cause of cancer death. Incidence rates vary by more that 25-fold worldwide; the highest rates are in developed countries that utilize PSA testing which detects clinically important tumors as well as other slow growing cancers that may never have caused problems [1]. In the U.S. in the late 1980's when prostate cancer screening with a PSA blood test came into vogue incidence rates rose from 84.4/100,000 cases in 1984 to 163/100,000 cases in 1991 [2]. Since the early 1990's prostate incidence has been declining although it is still the second leading cause of cancer death in U.S. males next to lung cancer. For an American male, the lifetime risk of developing prostate cancer is 16 percent, but the risk of dying of prostate cancer is only 2.9 percent [3].

Most prostate cancers detected in the U.S. are asymptomatic, clinically localized, and found on routine PSA testing [4]; this correlates with the new cases of prostate cancer at the Denver VA. Prostate cancer data for 2008-2010 was obtained from the Eastern Colorado Health Care System Tumor Registry. There were 209 cases of prostate cancer diagnosed since 2008 except for new patients arriving with the diagnosis. At least 75% of the cases were clinically

localized. The largest groups of men to receive the diagnosis (76%) were in their fifties and sixties.

PSA is a glycoprotein found in both normal and cancerous prostate glands. The absolute value of serum PSA is used to determine the extent of prostate cancer and a patient's response to treatment. The use of PSA as a screening test is controversial because its' ability to identify correctly those who have the disease (sensitivity) is overestimated and its' ability to identify correctly those who do not have the disease (specificity) is underestimated [5].

Mass population PSA testing was initiated in the late 1980's without well-conducted randomized clinical trials to support the benefit of screening. In 2009, two ongoing randomized trials of PSA screening provided the first quantitative estimates of the survival benefits due to early detection. The prostate arm of the National Cancer Institute-sponsored Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial found no survival benefits from annual PSA screening combined with digital rectal exam. A larger similar European trial of men aged 50 to 74 years found a 20% reduction in prostate cancer mortality following PSA screening every four years. This means that 1410 men needed to be screened, and 48 men needed to receive early treatment in order to prevent one cancer death at ten years [6]. Both trials found clear evidence of overdiagnosis.

Diseases diagnosed earlier by screening, versus later when symptoms develop, lead to earlier treatments (lead time). Unfortunately patients often die at the same time, thus all lead time did was cut off quality years of life. One of the pitfalls of the PSA test is that it markedly increases the lead time resulting in overdiagnosis because death from other-causes precedes the date of symptomatic disease and/or occurs during the lead time [7]. Therefore the modest absolute reduction in prostate cancer over time comes at the cost of treating clinically irrelevant cancers. Additionally, the harms of screening start immediately whereas the potential benefits are not realized for years to come [8].

The key points therefore to be aware of prior to undertaking a PSA test are the following:

- the PSA test facilitates the early detection of prostate cancer at a stage when potentially curative treatments can be offered\
- there is currently no strong evidence that PSA testing reduces mortality from prostate cancer
- not all men with raised PSA will have prostate cancer/the PSA test will not detect all prostate cancer
- prostate cancer is diagnosed through a prostate biopsy which can be uncomfortable or painful
- prostate biopsies will not detect all prostate cancers
- prostate cancers rage from aggressive to slow growing forms-slow growing tumors may not result in symptoms or shorten life expectancy
- there is no evidence about the optimum treatment for localized prostate cancer

- some treatments for prostate cancer can have significant side effects [9].

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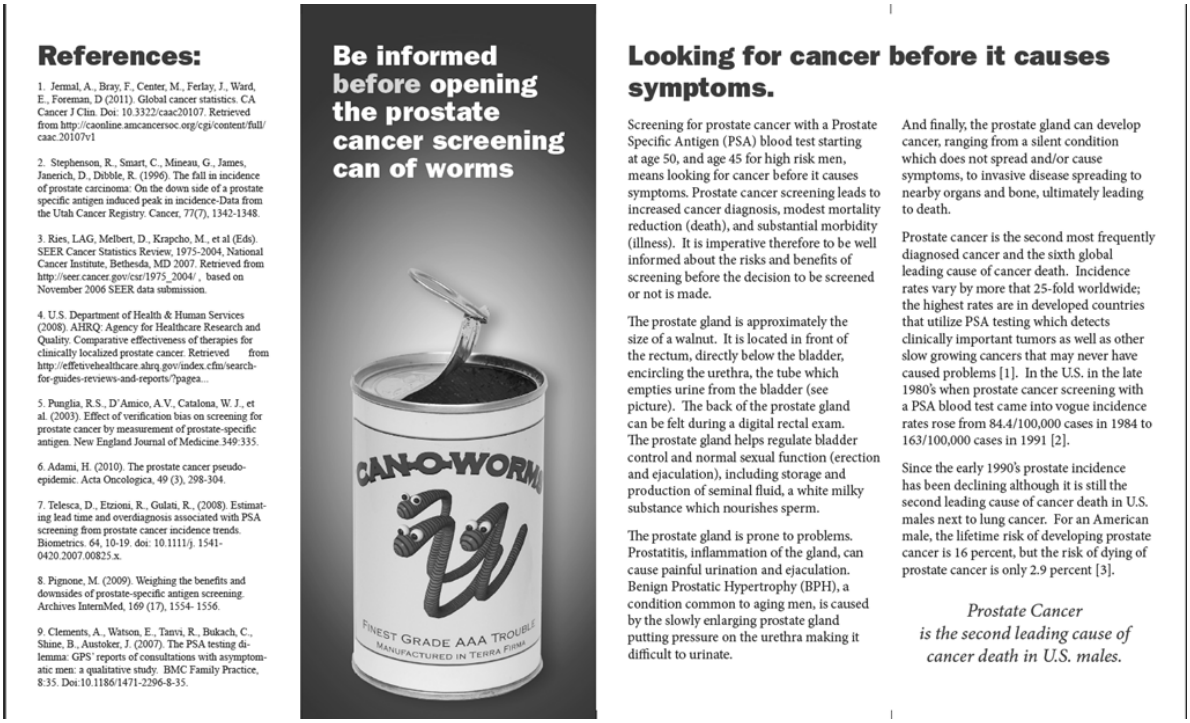

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Be informed before opening the prostate cancer screening can of worms

Looking for cancer before it causes symptoms.

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The prostate gland is approximately the size of a walnut. It is located in front of the rectum, directly below the bladder, encircling the urethra, the tube which empties urine from the bladder (see picture). The back of the prostate gland can be felt during a digital rectal exam. The prostate gland helps regulate bladder control and normal sexual function (erection and ejaculation), including storage and production of seminal fluid, a white milky substance which nourishes sperm.

