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Abstract

Introduction: Few lung cancer screening decision aids have been tested in diverse populations. The study objective was to determine whether the online decision aid www.shouldiscreen.com impacts knowledge of and decisional conflict around lung cancer screening in a diverse population.

Methods: Eligible patients had significant smoking histories, were at increased risk for lung cancer (ages 45-80, >20 pack-years, smoking within last 15 years) and had no history of prior lung cancer or screening. Data was collected and analyzed in 2017.

Results: 40 patients were enrolled: 80% were female, 62.5% black, 33% white, and 48% had a high school education or less. 80% were current smokers with a mean of 34 pack-years accumulated. 35% were eligible for screening by U.S. Preventive Services Task Force criteria. After reviewing the decision aid, knowledge increased in all categories including risk factors for lung cancer (3.58 to 4.30, $p<0.01$), benefits of screening (1.58 to 2.30, $p<0.01$), possible harms of screening (0.93 to 2.08, $p<0.01$), and eligibility for screening (2.10 to 2.65, $p<0.01$). Decisional conflict was reduced from 21.25 to 8.65 ($p<0.01$). After use of the decision aid, more patients expressed a preference not to be screened for lung cancer, such that concordance with USPSTF guidelines decreased among those who were eligible to screen increased among those who did not yet meet eligibility criteria; however, this finding was not statistically significant.

Conclusions: Even brief, unguided use of this web-based tool improved knowledge and reduced decisional conflict for a diverse group of smokers considering lung cancer screening.

Keywords

shared decision making; lung cancer; urban health; health disparities; cancer screening, decision aid

Cover Page Footnote

Abbreviations USPSTF: United States Preventative Services Task Force LDCT: Low-Dose Cat Scan CT: Cat Scan CI: Confidence Interval Acknowledgements We would like to thank Tanner Caverly, MD, Dr Rafael Meza, PhD, Lisa Lau, MPH and the rest of their University of Michigan group for allowing us to evaluate their website www.shouldiscreen.com for this research, and for providing helpful feedback on prior drafts. We would also like to thank Marilyn Shapira, MD, MPH for her guidance through the current literature and feedback on study design. Lastly, thank you to Jesse Carah, MA for statistical analysis. No financial disclosures were reported by the authors of this paper. The datasets analyzed during the current study are available from the corresponding author on reasonable request. The University of Pennsylvania IRB approved the study (Protocol #825854).

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Methods: Eligible patients had significant smoking histories, were at increased risk for lung cancer (ages 45-80, >20 pack-years, smoking within last 15 years) and had no history of prior lung cancer or screening. Data was collected and analyzed in 2017.

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INTRODUCTION

For many years, screening programs for breast, cervical, and colorectal cancer have enjoyed the privilege of generally well-publicized and understood screening practices. As such, many individuals at highest risk for mortality have been screened through mammography, pap smears, and colonoscopy. However, few such organized efforts exist for lung cancer, the second most common cause of cancer and the most common cause of cancer deaths in both men and women in the United States (American Cancer Society, 2016). Lung cancer is often diagnosed at late stages and carries a high but modifiable mortality. The aim of this study was to better understand how to educate patients about lung cancer screening harms and potential benefits. Specifically, we evaluated the efficacy of one online decision aid in improving knowledge of and reducing decisional conflict around lung cancer screening.

The field of lung cancer screening has changed significantly over the past decade since the National Lung Screening Trial demonstrated a 20% reduction in mortality with annual low-dose computed tomography (LDCT) in patients at high risk for lung cancer (National Lung Screening Trial Research Team, 2011). Based on these trials, the United States Preventative Services Task Force (USPSTF) currently recommends annual screening for lung cancer with LDCT in adults ages 55-80 who have a 30 pack-year smoking history and currently smoke or quit within the last 15 years (Moyer, 2014). Once high-risk individuals have been identified and referred for screening, they must undergo shared decision-making so as to understand the benefits and risks of screening, including false-positives, incidental findings, over diagnosis, and radiation risk. Shared decision making is recommended by the USPSTF, American Cancer Society, American Academy of Family Physicians, National Comprehensive Cancer Network, and others (U.S. Preventative Services Task Force, 2016). In fact, the Center for Medicare and Medicaid Services mandates that shared decision-making occur as a stipulation of lung cancer screening reimbursement (U.S. Center for Medicare and Medicaid Services, 2015).

