

Implementation and Impact of a Risk-Stratified Prostate Cancer Screening Algorithm as a Clinical Decision Support Tool in a Primary Care Network



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BACKGROUND: Implementation methods of risk-stratified cancer screening guidance throughout a health care system remains understudied.

OBJECTIVE: Conduct a preliminary analysis of the implementation of a risk-stratified prostate cancer screening algorithm in a single health care system.

DESIGN: Comparison of men seen pre-implementation (2/1/2016–2/1/2017) vs. post-implementation (2/2/2017–2/21/2018).

PARTICIPANTS: Men, aged 40–75 years, without a history of prostate cancer, who were seen by a primary care provider.

INTERVENTIONS: The algorithm was integrated into two components in the electronic health record (EHR): in Health Maintenance as a personalized screening reminder and in tailored messages to providers that accompanied prostate-specific antigen (PSA) results.

MAIN MEASURES: Primary outcomes: percent of men who met screening algorithm criteria; percent of men with a PSA result. Logistic repeated measures mixed models were used to test for differences in the proportion of individuals that met screening criteria in the pre- and post-implementation periods with age, race, family history, and PSA level included as covariates.

KEY RESULTS: During the pre- and post-implementation periods, 49,053 and 49,980 men, respectively, were seen across 26 clinics (20.6% African American). The proportion of men who met screening algorithm criteria increased from 49.3% (pre-implementation) to 68.0% (post-implementation) ($p < 0.001$); this increase

was observed across all races, age groups, and primary care clinics. Importantly, the percent of men who had a PSA did not change: 55.3% pre-implementation, 55.0% post-implementation. The adjusted odds of meeting algorithm-based screening was 6.5-times higher in the post-implementation period than in the pre-implementation period (95% confidence interval, 5.97 to 7.05).

CONCLUSIONS: In this preliminary analysis, following implementation of an EHR-based algorithm, we observed a rapid change in practice with an increase in screening in higher-risk groups balanced with a decrease in screening in low-risk groups. Future efforts will evaluate costs and downstream outcomes of this strategy.

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INTRODUCTION

Among men, prostate cancer is the most common non-skin cancer and the second most common cause of cancer-specific mortality.^{1, 2} Though prostate cancer is one of only five cancers in which randomized controlled trials (RCTs) have shown that screening leads to a reduction in cancer-specific mortality,^{3, 4} controversy has enshrouded prostate-specific antigen (PSA)-based screening for the past two decades.^{5, 6} In particular, there has been concern that harms of screening, including the resultant increase in diagnosis and overtreatment, outweigh the potential benefits.⁷ Indeed, in 2012, the US Preventive Services Task Force (USPSTF) recommended against PSA-based screening⁸ while other guideline groups, including the American Cancer Society (ACS)⁹ and the National Comprehensive Cancer Network (NCCN),¹⁰

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recommended a risk-stratified approach centered on informed decision-making.

In the ensuing years, PSA-based screening rates among men 50 years and older decreased from 41% in 2008 to 31% in 2013 with a resultant decrease in the incidence of local- and regional-stage disease.¹¹ However, the incidence of distant stage disease increased 1.4% per year from 2008 to 2013 for men ages 50 to 74.¹² With new evidence based upon longer follow-up of the RCTs,^{13, 14} the USPSTF changed to a recommendation of informed decision-making regarding screening among men 55 to 69 years.¹⁵ While the task force noted the increased incidence and risk of advanced prostate cancer among African American men and those with a family history, no special considerations were given additional weight. Importantly, African American men have not been sufficiently studied in RCTs,^{3, 16} despite being disproportionately impacted by lethal prostate cancer.^{1, 17} In contrast to the USPSTF, the ACS recommends a risk-stratified approach with early screening in high-risk individuals (African Americans, men with a first-degree relative diagnosed with prostate cancer prior to age 65) and in men age 50 and older who have a life expectancy of at least 10 years.¹⁸ In addition to using a risk-stratified approach with family history and race, the NCCN guideline¹⁹ incorporates the findings that a midlife baseline PSA for a man in his forties predicts future risk of prostate cancer death or metastases.^{20–22} Subsequent monitoring is based upon the age and the PSA level, along with the digital rectal examination.