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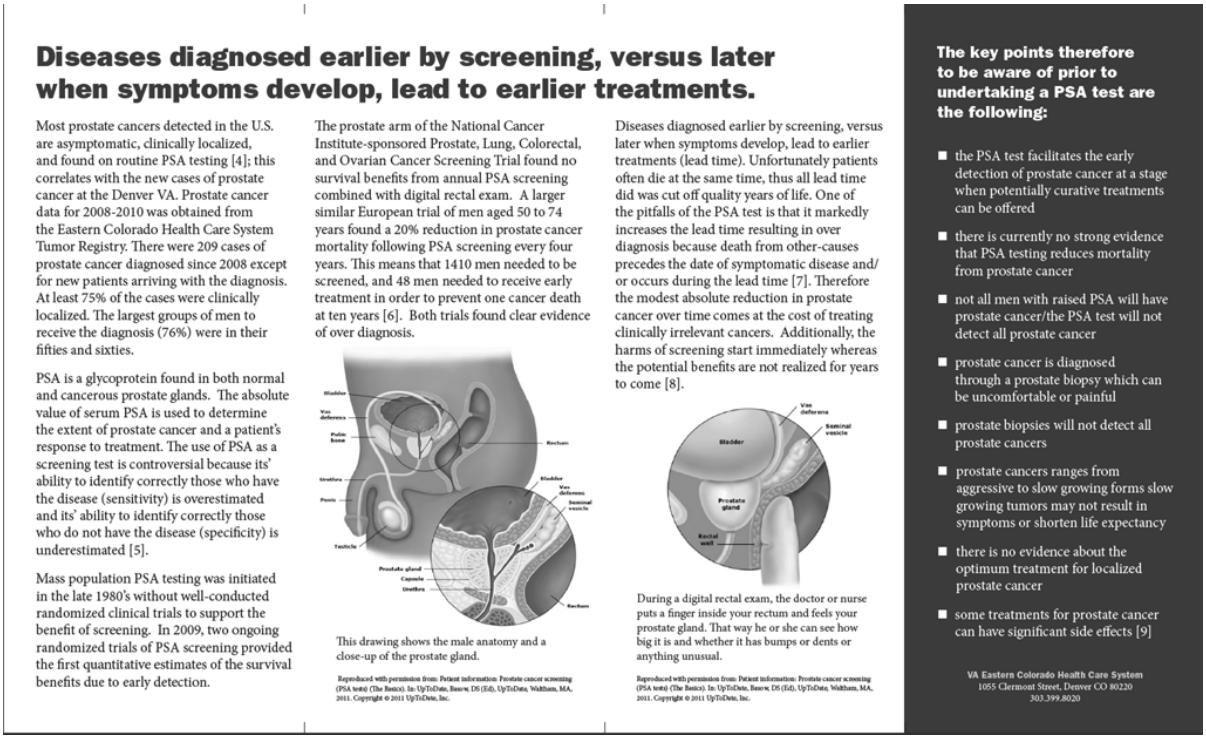
Prostate Cancer is the second leading cause of cancer death in U.S. males.

Figure C - 1: Detailed Pamphlet (Front Side)



Diseases diagnosed earlier by screening, versus later when symptoms develop, lead to earlier treatments.

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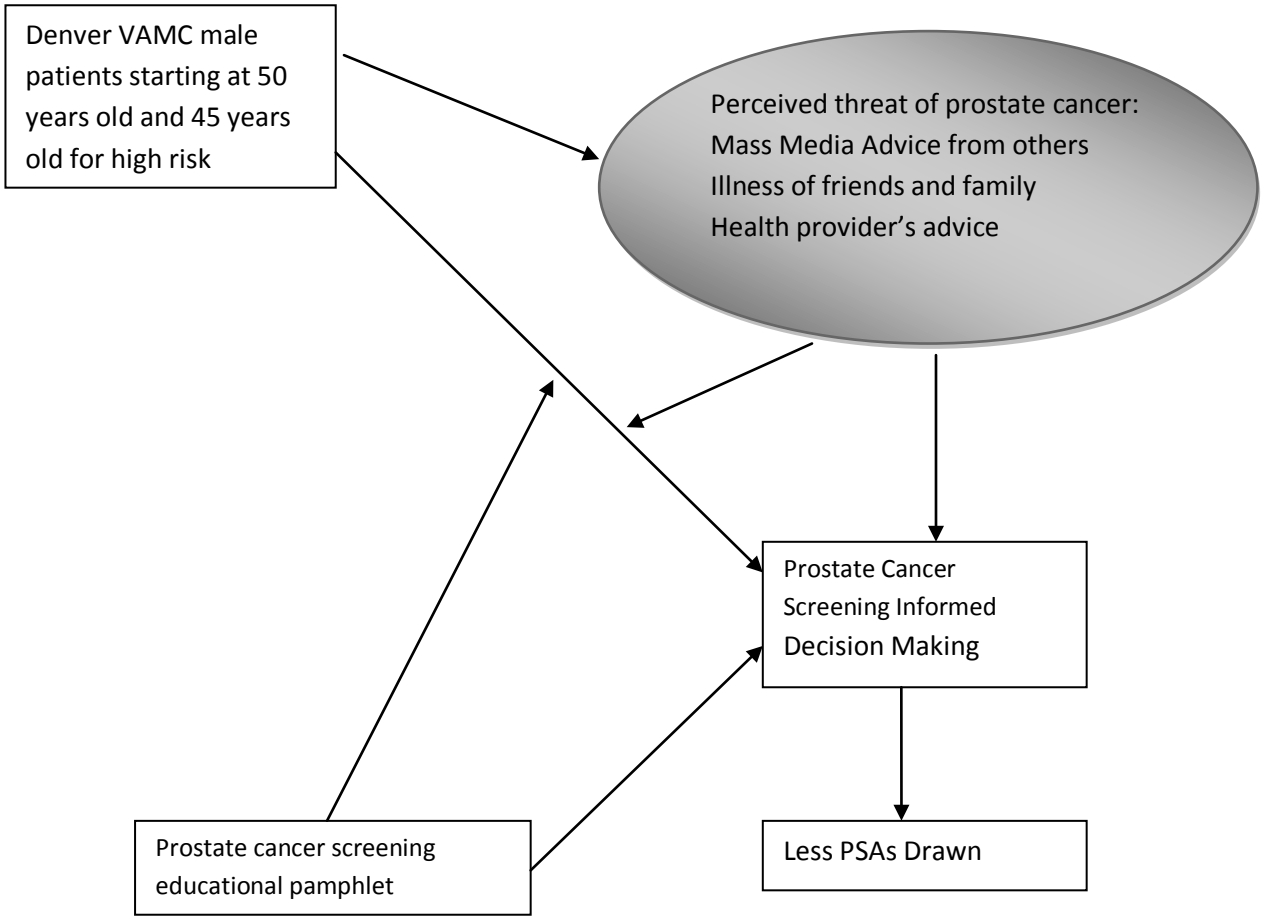
VA Eastern Colorado Health Care System
1055 Clermont Street, Denver CO 80220
303.399.8020

Figure C - 2: Detailed Pamphlet (Back Side)