Implementation of shared decision making about lung cancer screening has various challenges including low patient and provider awareness of the guidelines (Lewis, 2015), limited time during clinician visits, and variability of the process of shared decision making. A 2018 study observed a small sample of recorded conversations about initiating lung cancer screening in which physicians did not use decision aids (Brenner et al., 2018). They found that the quality of shared decision making was poor and the discussion of the harms of screening was minimal. Several shared decision-making tools have been developed to improve the quality of such conversations (Reuland et al., 2018). An initial educational video-based decision aid was acceptable to patients and generally increased knowledge of lung cancer screening, but was not individualized and did not aid patients in making specific decisions (Volk et al., 2014). More recently, a web-based decision aid (www.shouldiscreen.com) was developed which describes individual cancer risks and screening impact given user-entered patient demographics (Lau et al., 2013). This tool was tested and shown to be acceptable to users, increase knowledge and concordance with USPSTF guidelines, and decrease decisional conflict. However, this was studied in a population of 60 patients in Michigan in which 88% were white, 63% had at least a college degree, and only 18% were actually eligible for screening by USPSTF guidelines (Lau et al., 2015). Therefore, use of this decision aid should also be assessed among minority populations and those of lower socioeconomic status, such as Philadelphia.

This study sought to assess the efficacy of the online decision aid (www.shouldiscreen.com) by replicating the study in a more ethnically and socioeconomically

diverse sample of patients. Our main aim was to understand how this online tool impacts knowledge of and decisional conflict around screening. Effective tools for shared-decision making are necessary for implementation of future lung cancer screening programs.

METHODS

Study Sample

An uncontrolled, paired sample before-and-after study was conducted with 40 participants to assess the efficacy of the online decision aid (January through May 2017). Participants were recruited from general pulmonology and smoking cessation clinics at the University of Pennsylvania and were current or former smokers, aged 45-80 years, who had accrued at least a 20 pack-year smoking history, had smoked within the last 15 years, and had no prior history of lung cancer or LDCT lung cancer screening. Participants were offered the opportunity to view the decision aid at a computer in the clinic. No incentives were paid to participants. The study was approved by the University of Pennsylvania IRB.

Data Collection

Participants were directed to complete a questionnaire about demographics, smoking behaviors, knowledge of lung cancer screening, decisional conflict around screening, and readiness to screen. The questionnaire was administered via Qualtrics (www.qualtrics.com) at the University of Pennsylvania. Participants were asked to complete a “Before” questionnaire after which they were navigated to shouldiscreen.com. Participants were familiarized with the website layout and told to take their time in navigating through the general links on lung cancer screening and the personalized risk calculator. Once participants had viewed the website to their satisfaction they were directed to the “After” questionnaire.

Measures

Study questionnaires were adapted from the original validation study for shouldiscreen.com, which assessed knowledge of benefits and harms of lung cancer screening, decisional conflict, and concordance (Lau et al, 2015). These measures were originally based upon the Ottawa Decision Support Framework (O’Connor et al., 2011). Knowledge was assessed by asking a series of true-false questions about lung cancer risk factors (6 items), possible benefits (3) and harms of lung cancer screening (3), and yes/no questions about screening eligibility for four scenarios (4). There was an additional multiple-choice question asking what percentage of nodules found on CT would not be cancerous with a 5-point probability response scale that ranged from more than 90% to less than 5% (see Appendix-Table 2). The ten-item decisional conflict scale was composed of four subscales: uncertainty, informed, values clarity, and support. A total score of 0 indicates no decisional conflict, whereas 100 shows extremely high conflict. Concordance was measured between USPSTF recommendations and each participant’s preference as to whether or not to undergo screening. This was assessed by the question *Which option do you prefer now in terms of lung cancer screening?*, which was asked before and after exposure to shouldiscreen.com. Participants who answered *I prefer to screen* and were also USPSTF eligible were deemed concordant, as were participants ineligible for screening who answered *I prefer not to screen*. Lastly, personalized lung cancer incidence risk was calculated on the shouldiscreen.com website using an established risk model (Tammemägi et al., 2013).

Statistical Analysis

Our primary endpoints were improvement in knowledge and reduction in decisional conflict after exposure to shouldiscreen.com as compared to baseline. With a total sample size of

40 participants, we had 87% power to detect a 50% absolute difference in knowledge and decisional conflict after exposure to shouldiscreen.com. The criterion for significance (alpha) was set at 0.050. Paired t-tests were used to assess changes in knowledge and decisional conflict from baseline to after exposure to shouldiscreen.com. All analyses were conducted using RStudio (Version 1.0.143) and a p-value of < 0.05 was considered to be statistically significant.

