CANCER SCREENING GUIDELINE CHALLENGES AND CONTROVERSIES

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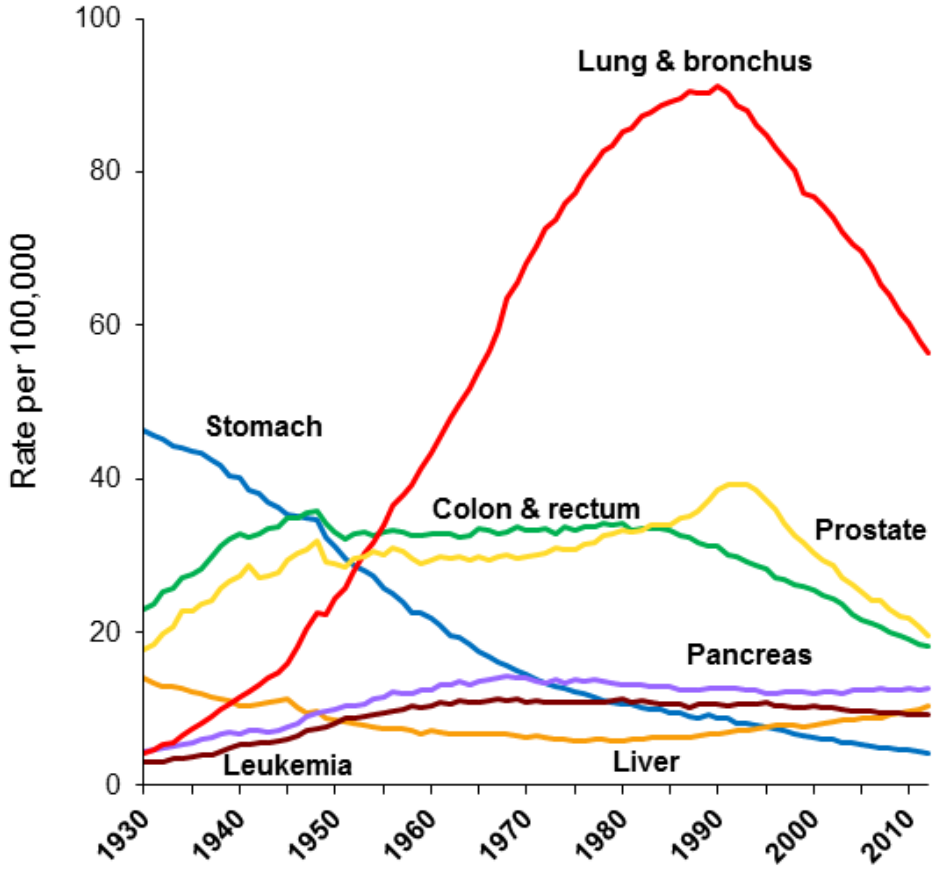
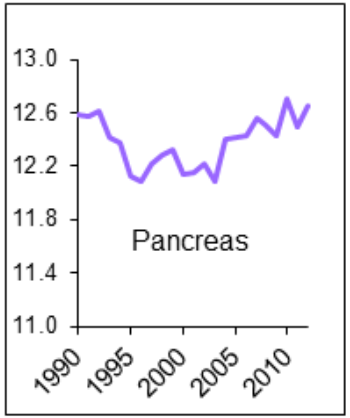
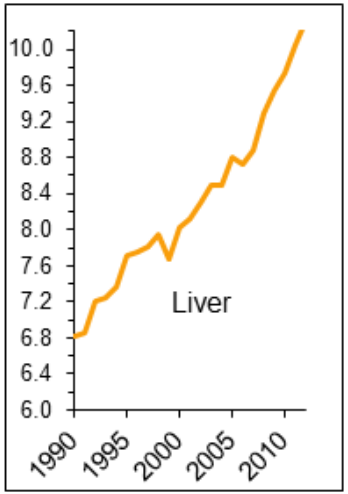
In 1996, the American Cancer Society issued a challenge goal to the nation to reduce age adjusted cancer mortality by 50% by 2015.