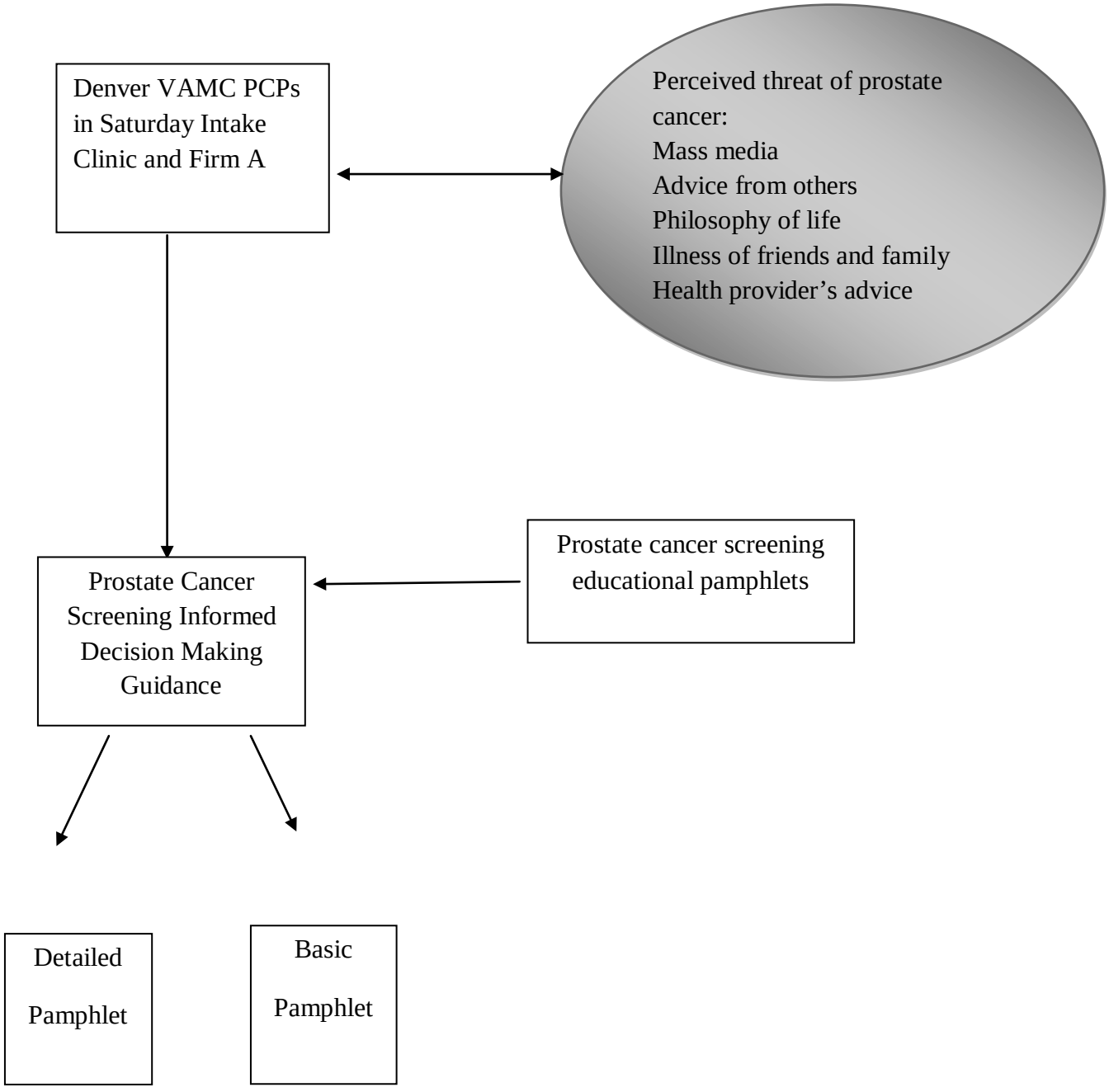
Appendix D

Conceptual Model for Informed Prostate Cancer Decision Making



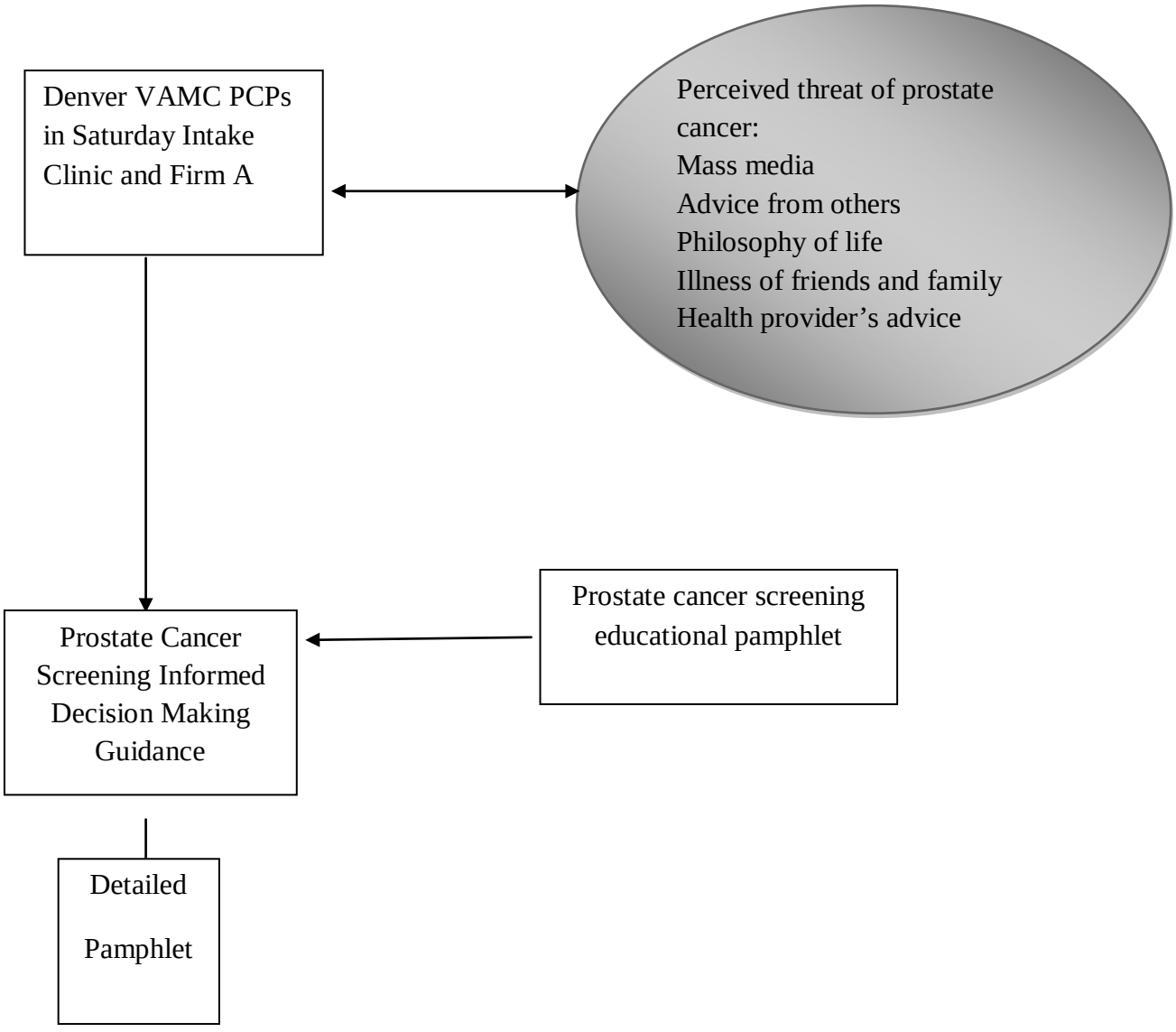
Appendix E

Conceptual Model for Informed Decision Making with the Guidance of Two Prostate Cancer Screening Educational Pamphlets



Appendix F

Conceptual Model for Informed Decision Making with the Guidance of a Prostate Cancer Screening Educational Pamphlet



Appendix G

Logic Model for Prostate Cancer Screening Informed Decision Making (Initial Capstone)

RESOURCES	ACTIVITIES	OUTPUTS	OUTCOMES	IMPACTS
Chief of Ambulatory Care and Urology Printing company	Approve Prostate cancer screening pamphlets Pamphlets made and distributed to clinics	# of patients to receive the prostate cancer screening educational pamphlet	Perceived threat of prostate cancer (decreased)	Prostate cancer screening recommendations (decreased)
Vista and Microsoft Office Outlook E-mail	Providers will be educated about the Evidence Based Requirement for informed decision making including the pros and cons of screening	# of providers engaging in shared decision making	Asymptomatic men deciding to be screened for prostate cancer (decreased)	Prostate cancer incidence (decreased)
Chemistry lab	Number of PSAs drawn will be recorded	# of patients diagnosed with stage I and II prostate cancer (# of prostate biopsies)	Overdetection (decreased)	Death rates (no change)
Urology Department	Number of patients referred for elevated PSA leading to prostate biopsy will be recorded	# of patients diagnosed and treated for stage I and II prostate cancer (watchful waiting, surgery, radiation, cryoablation, androgen deprivation therapy, high-intensity focused ultrasound therapy)	Overdetection and treatment (decreased)	Quality of life (increased)
Eastern Colorado Health Care System Tumor	Prostate cancer data including the accession year, date of diagnosis, clinical stage,	# of patients undergoing radical prostatectomy or radiation treatment	Treatment (decreased)	Treatment-related urinary, sexual, and bowel dysfunction