To provide a standardized approach for clinicians at Duke Health, where 21% of men are African Americans, a multi-disciplinary group from Duke Health, Duke Primary Care (DPC) and the Duke Cancer Institute (DCI), developed a risk-stratified prostate cancer screening algorithm incorporating an informed decision process ([Supplementary Material](#)).²³ This algorithm was coupled with the development of a risk-stratified treatment pathway based on two paradigms. First, there is insufficient evidence that radical prostatectomy reduces prostate-specific cancer mortality among most men with low-grade (or low-risk) disease.^{24, 25} Thus, for men with low-grade disease, we recommend conservative therapy, incorporating observation within an active surveillance program. Second, for men with high-risk disease, early initiation of multi-modality therapy is recommended;^{26–28} thus, these men are referred to our multi-disciplinary prostate cancer clinic. The screening algorithm was implemented as a low-cost and scalable clinical decision support tool into the system-wide electronic health record (EHR; Epic). The overarching goals of the development and implementation of a population-specific, risk-stratified prostate cancer screening algorithm were (1) to standardize the Duke Health network-wide clinical practice; (2) to identify individuals at high risk for aggressive prostate cancer; (3) and to avoid overscreening men at low risk. The primary aim of this study was to conduct a preliminary analysis of the impact of an

EHR-based clinical decision support tool integrating this algorithm. In future analyses, with greater duration of follow-up, we will evaluate over- and underscreening, referral patterns, patient management, downstream costs, and outcomes.

METHODS

Setting and Patient Population

DPC is a large primary care network consisting of almost 300 clinicians (physicians and advanced practice providers) located in 40 clinic sites (26 sites providing continuity care for adults, the remainder provide urgent or pediatric care) that are predominantly community-based and spread across seven counties in north central North Carolina. The DPC serves nearly 300,000 unique patients with over 700,000 patient visits per year.

We evaluated the impact of implementing the risk-stratified prostate cancer screening algorithm on screening rates among men seen by a Duke primary care provider (PCP) in one of the 26 continuity clinics. All men aged 40–75 who were seen by a PCP between 02/01/2016 and 02/21/2018 were included in the analysis. We used a pre-post implementation study design, comparing men seen by a PCP from 2/1/2016–2/1/2017 (pre-implementation) to 2/2/2017–2/21/2018 (post-implementation). Note, these intervals were not equal: the post-implementation data was extracted on 2/22/2018 so the time frame includes visits until that date.

This study was reviewed and deemed exempt by the Duke Institutional Review Board.

Development and Implementation of the Duke Risk-Stratified Prostate Cancer Screening Algorithm

As noted above, the algorithm was developed by a multi-disciplinary group and intended to be used system-wide. The group's goal was to provide clinicians with a standardized approach to prostate cancer screening that incorporated aspects of the USPSTF,¹⁵ ACS,¹⁸ and NCCN¹⁹ guidelines and acknowledged the shift in prostate cancer stage nationally. In particular, our algorithm included attention to high-risk individuals and risk stratification based on a midlife, baseline PSA.²¹ The algorithm and the importance of shared decision-making with patients were communicated by this multi-disciplinary group to primary care providers through various forums, including provider meetings at practices, practice medical director leadership meetings, and network-wide communication via email. We included several factors in the algorithm (Fig. 1), including age at time of examination, race (African American, other), and family history (first-degree relative with a history of prostate cancer prior to age 65; yes/no). We also incorporated the baseline and follow-up PSA levels in determining future monitoring intervals or referrals.

