Truth & Consequences: the Influence of the USPSTF on Skin Cancer Screening

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US Preventive Services Task Force

Makes recommendations on clinical preventive services for primary care clinicians

- USPSTF scope for clinical preventive services:
  - screening tests
  - counseling
  - preventive medications

- Services offered in a primary care setting
- Recommendations apply to adults & children with no signs or symptoms
USPSTF

- Independent panel of non-Federal experts in prevention & evidenced-based medicine
- Recommendations based on rigorous review of existing peer-reviewed evidence
  - Does not conduct the research studies, but reviews & assesses the research
  - Evaluates benefits & harms of each service based on factors such as age & sex
Grading Strength of Evidence about Clinical Interventions

Strongest

Systematic Reviews of RCTs
Individual RCT
Multiple Time Series - Germany, UPMC, US state
Nonrandomized Trial
Cohort
Case-Control
Time Series-Schleswig-Holstein (SCREEN)
Cross-sectional – VA Palo Alto pilot study
Case Series
Case Report

Weakest
Recommendations

Since 1998, AHRQ has been authorized by Congress to convene the Task Force

The Task Force assigns each recommendation a letter grade: (A, B, C, D, or I)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
<th>Suggestions for Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>The USPSTF recommends the service. There is high certainty that the net benefit is substantial.</td>
<td>Offer/provide this service.</td>
</tr>
<tr>
<td>B</td>
<td>The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.</td>
<td>Offer/provide this service.</td>
</tr>
<tr>
<td>C</td>
<td>The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.</td>
<td>Offer/provide this service only if other considerations support offering or providing the service in an individual patient.</td>
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<tr>
<td>D</td>
<td>The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.</td>
<td>Discourage the use of this service.</td>
</tr>
<tr>
<td>I statement</td>
<td>The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.</td>
<td>Read clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.</td>
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USPSTF = U.S. Preventive Services Task Force.
Skin Cancer Screening

USPSTF 2009 Statement:

- “Current evidence is insufficient to assess benefits and harms of whole-body skin exam by primary care clinicians or patient skin self-examination for early detection of melanoma in the adult general population.”

Worldwide data as of 2006: NO EVIDENCE from controlled studies to address benefit of skin cancer screening

Contextual Questions Not Addressed in 2009

- Can screening with whole-body examination by primary care clinicians or by self-examination accurately detect skin cancers?
- Does screening with whole-body examination or by self-examination detect melanomas at an earlier stage (thinner lesions)?
USPSTF Final Research Plan for Skin Cancer Screening

Analytic Framework

June 2014

Key Questions to be Systematically Reviewed

1. What is the direct evidence that visual screening for skin cancer by a primary care provider or dermatologist reduces skin cancer morbidity and mortality and all-cause mortality?
2. What are the harms of screening for skin cancer and diagnostic followup?
3. What are the test characteristics of visual screening for skin cancer when performed by primary care providers versus dermatologists?
4. Does visual screening for skin cancer lead to earlier detection of skin cancer compared with usual care?
5. What is the association between earlier detection of skin cancer and skin cancer morbidity and mortality and all-cause mortality?
6. What are the harms of surgical treatment of skin cancer?

Contextual Questions

Contextual questions will not be systematically reviewed and are not shown in the Analytic Framework.

1. Are there identifiable high-risk groups (e.g., via developed algorithms or various phenotypic features) who would have a more favorable balance of benefits and harms from screening for skin cancer compared with the general population?
2. What proportion of skin biopsies are excised completely (i.e., past the margin)?
USPSTF Statement 2016

- AHRQ systematic review of the worldwide evidence
  - January 1995 through June 2015, excluded skin self-exam data
  - Did not include most recent nationwide Germany or UPMC data
- Issued an “Insufficient, I” statement for visual skin examination by primary care clinicians for skin cancer detection due to
  - inability to adequately address the benefits or harms
  - lack of conclusive mortality/morbidity reduction

Continues to note value of screening individuals at highest risk of fatal melanoma

Targeted screening of high-risk populations recommended, along with counseling of young individuals aged 10-24 yrs regarding sun protection and risks of UV exposure on photoaging and skin cancer (“B” rating)
Assessing Magnitude of Harms

Harms of screening:
- psychological harm from labeling
- harms of work-up to confirm the presence of the condition

Harms of treatment:
- actual physical effects of early treatment
- effects of "over-treatment"

Potential harms of screening for skin cancer have not been adequately addressed, and these may include both physical and psychological effects related to:
- Misdiagnosis
- Overdiagnosis
- Resultant harms from unnecessary biopsies and overtreatment
SCREEN Project Germany

Efforts began in 1989
- Statewide screening in Schleswig-Holstein from July 2003 through June 2004
- 19% state popn, 27% women, 10% men (~3:1)

All screening MDs trained with 8-hour course
- Screenings included full-body skin exam
- Direct referral to derms possible based on risk alone

Conducted feasibility analysis and observational study of incidence and mortality

Nationwide screening began July 2008

Schleswig-Holstein SCREEN Pilot

- Northern most federal state of Germany
- 2.8 million inhabitants
  - >360K participated in SCREEN
  - Increased incidence (34%) during SCREEN
- 5 years after:
  - Decreased mortality in S-H
  - 47% in men, 49% in women
The SCREEN Project

360,288 participants

278,741
primary exams
(73%) GP

46,578
secondary exams (17%)
dermatologist

81,457
primary exams
dermatologist

15,983 excisions
(4.4%)

3103 skin cancers (585 melanoma, 1961 BCC, 392 SCC)
(0.83%)

Conclusions

“The current data represent strong evidence, but not absolute proof, that the skin cancer screening program produced a reduction in melanoma mortality in Schleswig-Holstein.”