Registry	pathologic stage, treatment, and age at diagnosis will be recorded			(decreased)
Primary Care Providers (PCPs)	PCPs will continue to educate patients about the risks and benefits of screening and treatment	# of patients diagnosed and treated for asymptomatic prostate cancer	Psychological and physical stress (decreased)	Ability to continue work (increased)
Primary Care Providers (PCPs)	PCPs will continue to educate patients about the risks and benefits of screening and treatment	# of patients visiting urology and radiation oncology for localized prostate cancer	Surgery and radiation (decreased)	Hospitalization rates (decreased)
Primary Care Providers (PCPs)	PCPs will continue to educate patients about the risks and benefits of screening and treatment	# patients undergoing prostate biopsies, surgery, radiation, cryoablation, androgen deprivation therapy, high-intensity focused ultrasound therapy	Health care dollar use (decreased)	Efficient use of health care dollars (increased)

Appendix H

Logic Model for Informed Decision Making with the Guidance of Two Prostate Cancer Screening Educational Pamphlets (Revised Capstone)

RESOURCES	ACTIVITIES	OUTPUTS	OUTCOMES	IMPACTS
Colorado Multiple Institutional Review Board (COMIRB)	Approve prostate cancer screening pamphlets	Shawn Fury, ECHCS Medical Media Program Manager, produces a few Detailed and Basic prostate cancer screening pamphlets for the Project.	Primary Care Providers (PCP) in S2 and Firm A receive Prostate educational materials (increased)	PCPs receive guidance from prostate cancer screening educational pamphlets (increased)
PCPs in Saturday Intake Clinic (S2) and PCPs in Firm A Clinic	Informed about the Project, a quality improvement initiative linked to assessment of the two prostate cancer screening educational pamphlets	# of PCPs to participate in the small scale intervention	PCPs use educational pamphlets to guide informed decision making (increased)	Prostate cancer screening recommendations (decreased)
Vista and Microsoft Office Outlook E-mail	Providers in Firm A and S2 will be educated about the Evidence Based Requirement for informed decision making including the latest USPSTF recommendation not to screen healthy men	# of providers engaging in shared decision making	Asymptomatic men deciding to be screened for prostate cancer (decreased)	Prostate cancer incidence (decreased)
PCPs in S2 and Firm A Clinic after pamphlet use	Discussions about the usefulness of the Detailed and Basic pamphlets	PCPs evaluation of the prostate cancer screening educational pamphlets	The Detailed and Basic pamphlet guided PCPs with prostate cancer	The Denver VAMC adopts the use of the two prostate cancer screening educational

			informed decision making (increased)	pamphlets.
Shawn Fury, ECHCS Medical Media Program Manager	The pamphlets are mass produced for use by the Denver VAMC	All Denver VAMC PCPs participate in prostate cancer screening education through Vista Microsoft Outlook E-mail. (Requirement for informed decision making including the latest USPSTF recommendation not to screen healthy men).	All Denver VAMC engage in informed decision making with the use of the two pamphlets (increased)	Asymptomatic Denver VAMC men deciding to be screened for prostate cancer (decreased)
Denver VAMC PCPs	PCPs will routinely educate male veterans about the risks and benefits of screening and treatment using the guidance of the two prostate cancer screening pamphlets	Less number of asymptomatic patients undergoing PSA testing	Unnecessary testing, interventions, and treatments (decreased)	Quality of life (increased)

Appendix I

Logic Model for Provider Opinion about Guidance Provided by a Prostate Cancer Screening Educational Pamphlet (Final Capstone)

RESOURCES	ACTIVITIES	OUTPUTS	OUTCOMES	IMPACTS
Colorado Multiple Institutional Review Board (COMIRB)	Approve prostate cancer screening pamphlet	Shawn Fury, ECHCS Medical Media Program Manager, produces Detailed prostate cancer screening pamphlets for the Project.	Primary Care Providers (PCP) in S2 and Firm A receive Prostate educational material (increased)	PCPs receive guidance from prostate cancer screening educational pamphlet (increased)
PCPs in Saturday Intake Clinic (S2) and PCPs in Firm A Clinic	Informed about the Project, a quality improvement initiative linked to assessment of a Detailed prostate cancer screening educational pamphlets	# of PCPs to participate in the small scale intervention	PCPs use educational pamphlet to guide informed decision making (increased)	Prostate cancer screening recommendations (decreased)
Vista and Microsoft Office Outlook E-mail	Providers in Firm A and S2 will be educated about the Evidence Based Requirement for informed decision making including the latest USPSTF recommendation not to screen healthy men	# of providers engaging in shared decision making	Asymptomatic men deciding to be screened for prostate cancer (decreased)	Prostate cancer incidence (decreased)
PCPs in S2 and Firm A Clinic after pamphlet use	Discussions about the usefulness of the Detailed pamphlets	PCPs evaluation of the prostate cancer screening educational pamphlet	The Detailed pamphlet guided PCPs with prostate cancer informed decision making (increased)	The Denver VAMC adopts the use of the Detailed prostate cancer screening educational pamphlet.

Shawn Fury, ECHCS Medical Media Program Manager	The pamphlet is mass produced for use by the Denver VAMC	All Denver VAMC PCPs participate in prostate cancer screening education through Vista Microsoft Outlook E-mail. (Requirement for informed decision making including the latest USPSTF recommendation not to screen healthy men).	All Denver VAMC engage in informed decision making with the use of the Detailed pamphlets (increased)	Asymptomatic Denver VAMC men deciding to be screened for prostate cancer (decreased)
Denver VAMC PCPs	PCPs will routinely educate male veterans about the risks and benefits of screening and treatment using the guidance of the Detailed prostate cancer screening pamphlet	Less number of asymptomatic patients undergoing PSA testing	Unnecessary testing, interventions, and treatments (decreased)	Quality of life (increased)

Appendix J

Measurement Tool

Prostate Cancer Screening Brochure Survey Questions:

