REVIEWS

The Psychological Harms of Screening: the Evidence We Have Versus the Evidence We Need

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BACKGROUND: Systematic reviews for the US Preventive Services Task Force have found less high-quality evidence on psychological than physical harms of screening. To understand the extent of evidence on psychological harms, we developed an evidence map that quantifies the distribution of evidence on psychological harms for five adult screening services. We also note gaps in the literature and make recommendations for future research.

METHODS: We systematically searched PubMed, PsycInfo, and CINAHL from 2002 to 2012 for studies of any research design that assessed the burden or frequency of psychological harm associated with screening for: prostate and lung cancers, osteoporosis, abdominal aortic aneurysm (AAA) and carotid artery stenosis (CAS). We also searched for studies that estimated rates of overdiagnosis (a marker for unnecessary labeling). We included studies published in English and used dual independent review to determine study inclusion and to abstract information on design, types of measures, and outcomes assessed.

RESULTS: Sixty-eight studies assessing psychological harms met our criteria; 62 % concerned prostate cancer and 16 % concerned lung cancer. Evidence was scant for the other three screening services. Overall, only about one-third of the studies used both longitudinal designs and condition-specific measures (ranging from 0 % for AAA and CAS to 78 % for lung cancer), which can provide the best evidence on harms. An additional 20 studies that met our criteria estimated rates of overdiagnosis in lung or prostate cancer. No studies estimated overdiagnosis for the non-cancer screening services.

DISCUSSION: Evidence on psychological harms varied markedly across screening services in number and potential usefulness. We found important evidence gaps for all five screening services. The evidence that we have on psychological harms is inadequate in number of studies and in research design and measures. Future research should focus more clearly on the evidence that we need for decision making about screening.

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INTRODUCTION

To develop rational recommendations about screening, guideline panels need evidence about potential benefits and harms.[1–3] However, reviews of screening often report that high-quality evidence about patient harms is scarce relative to evidence about benefits.[4,5] Further, there appears to be less emphasis on psychological harms that result from screening compared to physical harms. This may be due to a lack of high-quality evidence on psychological harms, or because some might consider these harms to be trivial.

Psychological harms resulting from screening can affect large numbers of patients and thus should not be overlooked. These harms can be mild to severe and include, but are not limited to, anxiety, distress and decrements in health-related quality of life.[6,7] One way to categorize these harms is along the steps in the "screening cascade"[3] where they occur. For example, harms may occur before having a screening test (e.g., anticipation of a positive result); after the screening test but before being told the results (e.g., anxiety about test results); after a positive or abnormal screening test (e.g., worry about and overestimation of the likelihood of a diagnosis); after a positive workup (e.g., distress at being diagnosed with the condition, referred to as "labeling"); and both before and during treatment (e.g., deterioration in health-related quality of life). Because screening leads to earlier diagnoses, an understanding of the effects of being labeled with a condition is

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of particular interest; further, in the case of overdiagnosis, this labeling is unnecessary.

To arrive at a broader understanding of patient harms, we need to know both the psychological "burden" that can result from the screening process and the frequency with which people experience these burdens. Burden refers to the magnitude of the psychological reaction experienced by the patient or family, including its severity, duration, and effect on daily functioning. Furthermore, as different individuals may experience different levels of psychological burden from the same situation (e.g., anxiety caused by receipt of a false-positive result), we also need to know the frequency with which people experience psychological burdens that could be considered severe, moderate, or mild.

When assessing screening harms, it is also important that the methodology used is adequate for establishing psychological burden. The strongest designs that can provide the most useful information about psychological harms use condition-specific measures that are responsive to the more subtle reactions that can result from screening.[8,9] They also use longitudinal designs to assess these burdens over crucial time points in the screening cascade. Cross-sectional studies or those that use only insensitive, general measures (such as the SF-36) are potentially less useful for studying screening harms.