RESULTS

Of 160 patients who completed an initial triage questionnaire between January and May 2017, 87 (54%) met inclusion criteria based on age and smoking status. Of the 62 participants that were excluded, 34 (54.8%) were due to insufficient pack years, 14 (22.6%) due to computer illiteracy, 7 (11.3%) due to lung cancer diagnosis, 3 (4.9%) due to visual or physical impairments rendering them unable to use the computer, 2 (3.2%) due to inability to speak English, and 2 (3.2%) due to having quit smoking more than 15 years ago. Of those eligible patients, 40 (46%) were consented and enrolled (Figure 1). For those participants that were eligible but chose not to enroll, their reasons included lack of time (77%), not interested in participating in research (19%), lack of financial incentive (2%), and not feeling well (2%). Compared to those who did not enroll, those who enrolled were more likely to be female (80% of those enrolled vs. 58% of those not enrolled). The average enrolled participant was aged 57 (standard deviation 6.41 years), 80% were female, and 62.5% were African-American (Table 1). 80% of participants were current smokers, and 35% met USPSTF eligibility criteria for lung cancer screening. Of those participants that were ineligible for screening, 50% were ineligible due to insufficient pack-years alone, 27% due to age alone, and 23% due to both insufficient pack-years and age. Regarding 6-year lung cancer risk, 45% of participants had greater than 2% risk. Average time spent on the shouldiscreen.com decision aid was 9.6 minutes (range 3 to 19 min), and average total time for questionnaire completion was 28 minutes (range 16 to 46 min).

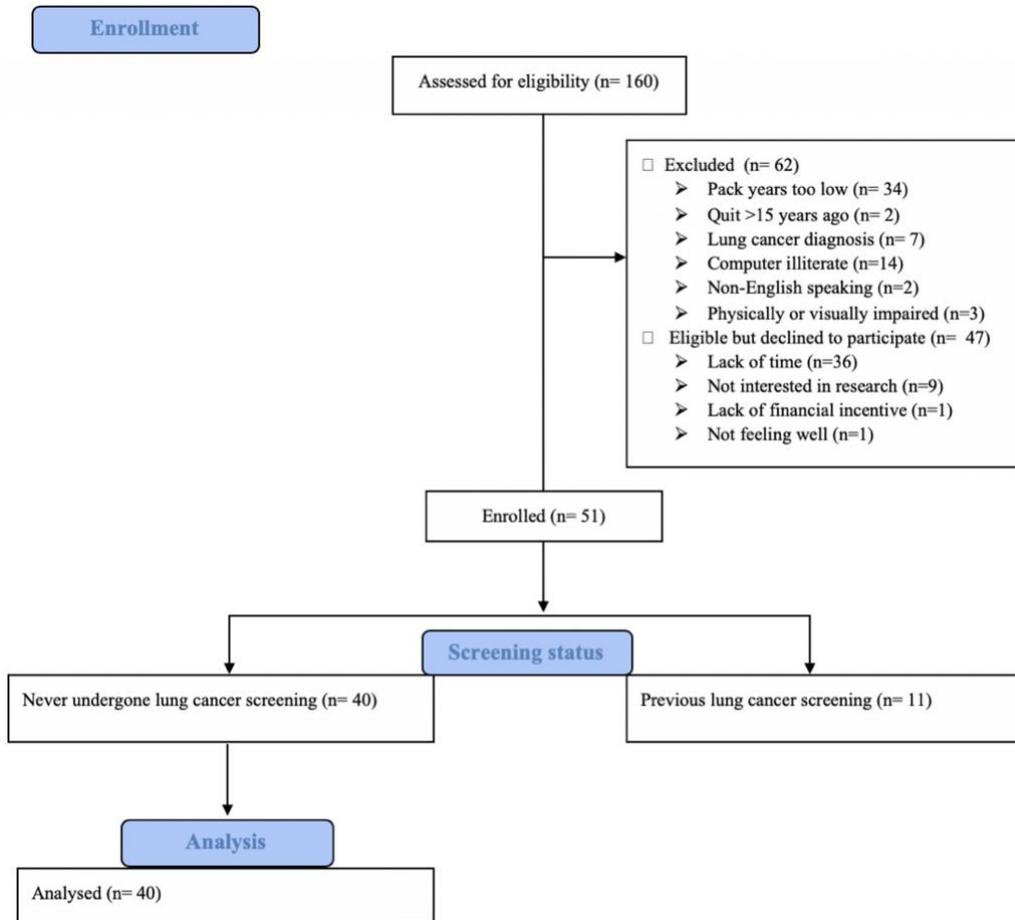


Table 1. Participant demographics [Number of participants (%)]