1. Is the pamphlet easy to read?
   Yes [ ] Somewhat or Maybe [ ] No [ ]

2. Is the pamphlet informative?
   Yes [ ] Somewhat or Maybe [ ] No [ ]

3. Is the pamphlet biased?
   Yes [ ] Somewhat or Maybe [ ] No [ ]

4. Do you think it would change decisions of vets to get a PSA?
   Yes [ ] Somewhat or Maybe [ ] No [ ]

5. Would you be willing to distribute this out to your patients?
   Yes [ ] Somewhat or Maybe [ ] No [ ]

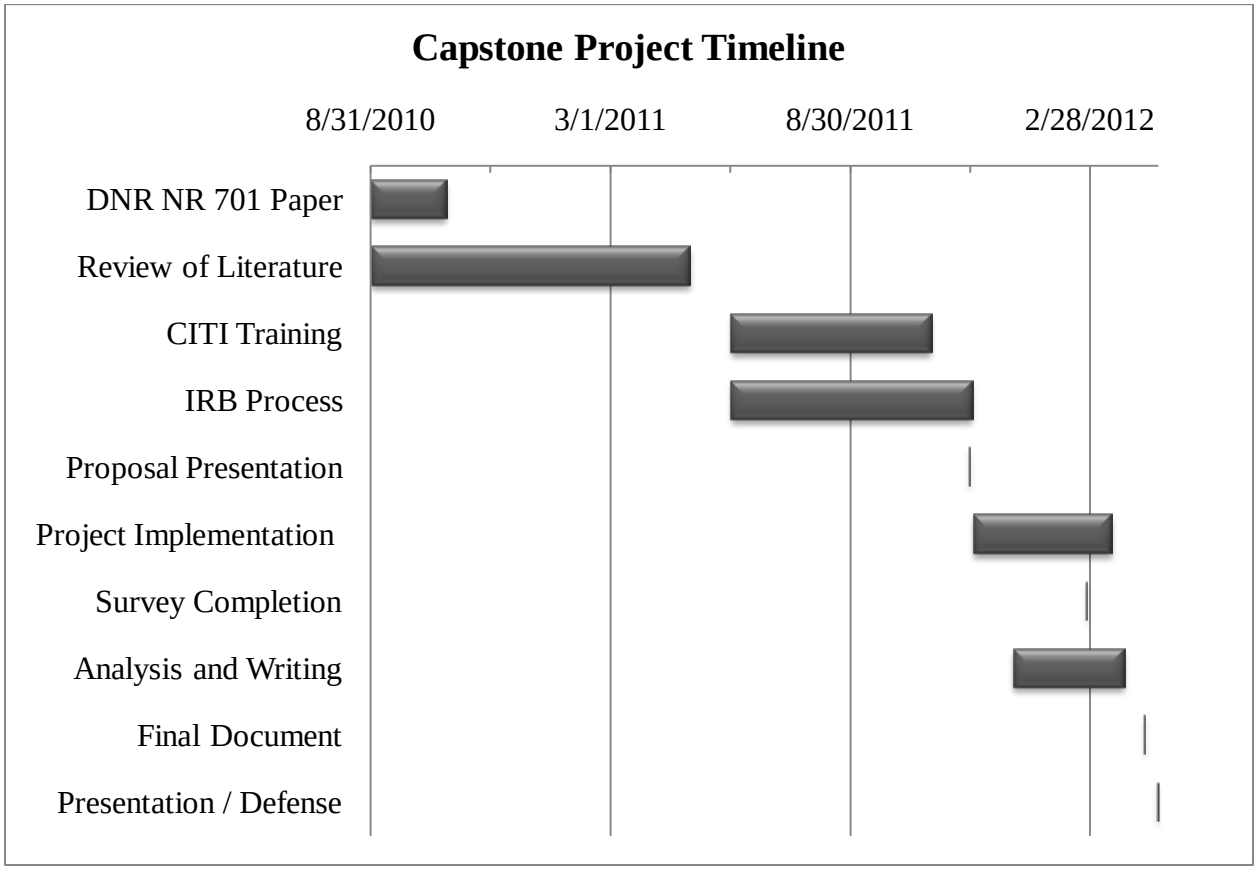
6. Are the graphics appropriate?
   Yes [ ] Somewhat or Maybe [ ] No [ ]

7. Will the pamphlet be useful for family members?
   Yes [ ] Somewhat or Maybe [ ] No [ ]

8. Is the format of the pamphlet user friendly?
   Yes [ ] Somewhat or Maybe [ ] No [ ]

Appendix K

Time Table Chart



Appendix L

Detailed Time Table of Accomplishments

September 2010-March 2012

September 2010	The author generated a practice safety issue (idea), specifically, the controversy of screening for prostate cancer with a PSA blood test.
September - October 2010	The author developed a problem statement that men over 40 years old who undergo prostate cancer screening with a PSA blood test, compared to men who do not undergo screening, suffer more morbidity and decreased quality of life.
September - October 2010	The author considered the following questions about prostate cancer that need to be answered: Does a prostate cancer screening educational pamphlet, proceeded and followed by the same four test questions, result in informed decision making, and if so, does informed decision making result in less PSA blood tests drawn ?
September - October 2010	The author developed the PICO: the population of interest is Denver VAMC males between ages 50-70; the intervention is a prostate educational pamphlet with returned visit with informed consent; the comparison is the number of PSAs drawn in a comparable time period without informed decision making; the outcomes of interest are informed decision making and less PSAs drawn.
September 2010- April 2011	The author conducted a literature review which supported the problem statement.
March 2011- April 2011	The author conducted a needs assessment of Denver VAMC male veterans including collecting data from the Veteran's Health Study, an observational study of health outcomes in patients receiving VA ambulatory care between 1993-1996 in four VA Boston are outpatient clinics (Selim et al., 2004).
March 2011- April 2011	The author contacted Nelson Jones for prostate data for 2008-2010 from the Eastern Colorado Health Care System (ECHCS) tumor registry.
January 2011- September 2011	The author contacted, or met with, Dr. Hans-Olov Adami (Harvard School of Public Health, Department of Epidemiology); VA Research Coordinators; VA Health System's Specialist; VA Education personnel; two nurse practitioners in Urology; Planetree, a consultant firm hired by the VA to improved patient centered care, and; finally, a meeting with the Assistant to the Chief of Staff and the Chief of Ambulatory Care in April, 2011 followed by communication with the Chief of Urology, two VA Oncologists, and continued meetings with the

	Chief of Ambulatory Care.
May 2011	The author revised the Capstone after the April meeting because a return visit for informed consent is not practical.
June 2011	The author developed two prostate cancer screening educational pamphlets.
June 2011	The author completed Regis Collaborative Institutional Training Initiative (CITI) training in preparation for starting the Regis IRB process.
July 2011	The author met with Shawn Fury, the ECHCS Medical Media Program Manager, to discuss design and production of the two prostate cancer screening educational pamphlets.
July 2011	The author began the Regis and VA IRB process including the Exempt Application for Colorado Multiple Institutional Review Board (COMIRB).
July –August, 2011	The author contacted Jason Davis, the Journal and Right's manager at *UpToDate* , for approval to use their graphics which he subsequently edited.
August – September, 2011	The author added a fifth question to the Basic pamphlet to avoid bias.
September, 2011	The author's mentor, the Chief of Ambulatory Care backed out of the project, and was replaced by a PhD RN mentor working in patient safety.
September-November, 2011	The author communicated and met with a VA Research PhD, RN
September-October, 2011	The author completed VA and UCHSC CITI courses in the Protection of Human Research Subjects and Health Insurance Portability and Accountability Act (HIPPA) and completion of a security course on the VA Talent Management System.
tember, 2011	The author changed and simplified the Capstone Project after the (IRB) pre-review at the Denver Veteran Affair Medical Center (VAMV) on September 14, 2011.
September, 2011	The author changed the PICO to: the population of interest are PCPs at the Denver VAMC; the intervention is providing a Detailed (Appendix A) and Basic (Appendix B*)* prostate cancer screening educational pamphlet to primary care providers (PCPs) in two Denver Veteran Affair Medical Clinics (VAMC); the comparison is the incidence of prostate cancer screening informed decision making in Denver VA Firm B Primary Care Clinics without the guidance of the pamphlet ; the outcomes of interest are to be quantified are the provider's pamphlet preference (Basic or Detailed) and their opinion (yes or no) about whether the prostate cancer screening educational pamphlets offered guidance

	for informed decision making.
September, 2011	The author met with Ita Leitner, the COMIRB exempt/expedited coordinator at University of Colorado Health Sciences Center (UCHSC).
October, 2011	The author upgraded the Detailed pamphlet to include graphics, including a "can of worms", to represent the dilemma caused by screening.
October, 2011	The author worked with Shawn Fury, the ECHCS Medical Media Program Manager, to create the Detailed pamphlet for COMIRB review.
October, 2011	The author received VA clearance letter on 10/5/2011 and Regis IRB approval as an exempt study on 10/18/2011.
October,2011	The author submitted the IRB Application, VA Clearance Letter, and pamphlets to COMIRB on 10/11/2011(running 5-7 weeks out for review).
November,2011	The author received a COMIRB ***Minor Modification Request*** on 11/02/2011.
November, 2011	The author received COMIRB approval for the Project, protocol 11-1514, on 11/9/2011 as Not Human Subject Research—Quality Assurance.
November-December, 2011	The author waited for approval by the VA Research and Development Committee scheduled to meet on 12/14/2011. The Protocol went for review as scheduled because there were no Conflict of Interest issues.
December, 2011	The author received ***VA Eastern Colorado Health Care System Authorization to Recruit & Conduct a Not Human Subjects Research Study*** **(**12/15/ 2011**)** signed by Dr. Keith, the Associate Chief of Staff , Research and Development Service on 12/20/2011**.**
December , 2011	The author sent a message via *Office Outlook* to Denver VAMC PCPS about the October, 2011 United States Preventative Services Task Force (USPSTF) guidelines not to screen healthy men for prostate cancer; major medical organizations recommendations for informed decision making; a copy of the Detailed prostate cancer screening pamphlet, and; a request for four volunteer PCPS in Firm A and four PCPS in Saturday Clinic to test the pamphlet on 12/22/2011.
December, 2011	The author received a word of caution from her former mentor, "I just want to be sure that you have followed the proper channels and rules to keep you and VA out of trouble…" (D. Weinshenker, personal communication, December 23, 2011). Received responses from three nurse practitioners (NPs) and one MD from the Aurora Clinic interested in testing the pamphlet.