To aid expert panels and clinicians engaging patients in informed decision making, we systematically searched the research literature to develop an evidence map of the psychological harms associated with five adult screening services, all reviewed by the United States Preventive Services Task Force (USPSTF) within the past 4 years. Our study aim was to assess the availability of current evidence on psychological harms, reporting the number and characteristics of studies addressing the burden or frequency of specific types of psychological harms for each screening service. In characterizing the studies, we gathered information about the study designs (qualitative, longitudinal or cross-sectional), types of measures (generalized vs. condition-specific), and types of outcomes assessed (anxiety, distress, etc.) To focus our study's scope, we did not assess additional quality indicators of the studies or report their results.

METHODS

Quantifying Psychological Harms Studies in USPSTF Reviews

As a preliminary step for our study, we quantified the number of citations on psychological harms, compared to physical harms, in the evidence reviews conducted for the USPSTF for five selected adult screening services related to prostate[10,11] and lung cancers,[12,13] abdominal aortic aneurysm,[14,15] osteoporosis,[16,17] and carotid artery stenosis.[18,19] To do this, one reviewer examined all full evidence reviews for these screening services, as published on the Agency for Health Care and Quality (AHRQ) website, and tabulated the numbers of citations that included information on psychological or physical harms (Table 1). A second reviewer confirmed these numbers.

Review of Additional Studies on Psychological Harms

Data Sources and Searches. To identify studies in addition to those identified by the USPSTF reviews, we systematically searched electronic databases (PubMed, PsycInfo, CINAHL), with the guidance of an experienced health science librarian, for research studies published from 1 January 2002 through 31 December 2012. We chose these dates to capture the most current evidence relevant to screening harms, as interest in this topic has accelerated during the past decade. We also searched reference lists of included studies and the full-evidence version of systematic reviews conducted for the USPSTF. Search terms are provided in Appendix A (online).

Study Selection. We selected five screening services to represent a balanced sample of conditions, including cancer and non-cancer conditions, services with higher and lower public visibility, and those with positive and negative USPSTF recommendation grades (Appendix B, online). Our previously published systematic reviews characterize the large literature on psychological harms related to mammography screening[6,7]; thus, we did not include breast cancer screening in our current review.The screening services we selected were:

- prostate-specific antigen (PSA) test to screen for prostate cancer;
- low-dose computerized tomography to screen for lung cancer;
- abdominal ultrasound to screen for abdominal aortic aneurysm (AAA);
- bone mineral density (DEXA) scanning to screen for osteoporosis; and
- Doppler ultrasound to screen for carotid artery stenosis (CAS).

For each screening service, we searched for research studies providing evidence about psychological harms that can occur at the various steps of the screening cascade. We simplified the steps of the screening cascade into three categories: (1) the

Table 1. Number of Citations in USPSTF Reviews on Screening and Treatment Harms

Disease screened for	Citations	
	Physical Harms	Psychological Harms
Prostate cancer	34	5
Lung cancer	22	5
Abdominal aortic aneurysm	17	8
Osteoporosis	29	2
Carotid artery stenosis	47	0

screening test itself or workup of an abnormal test result; (2) receipt of a false-positive result, defined as a positive or indeterminate screening followed by a negative workup; or (3) being labeled with a new diagnosis of a condition. We deemed false-positives as not applicable to osteoporosis and AAA screening (tests where the screening and diagnostic tests are the same). Although the abstracts and full-text articles we examined did not typically use the term "labeling", we considered studies that examined the psychological burden of people newly diagnosed, but not yet treated, to be evidence about labeling. We did not search for evidence on psychological effects of treatment, in order to focus the study's scope.

We also searched for studies that estimated rates of overdiagnosis for each screening service. We did this to indirectly assess the extent to which labeling occurs unnecessarily due to overdiagnosis. We defined overdiagnosis as detecting conditions that would never progress to important health problems, even without treatment. Examples include prostate or lung cancers that would not cause symptoms in the patients' lifetime, small AAA that are not large enough for surgery, CAS in people who would never suffer a stroke, or osteoporosis in people who would never suffer a fracture.