Nationwide Implementation of Screening in Germany (2008-2013)

- Goal: to screen every citizen age 35+
- Trained 45,000 physicians in skin cancer exam (77% German MDs)
  - Double screens for all participants, no pre-advertising though
- Estimated 26.5 million screenings conducted
- Mortality and thickness-specific incidence compared:
  - Nationwide, with historical rates
  - Germany and its 9 border countries using data from 1990-2015

First Analyses of German Screening Effort (2008-2013)

- Schleswig-Holstein melanoma incidence same as nationwide incidence since 2008
- NO reduction in mortality rates observed in Germany overall or in S-H 5 years after nationwide screening started
  - S-H mortality now same as Germany overall
- “Introduction of nationwide skin cancer screening in 2008 has not led to any measurable decline in mortality.”

Boniol M et al. *BMJ Open.* 2015:5:e008158
Potential Reasons Why

Nationwide screening “less thorough/intensive”
- no public/professional advertising compared to pilot
- may have missed higher risk groups (e.g. older men)
- pilot allowed derm referral for risk factors alone

Too soon to expect a screening effect

Effect of census rates on mortality in 2011-2013

Different age groups screened in pilot vs nationwide

Lack of valid data - analysis hampered by:
- unreliable annual participation rates
- thickness- and age- specific incidence poorly tracked

MD bias in SCREEN pilot to under-report melanoma deaths
Major Screening Effort in Western Pennsylvania (UPMC)

- 3-year screening “quality initiative” began in January 2014 with full endorsement of UPMC senior administration and physician leaders
- >300K screen-eligible pts age 35+ in 2014; >51K screened
- 500+ physicians trained with 1.5 hour INFORMED web-based skin cancer module via U-Learn system
- Recently designed 1.5-hour web-based skin cancer curriculum, entitled INFORMED (INTERNET curriculum FOR MELANOMA EARLY DETECTION):
INFORMED skin cancer course given to 54 primary care providers at 2 integrated health care delivery systems:

- assess derm referrals, skin biopsies during the 6 months after training

Scores for appropriate diagnosis and management increased from 36% pre-training to 47% post-training (OR, 1.6; 95% CI, 1.4-1.9)

- Greatest improvement for benign skin lesions
- No increase in dermatology utilization for suspicious lesions
- Skin biopsy rates & skin cancer diagnoses sim to pre-training period
- No increase in specialty referrals or over-biopsy/treatment, likely due to improvement in diagnosis and management of benign lesions

UPMC PCP-based Skin Screening Quality Initiative

- Compare thickness-specific incidence with 18 counties in Western Pennsylvania (Cancer Registry data)
- Compare skin surgeries, specialist referrals, thickness of detected melanoma, and mortality over time with administrative data on 275,000 non-screened individuals
- Measure anxiety, depression, other factors in screened vs. unscreened individuals
UPMC QI Preliminary Results

- Increased # melanomas diagnoses in subset of pts with more INFORMED-trained PCPs
- Little impact on skin surgeries or derm visits (suggests lack of screening-related harms) but no individual-level data to confirm

Hospital record and CA registry data collected:
- Screened pts 2.4 times more likely to be dx’d with melanoma
- Diagnosed with **sig thinner T1 melanoma** (mean 0.37 mm vs 0.65 mm, p<.001)
- More **melanomas in situ** (45.1% vs 12.5%, p<.001)

Ferris LK et al. *JAMA Oncol*. Published online February 23, 2017.
Feasibility of PCP Education and Screening at VA Palo Alto: pilot study

- Enlist 4-6 PCPs to screen 250-300 pts during Annual Health Habits visit
- Use INFORMED web-based program for PCP education
  - Pre- and post test (multiple choice, 40 questions total)
- Conduct qualitative (behavioral) Health Services research
  - PCP feedback regarding INFORMED training and screening process
  - Patient feedback re screening process/outcomes
- Easy to use EMR template for PCP CSE documentation
  - Track pts referred to Dermatology and presumptive diagnoses
  - Individual level data in a high-risk, high-yield population
Electronic Medical Record

PCP Skin Exam
VAPAHCS pilot results

- Patients: men and women 35 years+, mostly white, 98% males
- 6/2015-8/2016: CSE performed on 189/258 (73%)
  - No change in pre- vs post intervention derm referrals/skin surgeries
  - Most derm referrals for NMSC evaluation
  - Quality of PCP referrals to derm markedly improved
    - no measurable change in PCP diagnostic accuracy, referral for benign lesions (SKs)

Assessment of patient and provider satisfaction
  - Increased PCP confidence in CSE performance and triage
  - May improve the “quality” of the visit for both patient and provider
  - TIME IS AN ISSUE! – PCP workload, other pressing medical problems
Systematic Review of Skin Cancer Screening on Incidence/Mortality

- 15 studies b/w 2005-2015 (large ecological, cohort, case control and survey)

- Screening associated with:
  - increased incidence of in situ and invasive skin cancers,
  - increasing rates of thin melanoma
  - decreasing rates of thick melanoma

- One study to date with reduced mortality; 2 others with “fewer deaths than expected”

- Evidence level is LOW but indicates benefits of screening

In the absence of a USPSTF screening recommendation

- Large-scale, stand-alone, media campaigns to drive high-risk groups to screening
- Support state-based demonstration projects that combine media, provider reimbursement, and public education
- Strengthen skills for skin cancer exam among medical students, primary care residents, PCPs

With or without an eventual Task Force change:
- build collaboration with primary care to reduce melanoma deaths
- Focus on screening large percentage of white men (& women) >50 yrs
- Explore value of lesion-directed or waist-up exams over total body screening