December, 2011	The author received a response from former mentor after he saw the VA R&D approval letter, "Sounds like everything is in order. Good luck with the project! Don" (D. Weinshenker, personal communication, December 26, 2011).
January, 2012	The author sent out a second Email message requesting four volunteers in Firm A and one more volunteer in Saturday Clinic. A message was sent to participating PCPs to document that informed prostate cancer screening took place. Hoffman's (2011) article about prostate cancer screening in the *NEJM* was sent to participating providers.
January 2012	The author personally recruited two NPs and one physician from Firm A to participate on January 4, although the physician ignored the request. The project started in Saturday Clinic on January 7 when four NP PCPs used the pamphlet for the first time. A request was placed for 1000 more pamphlets because providers were giving the pamphlets to patients to take home.
January 2012	The author met with her mentor and was advised not to distribute the pamphlets yet. Further pamphlet production was halted and the participants were advised of the change. A third Email request was sent to providers in Firm A to participate in the project. One physician personally volunteered and two physicians personally declined.
January 2012	The author sent a message to PCPs about how fear of litigation is a valid concern because the structure of the U.S. legal system supports local screening and not ordering a PSA can be considered a malpractice error of omission (Guerra et al., 2007). Lewis, Gohagan, and Merenstein's (2007) article on the locality rule and Adami's (2010) article on the prostate cancer pseudo-epidemic was sent to all PCPs .
February, 2012	The author sent a message to all providers about the prostate cancer screening project and requested four PCPs in Firm B to discuss their prostate cancer screening practices without the use of the pamphlet. This led to a rebuttal by two physicians and subsequently became a topic of discussion at the physicians monthly Journal Club, leading to the comparison data needed.
February, 2012	The author distributed the survey to the eight participating participants resulting in collection of the quantitative data.
February, 2012	The author was contacted by the Health Promotion Disease Prevention Program Manager; a meeting took place to discuss a QI project currently in progress to reducing PSA screenings in men over 75 years.
February, 2012	The author sent a message to all providers about how Dr. Lithium Lin's poster on the Principles of Shared Decision Making can be used for patients that request PSA screening. This message resulted in four providers from Colorado Springs and Pueblo requesting copies of the poster and Detailed prostate cancer screening pamphlet.
February, 2012	The author contacted Shawn Fury for help in sending posters to the southern CBOCs. A message was sent to the CBOC providers to contact Shawn with the measurements they needed and further discussions followed.
February, 2012	The author sent providers an Executive Summary of the project and asked for comments about the Detailed pamphlet before it was sent to Public Affairs for approval for public use. One provider highlighted a few typos, grammatical errors.
March, 2012	The author sent the Detailed brochure to Public Affairs and received approval

	for public distribution the following day. “Patricia-This looks fine and I approve, but with one question: In the first paragraph of the “‘Looking for Cancer” section, the second sentence said “screening leads to…substantial morbidity (illness).” It reads as if screening leads to illness. If the sentence is correct, you’re good to go” (G. Clark, personal communication, March 6, 2012).
March, 2012	The author responded to Mr. Clark that the sentence is correct and messages were sent to all providers about the Detailed pamphlet approval for public use. Shawn Fury was contact to produce 1000 pamphlets who responded, “We are temporarily of hospital printing funds. I will process your request as soon as funds become available (S. Fury, personal communication, March,, 8, 2012).
March, 2012	The author received the following email: “Yes, Funds are now available and your order for 1000 Prostate brochures was placed earlier this week. It should take 2 or more weeks for delivery” (S. Fury, personal communication, March 16, 2012).

Appendix M

Budget and Resources

Resources needed for project

Category of Resource	Type of Resource
Staff time	Clinical staff time to assist with project
	Librarian time to assist with literature search
	Information technology time to assist with Microsoft
Consultants	Research design consultants (VA research office and two PhD- prepared nurse mentors)
	ECHCS Medical Media Program Manager
	Primary care Provider's input
Information technology	ECHCS computers with Microsoft Word
	Computers with internet access
Supplies and materials	Detailed pamphlet production

Resource Sheet is adapted from Houser, J.H. (2011). Evidence-based practice in health care. In J.H. Houser and K.S. Oman (Eds) *Evidence-Based Practice: An Implementation Guide for Healthcare Organizations.* (Table 2-2, p. 27). Sudbury, MA: Jones and Bartlett Learning.

Budget Estimates for Prostate Cancer Informed Decision Making Project

Costs	***Billed per project***	***Projected variable Costs***
• Labor	$50/hour	$50 x 80 hours = $4000
• Office supplies	$50/project	$50
• Commute/gas	$.65/mile	$.65 x 350 miles = $ 227
• Phones/communications	$150/month	$150 x 3 months = $450
• Internet access	$30/month	$30 x 3 months =$90
• IT support	$50/hour	$50 x 10=$500
• Library support	$0/hour	$0/hourx10=$0
• Membership	$200/professional membership	$200
• Pamphlet production	1000 pamphlets	$900
• Media Manger	$69/hour	$69 x 24 hours = $ 1656
• Consultation fees	$75/hour	$75 x 5 hours=$375
Total Costs		$8448.00

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Variable Fixed and Direct Costs is adapted from Cleverley, W.O., Song, S.H., & Cleverly, J.O. (2011). Cost Measurement. In W.O., Cleverley, S.H. Song, and J.O. Cleverly (Eds.) *Essentials of health care finance* (pp.324-325). Sudbury MA: Jones and Bartlett Learning.

Appendix N

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report
Printed on 6/11/2011

Learner: Patricia Hughes (username: hughestish)
Institution: Regis University
Contact Information Department: nursing
Email: hughes.tish@gmail.com
Social Behavioral Research Investigators and Key Personnel:

Stage 1. Basic Course Passed on 06/11/11 (Ref # 6161464)

Required Modules	Date Completed	
Introduction	06/10/11	no quiz
History and Ethical Principles - SBR	06/10/11	4/4 (100%)
The Regulations and The Social and Behavioral Sciences - SBR	06/10/11	5/5 (100%)
Assessing Risk in Social and Behavioral Sciences - SBR	06/11/11	5/5 (100%)
Informed Consent - SBR	06/11/11	5/5 (100%)
Privacy and Confidentiality - SBR	06/11/11	5/5 (100%)
Regis University	06/11/11	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

Appendix O

Human Research CITI Training

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report
Printed on 9/29/2011

Learner: Patricia Hughes (username: EOSHUGH)
Institution: Denver, CO-554
Contact information Department: emergency
Phone: 303-399-8020 ext 2425
Email: hughes.tish@gmail.com

VA Human Subjects Protection and Good Clinical Practices:

Stage 1. Basic Course Passed on 09/29/11 (Ref # 6777606)