At least two independent reviewers screened all titles and abstracts for relevance and reviewed the full text of relevant studies for potential inclusion. We included published empirical research of any study design (quantitative and qualitative) that reported either the burden or frequency of psychological harm. Included populations were adults who were age-eligible for screening. We did not make exclusions based on timing of the outcome data or study sample size. We excluded studies from non-OECD (Organization for Economic Co-operation and Development) countries or that were not published in English, or that focused on higher risk populations. We also excluded studies focusing solely on treatment effects, physical effects such as sexual functioning or pain, or decisional conflict or uncertainty regarding treatment. For studies on rates of overdiagnosis, we included modeling, ecological, pathology and randomized controlled trial designs.

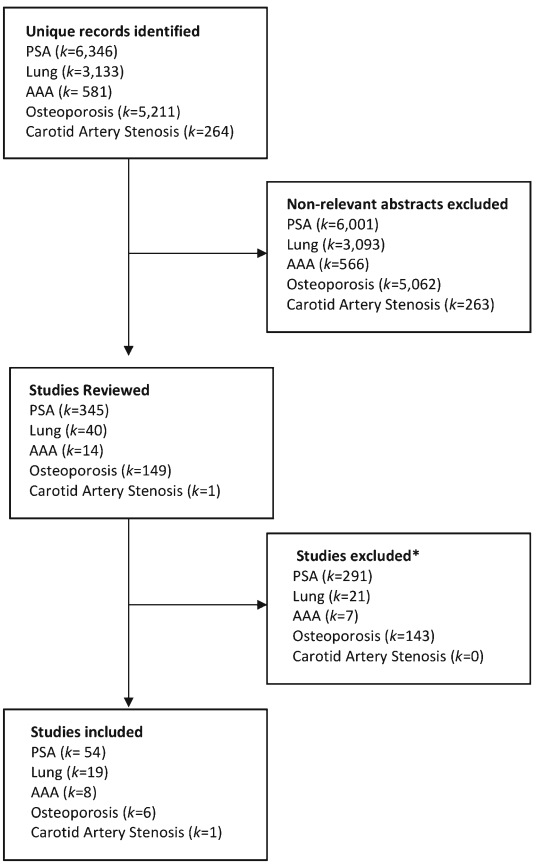
Data Abstraction. We abstracted general characteristics of the studies including category of psychological harm (i.e., screening test/workup; false-positive result; or labeling), study design, numbers of participants, type of measure (general vs. condition-specific), whether the study reported burden or frequency of psychological harm, and outcome variables. One reviewer abstracted the data, and a second reviewer confirmed it. We resolved disagreements through discussions with a third reviewer.

RESULTS

Our preliminary review of the USPSTF full evidence reviews found that they cited more studies about physical harms than about psychological harms for all five screening services (Table 1). Of the 169 citations, 88 % were about physical harms, while only 12 % were on psychological harms.

Our subsequent systematic search for studies on psychological harms yielded the most studies for prostate cancer screening (k=6,346) and the least for CAS screening (k=264) (Fig. 1). Studies meeting our criteria and included in our review (k=88) were 54 (61 %) for prostate cancer screening, 19 (22 %) for lung cancer screening, eight (9 %) for AAA screening, six (7 %) for osteoporosis screening and one (1 %) for CAS screening. Among the 88 studies, 68 were studies that assessed psychological harms and 20 estimated rates of overdiagnosis; we discuss these two categories of studies separately.

Studies varied in sample size from a small qualitative assessment on harms (n=7) to large randomized controlled trials on prostate (n=4,198) and lung cancer screenings (n=4,104) that included measures of psychological burden (Appendix C, online). We also included four registry-based studies on prostate cancer that assessed hospitalization, suicide or prescription of antidepressants. We found a variety of designs for the overdiagnosis studies. Most were modeling studies (k=10) followed by pathology/imaging studies (k=7); we found two



*Reasons for exclusion (in order of frequency): Wrong outcomes; not primary studies; foreign language; non-OECD studies; no full text available.

Figure 1. PRISMA diagram for five screening services.

follow-up studies from RCTs and one ecological study that used SEER data.

