Exnovation of Low Value Care: a Decade of PSA Screening Practices

Running Title: Individual and Regional PSA Screening Rate Change

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Impact Statement:
The potential impact of this research on clinical care or health policy includes the following:

When evidence emerges suggesting that a commonly used service has low-value, the factors that influence subsequent reductions in use in clinical practice are not well understood. Despite evidence and converging guidelines regarding PSA screening in older men over the decade from 2003-2013, PSA screening increased slightly among

men older than 68 in the U.S. Among men over age 75, guidelines appear to have had little consistent effect on lowering screening, while other non-clinical factors were associated with reduction in use. Efforts to reduce low-value care will require more active change strategies than release of guidelines.

Abstract

Background Reducing use of low-value services is a priority for improving quality and lowering cost of care. The release of trial evidence in 2009 showing low value for prostate-specific antigen (PSA) screening in asymptomatic men and the convergence of guidelines offers an opportunity to study how clinical practice evolves with mounting consensus about the low value of a service.

Objective Examine PSA screening practice change across subgroups of men defined in guidelines and across regions, identifying factors associated with change in screening practices.

Design Observational study using serial cross-sections, 2003 to 2013

Setting National fee-for-service Medicare

Participants Men age 68 and older eligible for prostate cancer screening

Measurements Outcomes are national PSA screening practices among men age 68 and older from 2003-2013 and change in regional screening rates among men age 75 and older.

Results The PSA screening rate among men age 68 and over was 17.2% in 2003, 22.3% in 2008, and 18.6% in 2013 ($p<.001$ for all differences); rates ended slightly lower than rates in 2003 only among men 80 and older. Racial disparities in screening became less pronounced over this period. Among men 75 and older, change in regional screening rates varied widely, with absolute rates growing by 15 per 100 enrollees in some areas and declining by the same

amount in others. Areas with high social capital, a measure associated with diffusion of new ideas, were more likely to decline while malpractice intensity and managed care penetration had no impact.

Conclusions Studying Medicare enrollees over time, we found little reduction in PSA screening and even increases by race and in some regions. The heterogeneous changes across regions suggest consistent reduction in the use of low-value care may require change strategies that go beyond evidence and guidelines to include monitoring and feedback on performance.

Key Words

Low value care, prostate cancer screening, Medicare

Introduction

There is a "pervasive asymmetry in human psychology" that makes it harder for healthcare workers to give up old clinical practices than to adopt new ones, even when they are revealed to provide low value.[1] Across disciplines, there is increasing interest in the idea of "exnovation" or the process by which practitioners turn away from an existing practice or process. [2-5] Screening for prostate cancer using the prostate-specific antigen (PSA) is an important case study of evolution of practice in response to emerging scientific evidence.

After years of debate, in March 2009 two randomized controlled trials provided evidence that screening for prostate cancer using the PSA test offered at best modest benefits, particularly among men older than 70. [6,7] In 2010 and 2011, systematic reviews concluded that PSA screening provides no significant reduction in prostate-cancer or overall mortality. [8,9] One concluded that the harms were frequent and moderately severe,[8] while the other found little information about harms. [9]

Before this period, guidelines for PSA screening repeatedly changed (Figure 1) converging on the notion that the value of PSA screening is low . For example, when proposing its latest update,[10-14] the U.S. Preventive Services Task Force (USPSTF) stated there is "a small net benefit for men ages 55 to 69 years, [but] the balance of benefits and harms in men remains close."[15] The guidelines are also nuanced, requiring complex estimations of benefit/harm ratios across subgroups of men who may not be well represented in trials. For

example, the USPSTF and the American Urological Association have consistently recommended against screening men with a limited life expectancy, sometimes naming a specific age cutpoint.[16-21] And due to the higher risk of prostate cancer in Black men, some guidelines recommend initiating screening earlier.[17,19,22]

Changing guidelines were on a background of widely varying regional screening practices. Given disparate screening practices, it is not clear that practice change, even for the oldest men where guidelines agreed, would occur uniformly across markets. Examining what happened in clinical practice over this period of evidence and guideline change provides an opportunity to understand the process of exnovation of low value services.

Using PSA screening, we aim to understand what factors influence practice change during a period when a decline in service use would be expected. First, we focus on national PSA screening in men older than 68 in fee-for-service Medicare from 2003-2013 and examine the influence of guidelines by assessing changes in likelihood of screening associated with factors directly mentioned in guidelines. Second, we focus on practice change across hospital referral regions (HRR) of the U.S. for men age 75 and over – where guidelines have been in agreement – to test whether practice variation declines and what contextual factors are associated with greater decline. We hypothesize that the degree to which practitioners and patients scale back their use of an existing practice in the face of converging evidence regarding effectiveness is influenced by both guidelines and the practice environment.