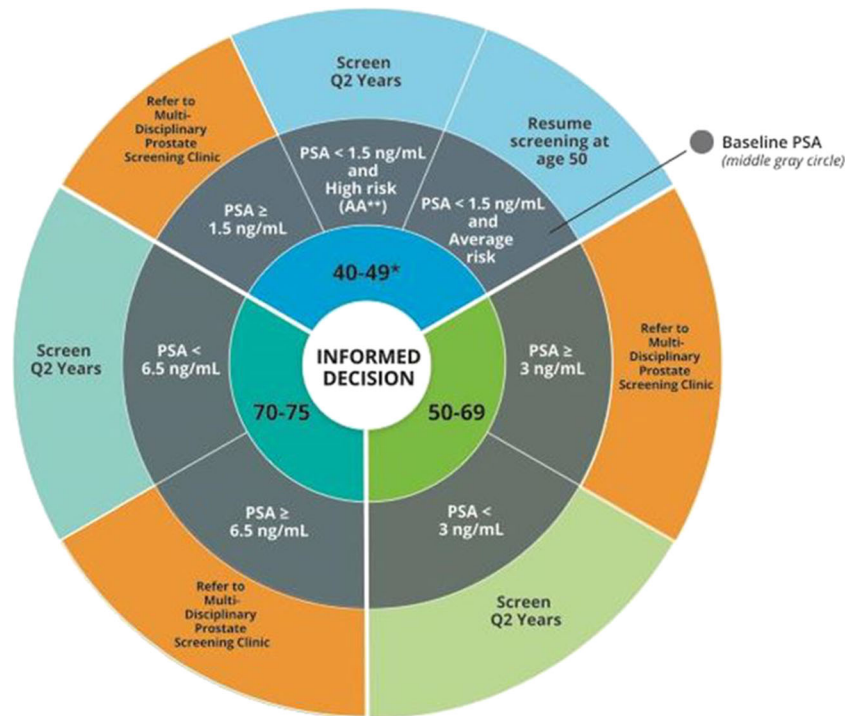


Figure 1 Risk-stratified prostate cancer screening algorithm. High risk = African American and/or family history of a first-degree relative with prostate cancer prior to age 65 years. EHR, electronic health record; PSA, prostate-specific antigen; Q, every.

Implementation of Algorithm in EHR

The algorithm was integrated as a clinical decision support tool into two components in the EHR. First, it was built within Health Maintenance, a task list that automatically populates and updates based on data in the EHR. This is an EHR section that is consistently utilized by PCPs to ensure patients are up-to-date on routine preventive and health maintenance care (Supplemental Figure 1). The Health Maintenance task list prompts a personalized “PSA Screening” reminder as per the algorithm. If the patient did not want to have PSA testing or if screening was not indicated (i.e., life expectancy < 10 years), then the clinician could record this in the Health Maintenance in the “Address Topic” field via drop down choices (i.e., “patient declines,” “not indicated”). However, this data is only captured as a snapshot in time in the EHR so it is not amenable for pre-post change analysis. Furthermore, the “Address Topic” field did not have to be filled and the informed decision documentation that takes place in a visit note is not captured by our analysis. Second, the algorithm age-based PSA cutoffs were built into the PSA laboratory results (Supplemental Figures 2–4). The age-specific criteria were then paired with a care recommendation to the ordering clinician to help determine next steps. The clinical decision support tool was not activated for patients with a history of prostate cancer. An example of the EHR logic is provided in Supplemental Figure 5.

Outcomes

Since we were interested in the uptake of the algorithm via the clinical decision support tool from 1 year pre- to 1 year post-

implementation, we evaluated both the percent (and number) of men who met screening algorithm criteria and the percent (and number) of men who had a PSA. Men who met screening algorithm criteria were defined as having a PSA value, based upon age, race, family history, and the previous PSA level (if present), on record within the 27 months prior to the date of their PCP appointment. The same definition was used for pre- and post-implementation. The 27-month window was decided upon instead of 24 months to take into account variability in patient and PCP schedules.