Evidence by Screening Service and Harms Category

We found considerable variation in the number of studies across screening service (Fig. 2). Among the 68 studies on psychological harms, 62 % (42/68) concerned prostate cancer screening and 16 % (11/68) concerned lung cancer screening. A combined 22 % (15/68) concerned screening for the other three conditions. We also found variation in the number of studies addressing different categories of psychological harms. Twelve studies assessed psychological harms associated with the screening test or workup for prostate cancer, but fewer for lung cancer screening (k=4) and osteoporosis screening (k=3); no studies examined screening or workup harms of screening for CAS or AAA. We found six studies that assessed effects of false-positive test results for prostate cancer screening and five for lung cancer screening. There were none for CAS screening. Other than the scant evidence on labeling, no other studies examined the psychological harms for AAA or CAS screening.

We found 26 studies assessing labeling effects for prostate cancer screening and eight studies for AAA screening; very few studies examined labeling for lung cancer (k=2), osteoporosis screening (k=3) and CAS screening (k=1). We found 20 studies that estimated rates of overdiagnosis (a marker of unnecessary labelling) for prostate cancer screening (k=12) and lung cancer screening (k=8); we did not find any studies on overdiagnosis for the three non-cancer screening tests.

Overall, studies assessing psychological harms more often described the burden of harm (k=58; 85 %); fewer studies (k=25; 37 %) reported the frequency with which patients experienced different levels of these reactions. Sixteen studies (24 %) reported information on both the burden and frequency of psychological harm.

Evidence by Design, Measurement and Outcome

Of the 68 studies assessing psychological harms of screening, 36 (53 %) used longitudinal study designs and 11 (16 %) used cross-sectional designs (Fig. 3). Nineteen studies (28 %) used qualitative study designs and two (3 %) used mixed methods. Qualitative studies largely came from the prostate cancer literature (k=13); few came from the osteoporosis (k=3), lung cancer (k=3), and AAA (k=1) literatures.

Of the 49 non-qualitative studies on psychological harms, 16 (33 %) used both a longitudinal design and included condition-specific measures to assess psychological burden, providing the best evidence for conclusions. Studies meeting these two quality criteria varied by screening service. For prostate cancer screening, 30 % (nine of 30) met these criteria and 78 % (seven of nine) met these criteria for lung cancer screening. One of the three studies met these criteria for osteoporosis screening. We found four studies with longitudinal designs for AAA screening, none of which used condition-specific measures. We found no studies using a longitudinal design for CAS screening.

Across screening services, the most commonly studied outcomes were psychological reactions such as worry and

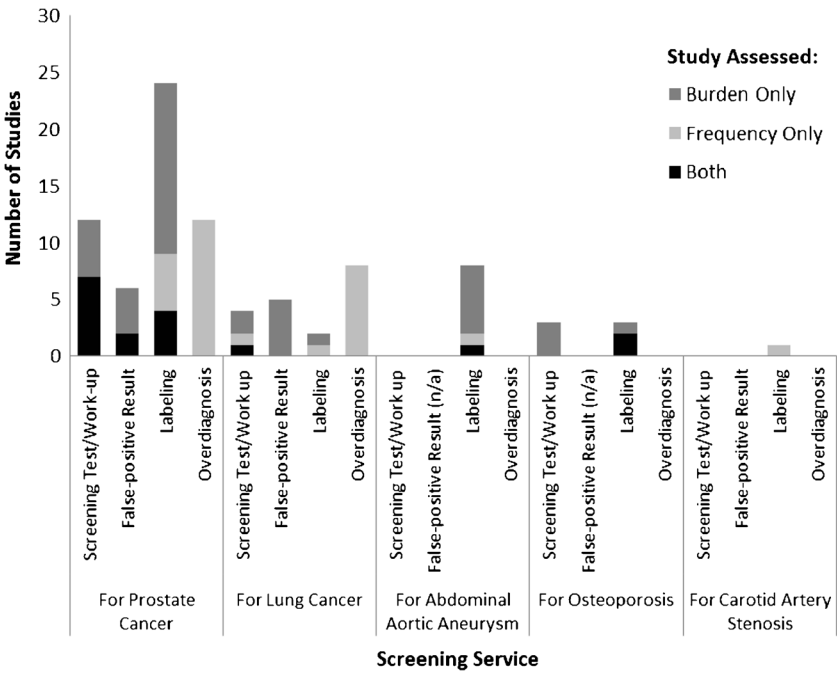


Figure 2. Number of studies assessing categories of psychological harms (k=68) and rates of overdiagnosis (k=20).