	Total (N=40)
Age, mean (SD, range)	57 (6.41, 45-69)
Female	32 (80%)
Race	
Black/African-American	25 (62.5%)
White	13 (32.5%)
American Indian/Alaskan Native	1 (2.5%)
Other	1 (2.5%)
Ethnicity	
Hispanic or Latino	1 (2.5%)
Not Hispanic or Latino	39 (97.5%)
Education	
Less than high school	5 (12.5%)
High school graduate	7 (17.5%)

Some training after high school	7 (17.5%)
Some college	10 (25%)
College graduate	8 (20%)
Postgraduate or professional degree	3 (7.5%)
Smoking history	
Current smoker	32 (80%)
Quit within past 15 years	8 (20%)
Pack years, mean, median (SD)	34, 30 (13.63)
More than 30 pack-years	21 (52.5%)
Lung cancer risk	
<1% risk	8 (20%)
1-2% risk	14 (35%)
>2% risk	18 (45%)
Eligible for screening by USPSTF criteria	14 (35%)
Ineligible for screening by USPSTF criteria	26 (65%)
Ineligible due to pack-years alone	13 (50%)
Ineligible due to age alone	7 (27%)
Ineligible due to both pack-years and age	6 (23%)
Time spent on decision aid (minutes) \pm SD	9.6 \pm 4.1

Table 2 shows changes in knowledge, decisional conflict, and concordance, before and after exposure to shouldscreen.com. Knowledge increased after reviewing the decision aid in all categories, including risk factors for lung cancer (3.58 to 4.30, $p < 0.01$), benefits of lung cancer screening (1.58 to 2.30, $p < 0.01$), possible harms of screening (0.93 to 2.08, $p < 0.01$), and eligibility for screening (2.10 to 2.65, $p < 0.01$). Additionally, mean overall decisional conflict was reduced from 21.25 to 8.65 ($p < 0.01$) with improvements primarily across the subcategories of information, values clarity, and uncertainty.

Table 2. Before and After Results for Knowledge, Decisional Conflict Scale, and Concordance.

		Before (mean)	After (mean)	p-values
Knowledge (overall)^a	Factors that increase the chances of getting lung cancer [6]	3.58	4.30	<0.01
	Possible benefits of lung cancer screening [3]	1.58	2.30	<0.01
	Possible harms of lung cancer screening [3]	0.93	2.08	<0.01
	Which individuals would be eligible for screening based on age,	2.10	2.65	<0.01

	given that they all meet smoking status and pack-year criteria? [1]			
	What percentage of lumps found on your lung by the CT screening is NOT going to be cancer? ^b [1]	0.075	0.325	0.0129
Decisional conflict^c	Overall decisional conflict	21.25	8.65	<0.01
	Uncertainty subscale	4.2	1.45	<0.01
	Informed subscale	9.5	3.55	<0.01
	Values clarity subscale	4.45	1.65	<0.01
	Support subscale	3.1	2.00	0.0569
Concordance^d	Overall concordance	15 (37.5%)	17 (42.5%)	0.820
	Concordance among USPSTF eligible	13 (32.5%)	11 (27.5%)	0.596
	Concordance among USPSTF ineligible	2 (5%)	6 (15%)	0.249

^a- The overall maximum score for the knowledge section is 14. The maximum score of each specific question is specified in square parentheses.

^b-The figures presented for question 5 are the proportion of participants that answered correctly as there was only one correct answer.

^c-Lower scores in the Decisional Conflict Scale signify less decisional conflict. A score of lower than 25 is associated with implementing the decision. The overall score is the average of the subscales' scores.

^d- Participants who preferred to get screened and were also eligible for screening based on USPSTF criteria were deemed "concordant" as were participants not eligible for screening who preferred not to get screened. The figures reported represent the frequency and proportion of those who were concordant.

Overall, preference to screen declined after navigating shouldiscreen.com, such that more patients expressed a preference not to be screened for lung cancer. Specifically, concordance with USPSTF guidelines decreased among those who were eligible to screen and increased among those who did not yet meet eligibility criteria. However, these findings were not statistically significant.