Analytic Approach

Descriptive statistics comparing patient characteristics and differences in the proportion of men who met screening algorithm criteria in pre- and post-implementation time periods were performed followed by a one-sample pre-post test for binomial proportion and a two-proportion z test. Logistic repeated measures mixed models, which account for correlations due to repeated measures within individuals and correlations among individuals within sites, were used to test for differences in the proportion of individuals that met screening criteria in the pre- and post-implementation study periods. Time was included as a fixed effect (i.e., pre- vs. post-implementation). Clinic and subject within clinic were included as random effects, and age and race were included as covariates. Two models were implemented: (a) main effects model, age as a categorical variable (40–49, 50–69, 70–75) and (b) interaction model, interactions of time × race and time × age with age as a categorical variable (40–49, 50–69, 70–75). Race categories were summarized as Caucasian/White, Black or African

Table 1 Patient Characteristics in Pre- and Post-implementation Periods for all Men Ages 40 to 75 Evaluated by a Network Primary Care Provider 1 Year Pre-implementation (2/1/2016–2/1/2017) and 1 Year Post-implementation (2/2/2017–2/21/2018) of a System-Wide Prostate Cancer Screening Algorithm

Category	Pre-implementation (2/1/2016–2/1/2017)		Post-implementation (2/2/2017–2/21/2018) [†]	
	N	%	N	%
Total men	49,053		49,980	
Age at appointment (year)				
40–44	6391	13.0	4137	8.3
45–49	7166	14.6	7785	15.6
50–59	14,979	30.5	15,788	31.6
60–69	14,046	28.6	14,861	29.7
70–75	6471	13.2	7409	14.8
Race				
African American	10,111	20.6	10,299	20.6
Asian	1993	4.1	2066	4.1
Caucasian	34,758	70.9	35,271	70.6
Other*	2191	4.5	2344	4.8

*All ethnicities not African American, Asian, or Caucasian

[†]Post-implementation data extraction from electronic health record on 2/22/2018

There were 37,893 men who were seen by a PCP in both periods

American, Asian, Other, and not reported/declined/unavailable, with Caucasian/White included as the reference group. Models were performed using the glmer function of the lme4 package²⁹ in R statistical software version 3.5.0.³⁰ Fixed effects results are presented as odds ratio (95% confidence interval) and random effects are presented as variance/standard deviations. Confidence intervals were found using the confint function of the lme4 package based on the Wald method. To test for the overall effect of the categorical race,

age, time × race, and time × age variables, likelihood ratio tests were performed.

Since the algorithm incorporated a discussion of screening among men aged 40–49, a more detailed evaluation regarding outcomes was performed in this age group. A retrospective chart review was conducted to determine the number of referrals to specialists, the number of men who had a prostate biopsy, and the number of cancers diagnosed for all men, pre- and post-implementation, aged 40–49, with a PSA level of 1.5 ng/ml or higher.^{21, 22}

Table 2 Percent of Men Meeting Algorithm-Based Screening and with PSA Completed in Pre- and Post-implementation Periods

Category	Pre-implementation		Post-implementation		% difference
	2/1/2016–2/1/2017		2/2/2017–2/21/2018*		
Date range	N	%	N	%	
Men meeting algorithm-based screening					
Total	24,193	49.3	33,976	68.0	18.7*
Race					
African American	5464	54.0	7360	71.5	17.4*
Caucasian	16,998	48.9	23,753	67.3	18.4*
Asian	806	40.4	1375	66.6	26.1*
Age categories (year)					
40–44	1168	18.3	1972	47.7	29.4*
45–49	2360	32.9	4425	56.8	23.9*
50–59	8828	58.9	11,577	73.3	14.4*
60–69	8561	60.9	11,032	74.2	13.3*
70–75	3276	50.6	4970	67.1	16.5*
Men with PSA completed					
Total	27,146	55.3	27,498	55.0	– 0.3
Race					
African American	6130	60.6	5811	56.4	– 4.2
Caucasian	19,116	55.0	19,314	54.8	– 0.2
Asian	870	43.7	1162	56.2	12.6
Age categories (year)					
40–44	1242	19.4	1726	41.7	22.3*
45–49	2545	35.5	3680	47.3	11.8*
50–59	9744	65.1	9001	57.0	– 8.0
60–69	9689	69.0	9010	60.6	– 8.4
70–75	3926	60.7	4081	55.1	– 5.6