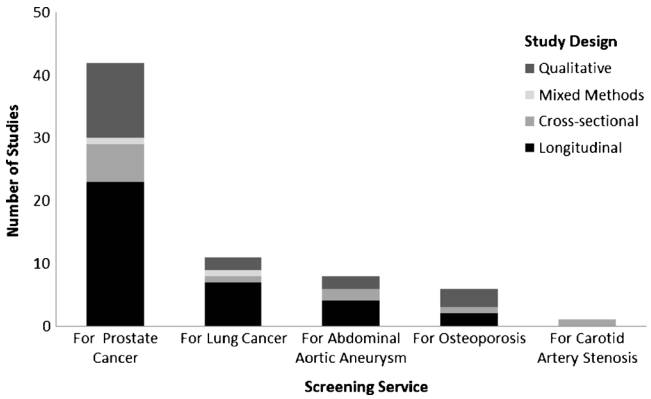


Figure 3. Designs of studies assessing psychological harms (k=68).

distress (k= 40), health-related quality of life (k= 38) and anxiety (k=23). There were fewer assessments of depression (k= 14). For each of these outcomes, the number of studies using longitudinal designs and condition-specific measures varied by screening service (Appendix D, online).

DISCUSSION

We found considerable variation across the five screening services in the available evidence on the psychological harms. Our search revealed only a small total number of studies on any category of psychological harm for any screening service, with more studies about the psychological harms of prostate and lung cancer screening than for non-cancer screening (AAA, osteoporosis and CAS). Even among the available studies on harms, few used both longitudinal designs and condition-specific measures, study characteristics that are most likely to provide the most useful information on psychological harms.

We found no studies meeting our criteria that estimated rates of overdiagnosis for any of the three non-cancer conditions; this evidence was available only for prostate and lung cancer. The absence of information on overdiagnosis for the non-cancer screenings may be due to difficulties in conceptualizing overdiagnosis (such as in osteoporosis, where diagnosis and treatment are conceptualized as reducing the risk of fractures), or because of a lower awareness of the possibility for overdiagnosis with these conditions. Evidence on the frequency of overdiagnosis is important in understanding the extent to which negative effects due to labeling (or treatment) occur unnecessarily.

It is interesting to speculate why such a disparity in evidence across screening services exists. Prostate cancer screening clearly dominates the psychological harms literature, likely because of its high incidence and visibility in the media. Lung cancer screening had the second largest number of studies, many conducted after a recently published randomized controlled trial of screening,[20] which increased the test's visibility. We found very little evidence about the harms of non-cancer screening; it may be that the potential for psychological harm from non-cancer screening is either not widely recognized or discounted as having a small burden. Yet, Salter and colleagues caution that simply labeling women "at risk" for osteoporosis based on screening test results can have a negative effect on their physical, mental and emotional states of well-being.[21] The lack of information about potential psychological burden caused by these seemingly harmless tests represents a major gap in the evidence.

In addition to the gap in the volume of evidence, we also found a gap in the potential usefulness of the evidence provided by the studies that are available. About one-quarter of the studies found in our search reported qualitative studies; most of them on prostate cancer screening. This design may be quite appropriate for guiding future work in the development of condition-specific measures or for gaining a deeper understanding of the burdens experienced by patients when undergoing screening. Qualitative studies, however, are limited by their inability to provide information about the frequency with which populations experience these burdens. Only one-third of non-qualitative studies used both a longitudinal design and a condition-specific measure of harm, an optimal design when examining psychological burden.[8] We found that most studies used either non-longitudinal designs or generalized measures, limiting potential interpretation.[7] This finding suggests that many studies may report null findings even when psychological harms are truly present.