We made it over half of the way to the goal, achieving a 26% reduction in mortality

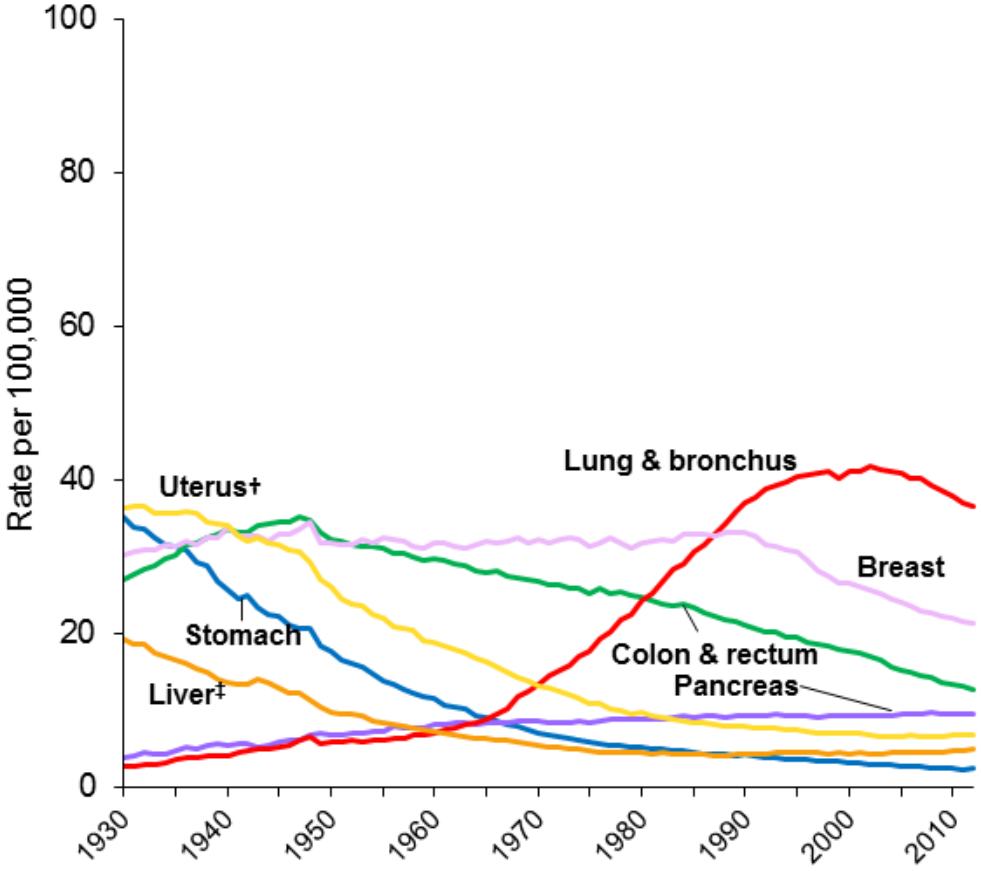
TRENDS IN CANCER DEATH RATES* AMONG MEN, US, 1930-2012