**p* < 0.001

[†]Post-implementation data pull on 2/22/18

PSA, prostate-specific antigen

Table 3 Results of Logistic Repeated Measures Mixed Models for Differences in the Proportion of Individuals That Met Algorithm-Based Screening Criteria in the Pre- and Post-implementation Periods

	Model A (no interactions) <i>N</i> = 99,043 BIC = 119,319.8	Model B (with interactions) <i>N</i> = 99,043 BIC = 118,692.7
Fixed effects*		
Time (post- vs. pre-implementation)	3.36 (3.23, 3.51)	6.49 (5.97, 7.05)
Age		
40–49	Reference	Reference
50–69	6.10 (5.74, 6.47)	9.50 (8.80, 10.26)
70–75	3.72 (3.46, 4.00)	5.67 (5.16, 6.27)
Race		
Caucasian/White	Reference	Reference
Black/African American (AA)	1.46 (1.38, 1.54)	1.57 (1.47, 1.69)
Asian	0.96 (0.86, 1.07)	0.79 (0.68, 0.91)
Other	0.93 (0.81, 1.06)	0.93 (0.78, 1.12)
Not reported/declined/unavailable (NR)	0.84 (0.73, 0.97)	0.84 (0.69, 1.02)
Time (post) vs. Black/AA	–	0.87 (0.80, 0.95)
Time (post) vs. Asian	–	1.46 (1.22, 1.75)
Time (post) vs. other	–	0.99 (0.79, 1.25)
Time (post) vs. NR	–	0.99 (0.79, 1.26)
Time (post) vs. age (50–69)	–	0.43 (0.39, 0.46)
Time (post) vs. age (70–75)	–	0.45 (0.40, 0.51)
Random effects†		
Clinic (<i>N</i> = 26)	0.37/0.61	0.39/0.62
Subject within clinic (<i>N</i> = 64,634)	2.43/1.56	2.55/1.60
Likelihood ratio tests		
Race	<i>p</i> < 0.0001	–
Age (40–59, 60–69, 70–75)	<i>p</i> < 0.0001	–
Time × Race	–	<i>p</i> < 0.0001
Time × Age (40–59, 60–69, 70–75)	–	<i>p</i> < 0.0001

*Fixed effects presented as odds ratio (95% confidence interval)

†Random effects presented as variance/standard deviation

RESULTS

The study involved 49,053 and 49,980 men in the pre- and post-implementation periods, respectively, with 37,893 men having a PCP clinic visit in both periods (Table 1). Of the overall cohort, 20.6% of the men were African American.

Overall Findings

The implementation of the clinical decision support tool resulted in an increase in the percent of men who met screening algorithm criteria, from 49.3% pre-implementation to 68.0% post-implementation (*p* < 0.001) (Table 2). This increase was observed across all races, age categories, and PCP clinics.

Importantly, the percent of men who had a PSA did not change substantively: 55.3% pre-implementation and 55.0% post-implementation (Table 2). The percent of men aged 40–44 and 45–49 who had a PSA increased from pre- to post-implementation: 22.3% and 11.8%, respectively (Table 2). In contrast, for men aged 50–59, 60–69, and 70–75, the percent of men who had a PSA decreased by 8.0%, 8.4%, and 5.6%, respectively.

Mixed Models Results

Results of repeated measures mixed models, including age, race, and random effects of the clinic and subjects within a clinic without and with interactions, are provided in Table 3.