Methods

Setting and Participants

This observational cohort study of older was drawn from a 20% national sample of the fee-for-service Medicare population during each of five years: 2003, 2006, 2008, 2010, and 2013. Men were eligible if enrolled in Medicare Parts A and B and not managed care. Because PSA claims (identified by Common Procedural Terminology codes[23]) do not distinguish screening from diagnosis, we applied an algorithm previously validated to exclude men with any history of prostate disease (cancer, surgery, or elevated PSA) during the prior 3 years or symptoms suspicious of cancer from visit diagnoses in the 3 months before a PSA test. [24,25] Men had to be age 68 and over to accommodate the disease-free interval. Men with no ambulatory visits were excluded because PSAs drawn during hospitalization were unlikely for screening.

Age and race were obtained from Medicare summary file while covariates additionally used claims information. Covariates include dual-eligibility for Medicaid, 10-year life expectancy as an aggregate measure of illness that aligns with guideline recommendations, and visit patterns. We created predicted 10-year mortality risk scores. Logistic regression predicted the 10-year mortality risk for the 2003 cohort – whose death status was known at the end of 2012– using these explanatory variables: baseline age, race, Medicaid status, ambulatory visits, skilled nursing facility stays, and Elixhauser comorbidity conditions. We used a random 50% sample to derive our prediction model and the other half to validate it (c-statistics 0.79 for both

cohorts).[26] Mean predicted mortality ranged from 0.27 in the lowest quintile to 0.96 in highest quintile. We included number and continuity of ambulatory visits which have been shown to influence whether a person receives preventive services or low-value care.[27,28] We used the Continuity of Care Index, a computation of dispersion in visits across the number of unique physicians, categorized into tertiles.[29]

HRRs to represent regional healthcare and were characterized by factors shown previously to influence physician behavior: screening practice norms;[25] penetration of managed care;[30,31] malpractice activity;[32] and social capital.[33] We represent the underlying PSA screening practice norm with the proportion of men aged 68-69 screened because they are the only age group in our data who meet guidelines for potential benefit.[34,35] Malpractice activity, which varies across areas,[32] was measured by state as per physician payment amounts in 2003, from which we created HRR measures weighted by the fraction of each state's residents. To account for potential spill-over effects from practicing in an area where population management strategies are prevalent,[30,31] we measured Medicare Advantage enrollment. Social capital measures the multidimensional social environment that influences behavior[36] and has been associated with uptake of innovations in and outside medicine.[33] A county-level social capital index is available for 2005 and 2009 based on the number of civic, religious, and sports organizations per capita, census response rate, voter turnout in presidential elections, and

number of non-profit organizations per capita.[37] We weighted the county measures to the HRR using the Missouri Census Data Center Geographic Correspondence Engine's 2010 data.[38]

Statistical Analysis

Differences in the characteristics of the men in each cohort year were tested using descriptive statistics. The large sample results in statistical significance, even when differences are small. National trends are reported as the crude screening rate by subgroup. Then the associations of age and race adjusted for other factors including region in 2013 were compared to 2003. To do so, the probability of having a PSA test was modeled using Poisson regression in a hierarchical framework adjusting for regional effects by use of a conditional likelihood approach. The Poisson model was chosen because it allows estimation of relative risk when the event probability is high. [39]

Regional screening rates for men age 75 and older in each year were calculated using random effects regression adjusting for population age, race, and predicted mortality. The adjusted and crude rates were highly correlated (r=.99) so we report the straightforward crude rates. We tested whether variation in practice declines over time by comparing the coefficient of variation across HRRs in 2013 to 2003. We then modeled whether 2003 area characteristics predict the absolute change in screening rate between 2003 and 2013. This study had IRB approval at Geisel School of Medicine. Analysis was performed using SAS 9.4 and STATA 14.1.

Results

Study Cohorts

Supplementary Figure 1 and Table 1 show details of the cohort creation and characteristics each year. Approximately 40% of men each year were excluded because of prostate disease, leaving about 1 million men in each study-year eligible for a screening PSA. Over time, mean age remained unchanged, but there were small shifts in racial distribution, probability of death, Medicaid enrollment, outpatient visits and continuity. Penetration of managed care increased from 16% to 35%.

Change in Screening Across Sub-Groups of Men

National PSA screening rates for men age $\geq$ 68 were 17.2% in 2003, rose to 22.3% in 2008, and declined to 18.6% in 2013 (Figure 2). This trend was similar for all race and age groups, including those over 90. The screening rate in 2013, when the new trial and guidelines had been out 1-5 years, remained 1.4% higher than the screening rate in 2003. The 2013 screening rate was slightly lower than in 2003 for men aged 80-84 (13.5% vs. 14.1% p<.001), 85-89 (9.2% vs. 10.3%, p<.001), and 90+ (5.8% vs. 6.3%, <.001). At the beginning of the period Black and Hispanic rates were lower than whites but rose faster until 2008 such that by 2013 there was little if any racial difference.