Required Modules	Date Completed	
Pre-Course Evaluation	09/26/11	no quiz
History and Ethical Principles	09/27/11	6/6 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	09/27/11	4/5 (80%)
Informed Consent	09/27/11	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	09/27/11	4/4 (100%)
Records-Based Research	09/27/11	2/2 (100%)
Genetic Research in Human Populations	09/27/11	1/2 (50%)
Research With Protected Populations - Vulnerable Subjects: An Overview	09/28/11	4/4 (100%)
FDA-Regulated Research	09/28/11	5/5 (100%)
Human Subjects Research at the VA	09/28/11	2/3 (67%)
Conflicts of Interest in Research Involving Human Subjects	09/28/11	4/5 (80%)
Good Research Practices for Protection of Human Subjects, Module 3: Good Clinical Practice and VA Research	09/29/11	4/4 (100%)
Good Research Practices for Protection of Human Subjects, Module 5: Monitoring Subject Safety	09/29/11	5/5 (100%)
Good Research Practices for Protection of Human Subjects, Module 6: Records and Reports	09/29/11	4/4 (100%)
Good Research Practices for Protection of Human Subjects, Module 7: Managing Investigational Products	09/29/11	4/4 (100%)
Good Research Practices for Protection of Human Subjects, Module 8: Patient Privacy and Confidentiality	09/29/11	3/4 (75%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and

CITI Collaborative Institutional Training Initiative

CITI Health Information Privacy and Security (HIPS) Curriculum Completion Report
Printed on 10/3/2011

Learner: Patricia Hughes (username: EOGHAN)
Institution: University of Colorado at Colorado Health Sciences Center - COMIRB
Contact information
Department: Emergency
Phone: 303-399-8020 ext 2425
Email: hughes.tish@gmail.com

CITI Health Information Privacy and Security (HIPS) for Students and Instructors: This course for **Students and Instructors** will satisfy the mandate for basic training in the HIPAA. In addition other modules on keeping your computers, passwords and electronic media safe and secure are included.

Stage 1. Basic Course Passed on 10/03/11 (Ref # 6777601)

Required Modules	Date Completed	Score
Introduction	10/02/11	no quiz
About the Course	10/02/11	1/1 (100%)
Privacy Rules: Introduction to Federal and State Requirements*	10/02/11	9/10 (90%)
Privacy Rules: Students and Instructors*	10/02/11	4/4 (100%)
Security Rules: Basics of Being Secure, Part 1*	10/03/11	no quiz
Security Rules: Basics of Being Secure, Part 2*	10/03/11	10/10 (100%)
Completing the Privacy and Security Course	10/03/11	no quiz
COMIRB	10/03/11	no quiz
Elective Modules	**Date Completed**	**Score**
Security Rules: Protecting your identity*	10/03/11	7/7 (100%)
Security Rules: Safer Email-ing and IM-ing, Part 1*	10/03/11	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report
Printed on 10/4/2011

Learner: Patricia Hughes (username: PHug [illegible])
Institution: University of Colorado at Colorado Health Sciences Center - COMIRB
Contact information
Department: Emergency
Phone: 303-399-8020 ext 2425
Email: hughes.tish@gmail.com

Group 2 Social and Behavioral Research:

Stage 2. Refresher Course Passed on 10/04/11 (Ref # 6777600)

Required Modules	Date Completed	Score
Biomedical 101 Refresher Course - Introduction	10/03/11	no quiz
SBR 101 REFRESHER MODULE 1 - History and Ethics	10/03/11	5/5 (100%)
SBR 101 REFRESHER MODULE 2 - Regulatory Overview	10/03/11	4/5 (80%)
SBR 101 REFRESHER MODULE 3 - Risk, Informed Consent, and Privacy and Confidentiality	10/03/11	5/5 (100%)
SBR 101 REFRESHER MODULE 4 - Vulnerable Subjects	10/04/11	4/4 (100%)
SBR 101 REFRESHER MODULE 5 - Education, International, and Internet Research	10/04/11	4/5 (80%)
How to Complete The CITI Refresher Course and Receive the Completion Report	10/04/11	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

Appendix P
VA Clearance Letter

VA Clearance Letter

(Purple Clearance)

Date: October 5, 2011

To: Principal Investigator/Primary Contact

From: VA Research Office

COMIRB #	11-xxxx		
Protocol Title	Informed Decision Making with the Guidance of Two Prostate Cancer Screening Educational Pamphlets		
Principal Investigator	Patricia Hughes, ANP	Service	ER/VA
VA Investigator	Same	Service	same

Eastern Colorado Health Care System (ECHCS)

This form serves to notify the Colorado Multiple Institutional Review Board (COMIRB) that the above-entitled protocol has been pre-reviewed by the VA Research Office for VA requirements. This also includes a review for scientific quality & merit and VA appropriateness by a member of the R&D Committee. The RCD member's review addresses the following issues:

- **The research uses procedures consistent with sound research design.**
- **The research design is sound enough to yield the expected knowledge.**

Attached is the Privacy and Security review verification report.

Therefore, COMIRB is authorized to proceed with the review and approval process per COMIRB policies and procedures.

Connie Steinbrunn CCRP 10/5/11

VA Research Service Clearance Signature

REMINDER: THIS IS NOT THE R&D COMMITTEE APPROVAL LETTER. YOU MUST RECEIVE COMIRB APPROVAL LETTER, VA SUBCOMMITTEE ON RESEARCH SAFETY (SRS) APPROVAL, AND THE R&D COMMITTEE APPROVAL LETTER (PLUS R&D STAMPED VA CONSENT FORM, IF APPLICABLE) PRIOR TO INITIATING YOUR STUDY.

COMMENTS (if applicable): VA pre-review requested the protocol be summarized under Protocol Information; full protocol was included within Application.

Privacy and Security Review

Per VHA Handbook 1200.05 the Privacy and the Information Security Officer are to complete a review of all proposed research and are to inform the IRB of all their finding as it relates to Privacy and confidentiality, and information security.

This notice is to be included into the IRB record for acknowledgement of Privacy and Security Review and findings

Privacy Officer:

X I certify that I have reviewed the above project. All procedures described meet VA and other regulatory requirements for access, maintenance, and storage of protected health information.

Privacy Officer: Marie Zaepfel **Date** 10-5-2011

_____ I certify that I have reviewed the above project. I have the following concerns regarding the procedures described for the access, maintenance, and storage of protected health information.

Comments:

Privacy Officer: _____ **Date** _____

Information Security Officer:

✓ I certify that I have reviewed the above protocol. All policies and procedures described meet VA and other regulatory requirements for access, maintenance, transmission, and storage of sensitive research data to include the following:

1) The investigator adequately explains how information will be protected during transmission.
2) If information will be stored outside of the VA network, the investigator includes all required protections in the explanation of how the data is to be stored.
3) The investigator has indicated the appropriate knowledge of incident reporting procedures in the event information or equipment is lost, stolen or misplaced

_____ I certify that I have reviewed the above project. I have the following concerns regarding the policies and procedures described for the access, maintenance, transmission and storage of sensitive research data

Comments:

Information Security Officer Edward A. Hyr **Date** 10/05/2011

Appendix Q
Regis IRB Approval Letter

REGIS UNIVERSITY

Academic Affairs
Academic Grants

3333 Regis Boulevard, H-4
Denver, Colorado 80221-1099

303-458-4206
303-964-3647 FAX
www.regis.edu

IRB – REGIS UNIVERSITY

October 18, 2011

Patricia Hughes
279 Cottonwood Drive
Evergreen, CO 80439

RE: IRB #: 11-298

Dear Patricia:

Your application to the Regis IRB for your project "Informed Decision Making with the Guidance of Two Prostate Cancer Screening Educational Pamphlets" was approved as exempt on October 18, 2011.

Supporting reference information from the chair: "…approved as an exempt study under 45CFR46.101(b)(1)(ii) (health education curricula).

The designation of "exempt," means no further IRB review of this project, as it is currently designed, is needed.

If changes are made in the research plan that significantly alter the involvement of human subjects from that which was approved in the named application, the new research plan must be resubmitted to the Regis IRB for approval.

Sincerely,

Daniel Roysden, Ph.D.
Chair, Institutional Review Board

cc: Patricia Mullen, Ph.D.