Table 4 Outcomes for Men Aged 40 to 49 with Abnormal PSA (> 1.5 ng/ml) in the Pre- and Post-implementation Periods

Category	Pre-implementation		Post-implementation	
	<i>N</i>	%	<i>N</i>	%
Total number of men with abnormal PSA	366	2.7*	583	4.9*
Age 40–44	83	22.7	137	23.5
Age 45–49†	283	77.3	427	73.2
PSA repeated by PCP	23	6.3	166	28.5
PCP-referred patient	38	10.4	323	55.4
Referral completed	22	6.0	205	35.2
Men with prostate biopsy	12	3.3	33	5.7
Men with prostate cancer on biopsy	3	0.8	11	1.9

*Percent of total men aged 40 to 49 seen in the respective period

†Age 45–49 in the post-implementation does not also include 3.3% aged 50–55
PSA, prostate-specific antigen; PCP, primary care provider

Since the interactions were significant (time period \times race and time period \times age), the estimates we provide below are from the model with interactions. Overall, results suggest that the odds of meeting screening algorithm criteria was 6.5-times higher in the post-implementation period than in the pre-implementation period (95% CI, 5.97 to 7.05). Notably, the odds of meeting screening algorithm criteria or having a PSA completed in the post-implementation period was lower for men aged 50–69 and 70–75 (0.43 and 0.45, respectively). This was likely due to a decrease in PSA test ordering in the older age groups in the post-implementation period due to over-screening in the pre-implementation time frame. African American men were 1.57-times more likely to meet algorithm-based screening than Caucasian men (95% CI, 1.47 to 1.69). In contrast, Asian men were 21% less likely than Caucasian men to meet screening algorithm criteria (OR = 0.79, 95% CI, 0.68 to 0.91). The variance of the random clinic effect was 0.39 and the variance of the subject within clinic effect was 2.55. The intraclass correlation coefficient (ICC) of generalized linear models varies according to the values of the covariates and is less interpretable than the median odds ratio (MOR).³¹ Therefore, to better understand random effect variation, we present the median odds ratio. The MOR from the multi-level mixed model was 1.81 whereas ORs for patient-level characteristics (i.e., age) were of greater magnitude suggesting that unexplained between-clinic variation was not as relevant as patient-level characteristics for understanding rates of meeting screening criteria.

Subanalysis of Men Aged 40–49 Years

About 3% and 5% of men aged 40–49 had a PSA > 1.5 ng/ml in the pre-implementation and post-implementation period, respectively (Table 4). Of those men, about a quarter were aged 40–44 in either the pre-implementation (22.7%) or post-implementation (23.5%) and about three-quarters were aged 45–49 in either the pre-implementation (77.3%) or post-implementation (73.2%). Whereas PCPs repeated the PSA in the pre-implementation period in only 6.3% of these men, they repeated the PSA in 28.4% of the men in the post-implementation period. Of note, while the number of men who were referred to Duke Health's urology service increased, the percent of referred men who had a biopsy decreased from 31.6 to 10.2%. The percent of men with prostate cancer on biopsy stayed about the same (27.2% pre-implementation; 33.3% post-implementation). In the pre- and post-implementation period, three and eleven men, respectively, were diagnosed with prostate cancer.

DISCUSSION

To our knowledge, this is the first study to evaluate the impact of an EHR-based clinical decision support tool incorporating a population-specific, risk-stratified prostate cancer screening algorithm. This low-cost, easily adaptable approach resulted

in an increase in the percent of men seen by PCPs at Duke Primary Care who met screening algorithm criteria with a concurrent reduction in inappropriate screening. This change was observed across all primary care clinics. Moreover, while the percent of men who met screening algorithm criteria increased by almost 20%, from 49 to 68%, the percent of men who had documented PSA testing did not materially change. Rather, we observed a reduction in practice variation and a decrease in the rate of annual PSAs ordered by PCPs.

Historically, changing clinician practice is challenging. A classic example is the lengthy interval from evidence of the benefits of beta blockers following a myocardial infarction to implementation in clinical practice.^{32–34} Guideline dissemination methods have varying effectiveness and many lead to only modest or even no impact on changing practice.^{35–38} While incorporation in the EHR has been considered a potential implementation strategy, findings from studies have been mixed.^{37, 39–42} The Duke Health simple implementation strategy using Health Maintenance combined with tailored laboratory results with follow-up recommendations resulted in substantially improved algorithm-based screening while reducing practice variation. Utilizing the EHR and seamlessly integrating it into the workflow of PCPs offer a generalizable and scalable implementation strategy that can be applied to other topics and in other settings.