Bivariate analysis of proportions screened by individual characteristics is shown in Supplementary Table 1. Using multivariable regression controlling for region, we found

independent effects of age, predicted mortality, race, dual eligibility, visits and continuity, although their influence changed over time. Figure 3 shows these results graphically by comparing each factor's strength of association with likelihood of PSA screening in 2003 to the strength of association in 2013 (full model in Supplementary Table 2). Predicted 10-year mortality was consistently associated with lower likelihood of screening, but age independent of life expectancy became important over time. For example in 2003, only men over age 90 had lower risk of being screened, but in 2013 a lower risk of screening was found beginning at age 75. This finding suggests age alone has become a deciding factor on whether to screen.

The relationship between race/ethnicity and likelihood of screening changed over time. Black and Hispanic race/ethnicity were associated with lower screening ((RR=0.81, (95% C.I., 0.78 to 0.84) and (RR=0.86, (95% C.I., 0.78 to 0.94) respectively) in 2003, but the strength of association decreased for Blacks and became insignificant for Hispanics by 2013 ((RR=0.91, (95% C.I., 0.87 to 0.94) and (RR=0.93, (95% C.I., 0.87 to 1.00)). As a result, racial/ethnic disparities in screening rates declined during this period. Dual-eligible enrollees, who were less likely to be screened in 2003 (RR=0.66, (95% C.I., 0.63 to 0.70)), were not so in 2013 (RR=0.93, (95% C.I., 0.82 to 1.02)). Finally, no change was seen in the relationship between visit patterns and screening: more ambulatory visits was consistently associated with greater likelihood of screening and greater continuity slightly reduced screening.

Change in Screening Across Regions

In 2003, HRR rates of PSA screening varied widely for men age 75 and over, from 2.3% in Contra Costa County, CA to 42.1% in Sun City, AZ; the median was 14.1% with a coefficient of variation of 0.43. The coefficient of variation rose slightly to 0.49 in 2013 demonstrating greater practice variation.

The direction of change in screening rates among men older than 75 across regions demonstrated unanticipated results with nearly as many HRRs experiencing a rise in screening as experiencing a decline (Figure 4). While the median HRR showed a decline by 1.5 absolute percentage points, the screening rate in some HRRs *increased* by as much as 15 points, while others declined by 15. Some HRRs declined in every interval studied (N= 42 HRRs, 14%) but 14 increased after the trials were released. Decline in screening was predicted by higher level of screening at baseline and higher social capital. High proportion minority population predicted rising rates (Supplementary Table 3). Other population characteristics, malpractice activity, and penetration of managed care were not consistently associated with change.

Discussion

From 2003-2013, questions about the value of PSA screening were reflected in guideline changes later supported by new evidence. PSA screening in men age 68 and older which had been rising fell gradually from 2009-13 after the trials were released, but still ended slightly higher in 2013 than in 2003. More surprisingly, we observed an increase in regional variation for screening men over age 75, suggesting more rather than less divergence in clinical practice.

Indeed, screening rates for men age 75+ increased during this period in nearly as many HRRs as they decreased. Despite these variations, we find evidence that guidelines had aggregate effects for some subgroups, such as a reduction in screening in those over 75, and an attenuation of racial and ethnic disparities, but those effects are modest compared to the large variations in regional patterns of use.

Two recent reviews indicated that screening rates have declined. [40,41] However, these reviews synthesized heterogeneous data including self-reports (which have been shown to be biased[42]), small areas, and different time periods. Two studies that used objective screening measures spanning 2008-2012 showed the same pattern as ours,[43,44] while others using shorter time periods or limited areas showed only declining rates.[45-50] We found no prior studies of change in PSA screening rates in response to guidelines by race, although two studies found no differential effect of race when examining referral or stage of disease.[51,52] In comparison to these prior studies, ours has the advantage of using consistent measures of PSA testing well before and after evidence change with a large enough sample to examine heterogeneity of change across sub-groups of men and across areas. Unlike prior studies, by taking a longer view we find a mixed picture on the influence of guidelines: some minor changes within named sub-groups but no large, consistent shifts in practice toward lower screening.