Appendix R

COMIRB Modification Letter

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
Aurora, Colorado 80045

303.724.1055 [Phone]
303.724.0990 [Fax]
uchsc.edu/comirb [Web]
comirb@ucdenver.edu [E-Mail]
FWA00005070 [FWA]

University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
The Children's Hospital
University of Colorado Denver
Colorado Prevention Center

Minor Modifications Required

02-Nov-2011

Investigator:	Patricia Hughes
Sponsor(s):	
Subject:	COMIRB Protocol 11-1514 Initial Application
Review Date:	01-Nov-2011
Title:	Informed Decision Making With The Guidance Of Two Prostate Cancer Screening Educational Pamphlets

Protocol Requires Minor Modifications

Committee sees no problem or unacceptable risks in the protocol and consent, but stipulated changes to certain documents are needed. These are described in the reviewer comments below. The proposal will not be approved until these stipulated changes are made and reviewed.

If the modifications are not received in COMIRB within **30 days**, your protocol will be **WITHDRAWN**.
No research activities may begin on this protocol until final approval is received.

Comments:

1. Your sample will not allow you to do the statistical analysis you are proposing.
2. Do you want this reviewed as a QI project? Your protocol and documents mention both research and QI throughout. If you want this reviewed as QI, then you can not publish the results under research, only as a QI project.
3. More review may be required if this is a research project.

PAPER SUBMISSION - HOW TO RESPOND TO A DETERMINATION OF MINOR MODIFICATIONS:

1. Please ensure all documents are single-sided and have the PIâ€™s name and COMIRB protocol number on them.

2. Submit one copy of an itemized cover letter describing your response to each issue raised by the reviewer and the changes you made.

3. Exempt Review: If changes are made to the Request for Exemption form, resubmit one copy and enter revision date on pg. 1.

4. Expedited Review:
a. If changes are requested to any part of the Application for Protocol Review, or any one of the application attachments (A, F, H, etc.), resubmit one copy of the revised Application form and ALL the application attachments, enter revision date on pg. 1, section A, and the same version date on all application attachments.
b. If changes are requested to the Protocol, submit one highlighted copy of the revised protocol.

5. Exempt and Expedited Review: If changes are requested to subject materials (consent, assent, questionnaire, survey, advertisement, etc.), submit one highlighted copy showing changes made and one clean copy of each revised document. For consent revisions, enter new version date and version # in the header.

Appendix S
COMIRB Approval Letter

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
Aurora, Colorado 80045

303.724.1055 [Phone]
303.724.0990 [Fax]
COMIRB Home Page [Web]
comirb@ucdenver.edu [E-Mail]
FWA00005070 [FWA]

University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
The Children's Hospital
University of Colorado Denver
Colorado Prevention Center

Not Human Subject Research

09-Nov-2011

Investigator:	Patricia Hughes
Sponsor(s):	
Subject:	COMIRB Protocol 11-1514 Initial Application
Effective Date:	08-Nov-2011
Title:	Informed Decision Making With The Guidance Of Two Prostate Cancer Screening Educational Pamphlets

Not Human Research

Your research project submitted to COMIRB under protocol number 11-1514 has been reviewed and our determination is that it is not human research as defined by our policies and current regulations and in accordance with OHRP and FDA guidelines.

Therefore, you may proceed with the project strictly following the protocol as submitted and reviewed by COMIRB. No continuing review of the project will be required, however, you must resubmit the protocol to COMIRB for approval if any substantive changes are made to the protocol in question.

Review Comments:

COMIRB determined project to be Not Human Subject Research Quality Assurance.
Please note that any publications cannot use the term 'research' under DHHS regulations but must clearly indicate that this is a Quality Assurance project only and that its results are not generalizable.

These documents were reviewed for determination of Not Human Subject Research:

Application
Application For Review/Approval (Word Version, Form A)
Appendix B - Prostate Detailed Educational Pamphlet
Appendix C - Basic Prostate Cancer Screening Pamphlet
VA Prostate Cancer Brochure - for Providers
VA Prostate Educational Pamphlet - for Providers
VA - Be Informed before opening the prostate cancer screening can of worms
Sincerely,

UCD Panel A

Appendix T

VA Eastern Colorado Health Care System Authorization Letter

DEPARTMENT OF VETERANS AFFAIRS
EASTERN COLORADO HEALTH CARE SYSTEM
1055 Clermont Street
Denver, Colorado 80220
303-399-8020

Medical Center &
Community Living
Center
1055 Clermont St
Denver, CO 80220
303-399-8020

Community Living
Center
2980 Oakshire Lane
Pueblo, CO 81001
719-295-7269

OUTPATIENT
CLINICS

622 Del Sol Dr
Alamosa, CO 81101
719-587-6600

1500 E. Mississippi
Suite 209
Aurora, CO 80012
303-340-6340

28 N. Spruce St.
Colo. Springs, CO
80905
719-327-5600

3360 Carson Ave.
Suite 105
La Junta, CO 81050
719-383-5195

155 Van Gordon
Suite 365
Lakewood, CO
80228
303-913-2680

201 Kendall Dr.
Lamar, CO 81052
719-336-5672

4132 Outlook Blvd.
Pueblo, CO 81008
719-553-1600

3241 Fontanero St.
Colo. Springs, CO
80907
719-866-6200

1177 Rose Ave.
Lexington, CO
80067
719-346-5239

ST. PBQRI
CLINICS

[illegible]
P.O. Box 350
La Junta, CO
81050
719-456-6086

Date: December 15, 2011

To: Patricia Hughes

From: Associate Chief of Staff, Research and Development Service (151)

Protocol Title: 11-1514 Informed Decision Making with the Guidance of Two Prostate Cancer Screening Educational Pamphlets

COMIRB Determined Not Human Subjects Research: November 8, 2011
SRS # and Approval Date: S-11325IE October 6, 2011
R&D Approval Date: December 14, 2011

VA Eastern Colorado Health Care System
Authorization to Recruit & Conduct a
Not Human Subjects Research Study

This notice authorizes the above-referenced investigator to conduct the above referenced not human research protocol as approved by the Subcommittee on Research Safety and R&D Committee.

This authorization remains in effect until such time that any one of the following occur:

- SRS or R&D Committee withdraws approval for any reason
- The research project is closed by the investigator or sponsor
- **The investigator fails to maintain a current approved continuing review by R&D Committee.**
- The VA ECHCS determines that the research project can no longer be conducted at the VA ECHCS for failure to comply with any applicable regulation or local policy or deviation from the approved protocol.

If multiple sites are involved with this study the VA R&D Committee has only approved the VA component of this protocol.

Robert Keith, M.D.
Associate Chief of Staff, R&D

Gmail by Google

Tish Hughes <hughes.tish@gmail.com>

Project Closure

2 messages

Tish Hughes <hughes.tish@gmail.com> **Tue, Mar 13, 2012 at 9:05 AM**
To: "Leitner, Ita" <ita.leitner@ucdenver.edu>

Dear Ms. Leitner,

The project, protocol number 11-1514, was completed March, 2012. The prostate cancer screening educational pamphlet was approved for public use. Can you close the project with COMIRB.

Thank-you for your courtesy and cooperation,

Patricia Hughes

Leitner, Ita <Ita.Leitner@ucdenver.edu> **Tue, Mar 13, 2012 at 9:47 AM**
To: Tish Hughes <hughes.tish@gmail.com>

Good Morning Tish,

As it was determined to be Not Human Subject Research no need to do any additional paper work for it. As we review it once and if you are done, that is fine.

Thanks for the notice and Congratulation on completing this project!

Ita

Ita Leitner
ita.leitner@ucdenver.edu
Exempt/Expedited Coordinator
303-724-1068, fax 303-724-0990
Mailing Address:-
COMIRB, Mail Stop F490
13001 E. 17th Place, Room N3214
Aurora, CO 80045

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