DISCUSSION:

The web-based decision aid shouldiscreen.com was acceptable and feasible in a socioeconomically and racially diverse group of smokers. Use of the aid improved lung cancer screening knowledge and decreased decisional conflict, demonstrating its utility both as an informational and decision guiding tool. At baseline, participants exaggerated the potential benefits from screening, with only 7.5% correctly answering that >95% of lumps found on a screening CT would be non-cancerous. After use of the decision aid, 32.5% of participants

correctly answered this question, demonstrating a more accurate understanding of the potential benefits and harms of screening. With this, we saw an overall preference for screening decline after decision aid viewing. This may stem from the fact that benefits to screening are generally well publicized whereas risks of screening, such as false positives, subsequent unnecessary testing and possible complications, are less publicized. Use of the decision aid informed participants of the realistic potential benefits and harms of screening, and this may have in turn discouraged them from future screening. Future qualitative studies aimed at understanding patient attitudes towards screening after use of decision aids would help to expand on this finding. This finding highlights the importance of a structured tool in the shared decision-making process, as clinicians may be highly variable in their own attitudes towards screening and may thus present risks and benefits to patients in inconsistent or misleading ways (Ebell et al., 2018). The decision aid is not meant to replace a shared decision-making conversation. It is a tool and a starting point for such discussions, providing a patient with information and empowering them to assess their personalized risks and benefits through a discussion with their physician.

Limitations

This study is limited to a brief interaction with a lung cancer screening decision-aid, and its immediate impact on patient knowledge, attitude, and willingness to screen. The majority of participants were female which is problematic given that lung cancer accounts for the highest number of cancer deaths among African-American males in the U.S. (American Cancer Society, 2019). Many African-American males were eligible and approached for the study, but chose not to participate. Future studies may benefit from offering a small monetary incentive to participants to improve enrollment. Additionally, only 35% of participants were USPSTF eligible for screening. The overall lung cancer risk was still higher than that seen in prior validation studies, and the overall low screening eligibility would be expected to contribute to the low post-decision aid willingness to screen as seen in our data.

One major limitation of this study was the inclusion of patients 45 to 80 years old, whereas the current USPSTF criteria includes only patients 55 to 80 years old. The decision was made to include younger patients for multiple reasons: for one, all of the participants, including those younger than 55, had a >20 pack year smoking history and 80% of all participants were active smokers. Therefore, it is likely that the majority of the participants under 55 will be eligible for lung cancer screening in the coming decade if they continue to smoke. Additionally, patient populations that are at increased risk for lung cancer are not represented in the current lung cancer screening criteria (Wood et al., 2018). Research has shown that African-Americans have a higher risk of lung cancer than whites even if they smoke less over time, and are diagnosed with lung cancer at a younger age compared with whites (Aldrich et al., 2019). Given this, the current USPSTF guidelines may be too conservative for African-American smokers, which comprised 62.5% of our participant population. Other risk models have been developed to try to expand eligibility to such high-risk individuals that are not currently included in the USPSTF eligibility criteria (Tammemägi et al., 2014). One such study including U.S. ever smokers age 50-80 showed that a risk-based model for screening was associated with a greater number of lung cancer death prevented over 5 years when compared with the current USPSTF model (Katki et al., 2016).

Since this was a single day study, there was no follow-up to see if knowledge gains were durable or if participants who preferred to get screening ever actually did so. However, one recent study demonstrated persistent knowledge gains one month after use of an online decision aid (Mazzone et al., 2017). Another study followed patients three months after exposure to an online

decision aid, and found heterogeneous screening behaviors (Reuland et al., 2018). Lastly, a limitation to our study was the requirement that participants have experience with computers in order to use the web-based tool. Of the 62 participants that were excluded, 14 (22.5%) were due to computer illiteracy and 3 (4.8%) were due to visual or physical impairments rendering them unable to use the computer. A recent study showed that use of audio in future decision aids may improve patient participation for those unable to use computers (Hoffman et al., 2018). Expansion to other languages would also allow for wider decision aid use. Since this study, a Spanish-language version has been developed and can be found at the following website: www.shouldiscreen.com/Español/inicio. Future studies should address how best to effectively integrate such an intervention into current clinical practices or a larger lung cancer screening program, as a standalone decision aid could be viewed at home pre-visit or while waiting for a physician in the office but would require even more literacy and autonomy on the part of the patient.

Finally, this study was a single-group, pre-post study and future work should include a usual care or control group in the design to determine if this decision aide is effective compared to usual care.

Despite these limitations, this study shows that a web-based decision aid can be helpful tool for increasing knowledge and reducing decision conflict about lung cancer screening in a racial and ethnically diverse group of smokers in an urban academic clinic who are at increased risk of lung cancer.

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We would like to thank Tanner Caverly, MD, Dr Rafael Meza, PhD, Lisa Lau, MPH and the rest of their University of Michigan group for allowing us to evaluate their website www.shouldiscreen.com for this research, and for providing helpful feedback on prior drafts. We would also like to thank Marilyn Shapira, MD, MPH for her guidance through the current literature and feedback on study design. Lastly, thank you to Jesse Carah, MA for statistical analysis.

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