We did not expect to find that PSA screening in men over 75 would increase in some regions, which makes the analysis of contextual factors particularly important. Our hypotheses

were that factors might have affected greater decline, such as average age in the region, income, racial distribution, and contextual factors including malpractice activity, prevalence of integrated healthcare, and social capital. We found that average age and income were not important, although higher minority population predicted greater *increase* in screening, possibly due to efforts to reduce disparities in access to care or in response to concerns about higher prostate cancer risk. Importantly in light of the observed increase in some areas, malpractice intensity was not a significant predictor, nor was managed care penetration, but higher social capital was. Social capital suggests that there is something in the local culture that may make it more receptive to let go of an existing practice. A similar association has been found for uptake of new technologies like beta blockers for acute myocardial infarction but has not previously been shown in association with exnovation.[33]

The modest reduction in screening rates in men older than 75, who are more likely to experience harm than benefit from PSA screening, warrants asking why the evidence and converging guidelines have done so little to reduce low-value care. One reason could be discomfort with age-based cut-points when age is only a proxy for life expectancy. Life expectancy is the most important predictor of screening in our data. With release of the age-based recommendations, age alone was increasingly used as a deciding factor. The main challenge patients and providers face likely hinges less on this decision to use age or life

expectancy, and more on having the time necessary for a well-informed decision that includes mortality risk and time to benefit considerations.[54]

Primary care providers, many of whom agree with the guidelines[55], are key players for changing screening practice because of their role in cancer prevention and frequent contact.[56] Yet evidence to date suggests patients are informed infrequently and providers have not changed their practices much.[43,46,56] Change strategies that rely on encouraging shared decision making without providing systematic support for the time those patient-provider interactions require are unlikely to lead to wholesale change in use of low-value care. Moreover, lack of feedback about a provider's current performance precludes the ability to evaluate and change one's practice. Performance reports regarding indicated services, such as diabetes testing, are common but reporting on avoidance of a service that is not recommended occurs less often. Our results highlight the need, as alluded to by Vickers,[57] to apply as much attention to evaluating changes in our practice when incorporating new evidence as on developing and evaluating the evidence itself.

What can we learn generally from this study about scaling back an existing practice? First, when guidelines recommend discontinuing a service as opposed to adding or increasing use, the response may be sluggish. Second, when guidelines change multiple times and require a nuanced decision process, they may not meet with uniform adoption. Indeed, during the early period of observation when guidelines indicated doubt about PSA value while the trials were

pending, the rates of screening actually rose. One explanation could be that publicity around the controversial recommendations led to greater attention and hence use. Third, we found that fragmented physician contact increased the likelihood of a man having PSA screening. Greater continuity may relate to greater patient-physician trust when making a difficult decision to scale back use. Lastly, while the social capital of an area is not in itself modifiable, awareness of this community factor allows policy and clinical leaders to anticipate where adoption may be rapid and other areas where a more active change strategy may be needed.

There are several limitations of the study. Importantly, we cannot discern who is driving the change in practice, patients or providers. We can say however that there were no changes in Medicare coverage of PSA screening which eliminates patient cost as a potential explanation.[53] This limitation does raise the important point that an additional approach to changing low-value practice is through consumer-directed efforts. Second, our study is restricted to the fee-for-service Medicare population so results may not be generalized to that managed care setting.

Summary

Screening for prostate cancer serves as an excellent case study of how exnovation occurs, or does not, when evidence and guidelines suggest use should decline. Studying Medicare enrollees over time, we found little reduction and even increases by race and in some

regions. The presumption that improved clinical evidence and guidelines alone will lead to a significant reduction in the use of potentially low-value care may be overly optimistic, especially when the recommendations require nuanced application. Messaging that prioritizes potential benefit in one sub-group risks overdiagnosis and overtreatment when that message is generalized. In addition to careful guideline messaging, attaining better evidence-driven, patient-centered care may require more systematic approaches that include local monitoring of and feedback on behaviors we aim to reduce.

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Figure Legends

Figure 1. A history of clinical practice guidelines and evidence pertaining to PSA screening of asymptomatic men, including all USPSTF guidelines, publication of pivotal evidence, and selected other guidelines

Figure 2. U.S. national rates for PSA screening by age and race for 2003- 2013 when evidence and clinical guidelines changed regarding PSA screening

Figure 3. Adjusted Risk of PSA Screening for a man age ≥ 68 years associated with each individual factor in 2003 and 2013

Figure 4. Variation across HRR in the Absolute change between 2003 and 2013 in PSA screening rate among men age 75 and older

Supplementary Figures and Tables

Supplementary Figure 1. Defining national cohorts of men age 68+ eligible for PSA screening for prostate cancer for years 2003, 2006, 2008, 2010, and 2013

Supplementary Table 1. Bivariate Analysis of Percent of Men Screened with PSA by each Factor in 2003-2013

Supplementary Table 2. Predicted Likelihood of Men age 75 years or older Screened with PSA Test Associated with Each Individual Factor in 2003 and 2013

Supplementary Table 3. HRR Characteristics in 2003 Associated with Predicted Absolute Change (2003-2013) in PSA Screening Rates in Men aged 75 and older.* Statistically significant results bolded.