Finally, our work highlights a lack of attention to the psychological harms of unnecessary labeling due to overdiagnosis. Although being labeled with a condition may theoretically bring about positive health effects (e.g., beneficial lifestyle changes), any benefit must be viewed in light of the potential negative effects (e.g. anxiety, altered self-concept etc.). Thus, labeling constitutes an important potential harm of screening. To understand the effects of unnecessary labeling, we must understand any psychological effects and also the extent to which overdiagnosis occurs for a given condition. We found variation in the availability of information on labeling (regardless of overdiagnosis) across screening services. We found some studies that provide information about the burden of labeling for prostate cancer and AAA screening, but few studies for the other screening tests. Evidence on labeling from prostate cancer screening largely came from the literature on men's psychological reactions while pursuing a watchful waiting strategy or undergoing active surveillance. This literature contributes to the understanding of labeling, because it disentangles the effects of diagnosis from treatment. Evidence on labeling in the AAA screening literature comes mostly from patients under surveillance for small abnormalities, but we found that this literature was limited by design and measurement. Considering the availability of evidence on overdiagnosis and labeling together, we can draw very few conclusions about the extent to which labeling effects occur unnecessarily. This topic signals another major gap in the evidence.

Our findings have implications for future research. Gaps in the available evidence indicate the need for researchers to have a systematic framework for considering the psychological harms of screening. We have previously proposed a taxonomy of harms that may be useful in this regard.[3] Our taxonomy may be especially useful for non-cancer screening, as there may be less appreciation of the psychological harms associated with these screening services. Researchers should also consider longitudinal research designs and sensitive, condition-specific measurement instruments when assessing psychological harms.[7,8,22] Finally, studies should provide information on both psychological burden and the frequency with which patients experience various levels of burden.

Our study also has implications for clinicians' interpretations of guidelines and their communications with patients about screening. Balanced decision making about screening requires adequate evidence about both benefits and harms. Our findings suggest that, for some screening services, evidence about the potential for psychological harms is absent or based on studies of weak methodological quality. Yet, the absence of high-quality evidence on psychological harms does not mean that these harms are not present. Clinicians and patients should consider the uncertainty due to lack of useful evidence when making screening decisions. Clinicians should include psychological harms in communicating the balance of potential benefits and harms to patients.

Psychological harms may be important either by carrying a high burden or by occurring very frequently (or both). Some psychological harms may not be severe enough to classify as pathology, but the distress may affect large numbers of people and thus should not be routinely dismissed as small. Other harms may lead to severe psychological problems for a small number of predisposed people.[23] In neither case should clinicians draw the conclusion that harms are trivial and can be discounted.

Our study has some limitations. First, while we assessed some quality indicators including the designs of studies and their use of condition-specific measures, we did not conduct additional quality assessments (e.g., assess whether studies used an appropriate control group). It is likely that some of the studies we found were limited in ways beyond research design and measures. This, however, would make our conclusions about the lack of high quality evidence even stronger; the body of high-quality evidence may be even smaller than our findings suggest. Second, we acknowledge that lack of evidence on psychological harms could be due to publication bias when the harm is trivial. Third, the generalizability of our findings beyond the five screening services that we examined is uncertain. However, we carefully selected a balanced group of services for examination. We encourage further reviews of the evidence about screening harms for other services. Lastly, our review only considered psychological harms; the extent to which other domains of harms are understudied (i.e. financial strain, opportunity costs and hassles) is not clear, but we suspect that little research also exists for these domains.

In summary, our findings point to important gaps in the evidence that we have on psychological harms, as contrasted with the evidence we need, to make balanced decisions about screening. We also encourage guideline panels and clinicians not to interpret the lack of evidence as indicating that harms are absent or trivial. We encourage future researchers to adopt a broader conceptualization of screening harms to ask the important questions, and to design high quality research to answer them. Only then can the evidence we have on screening harms match the evidence we need.

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Conflicts of Interest: *The authors declare that they do not have any conflicts of interest.*

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