The debate regarding prostate cancer screening has often vacillated between doing more versus less. The Duke Health multi-disciplinary group's goal was to improve appropriate screening recognizing an important at-risk population in the community, African American men. After implementation, the number of men who met screening algorithm criteria increased, regardless of age, race, or clinic. This change occurred without driving more testing as the volume of men with PSAs stayed constant. This was due to reduced testing among men in the older age groups and increased screening among men aged 40–49 in the post-implementation period.

As noted earlier, national guidelines have differed in whether to discuss prostate cancer screening among men aged 40–49. Based upon the findings of Vickers, Preston, and others showing the benefit of a baseline PSA for men in their forties,^{21, 22, 43} the multi-disciplinary group at Duke Health opted to start the discussion sometime between the ages of 40 and 49 years. This likely resulted in an increase in cost of care for this age group, as the number of men who had a test, were referred to a specialist for an elevated PSA, and had a biopsy increased. Whether the number and the aggressiveness of prostate cancer among men in this age group will offset the cost of care cannot be ascertained at this point. Currently, several men are still undergoing evaluation; it will require a longer interval of follow-up and a detailed cost analysis to better assess the impact of the algorithm on this age group. Nevertheless, after this preliminary evaluation and as part of our Learning Health System,^{44, 45} the multi-disciplinary group decided

to change the system-wide recommendation to initiating the discussion between the ages of 45 and 49 rather than between 40 and 49.

While this study has several strengths, including a system-wide evaluation of a simple EHR implementation strategy among a large number of men from diverse backgrounds, there are several limitations that need to be considered when interpreting the findings. There is no broad consensus on PSA screening so the algorithm itself is without clinical and trial data that directly supports it. Additionally, evidence supporting broader screening for high-risk and African American men is limited which is why USPSTF does not make specific recommendations for these groups^{3, 16}. This was a single-health care system implementation; implementation may be more difficult in a non-integrated system without a shared EHR. This was a prospective quality improvement project that was not randomized and with a time frame that was too short to evaluate the impact of the algorithm on prostate cancer detection, particularly among African American men. The pre- post-design and short time frame also limit delineation of temporal trends and factors that can impact screening rates. Future efforts will be able to better capture outcomes and costs associated with the algorithm implementation. Through data extraction from the EHR, we were not able to easily capture the cases in which the PCP discussed screening and the patient declined to have PSA screening; thus, we likely underestimated the percent of men meeting algorithm-based screening and do not have much insight into patient preferences around screening. Lastly, family history is not easily and reliably captured in the EHR as it is a hand-entered variable.

In conclusion, an EHR-based clinical decision support tool led to a significant increase in PCPs following the Duke Health system-wide PSA screening algorithm while avoiding an increase in number of men with a PSA. In other words, this preliminary analysis demonstrates that the Duke Health multi-disciplinary group may meet the goal of screening those who might be most likely to benefit and reducing screening in those who are unlikely to benefit. Our study highlights a potential pathway to leverage the EHR to influence and standardize PCP practice through better guideline adherence and reduced practice variation.

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Compliance with Ethical Standards:

This study was reviewed and deemed exempt by the Duke Institutional Review Board.

Conflict of Interest: Thomas J. Polascik reports consultancies in the last 3 years and honoraria in the last 3 years from Healthtronics [training agreement]. Terry Hyslop reports consultancies in the last 3 years from AbbVie. Glenn M. Preminger reports consultancies in the last 3 years from Boston Scientific, Auris Robotics, and Kalera Medical and reports other relationships as an Associate Editor for *Up to Date*. Kevin Shah reports stock ownership/options other than mutual funds from Infinity Pharmaceuticals. Anand Shah reports stock ownership/options other than mutual funds from Pfizer Inc. All other authors report no conflict of interest.

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