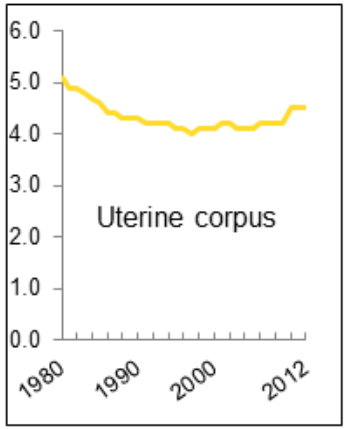


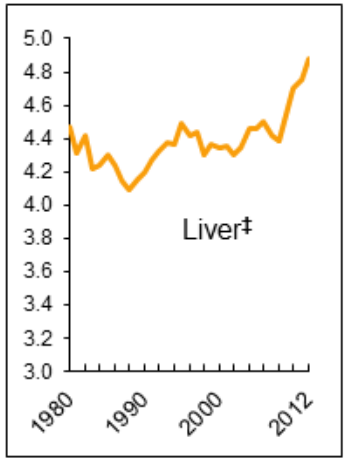




TRENDS IN CANCER DEATH RATES* AMONG WOMEN, US, 1930-2012







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COLORECTAL CANCER INCIDENCE

Sedentary lifestyles, increase in red meat consumption and obesity increase risk for colorectal cancer.

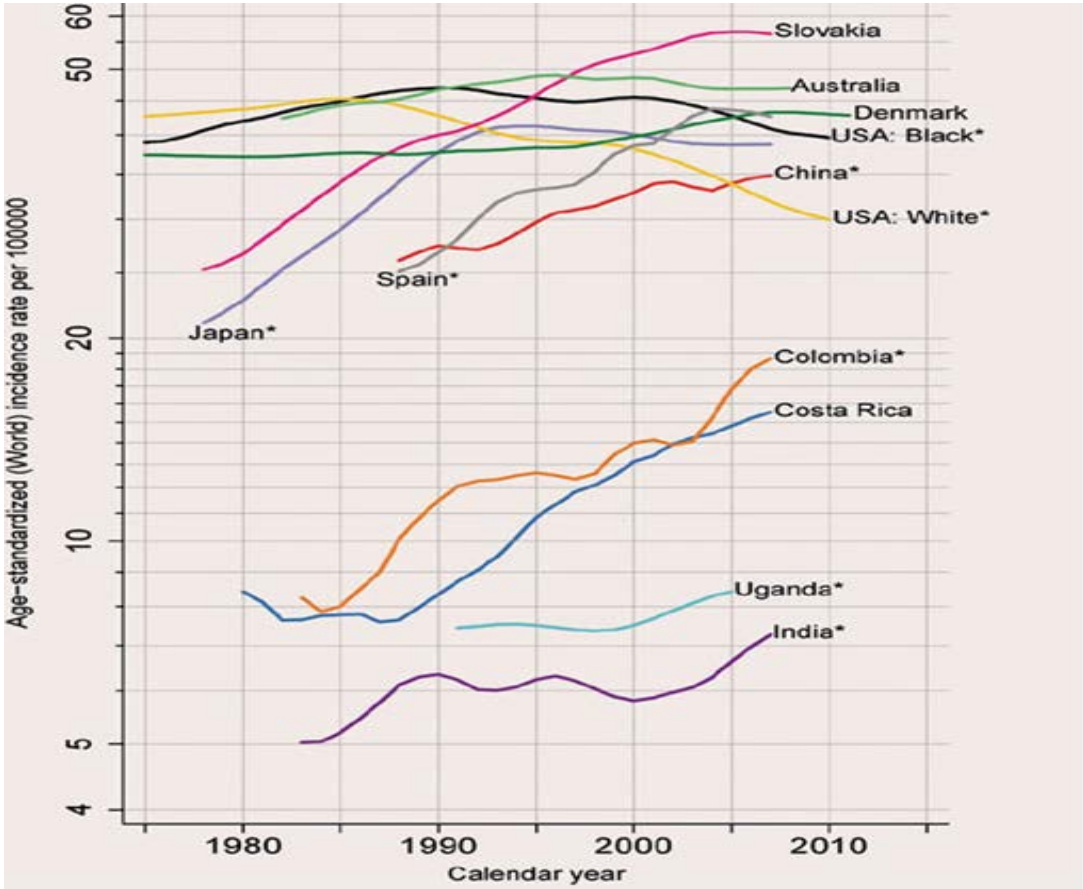

Chart 5.5.2. Age-standardized (World) incidence rates per 100 000 by year in selected populations, for colorectal cancer in men, circa 1975–2012.

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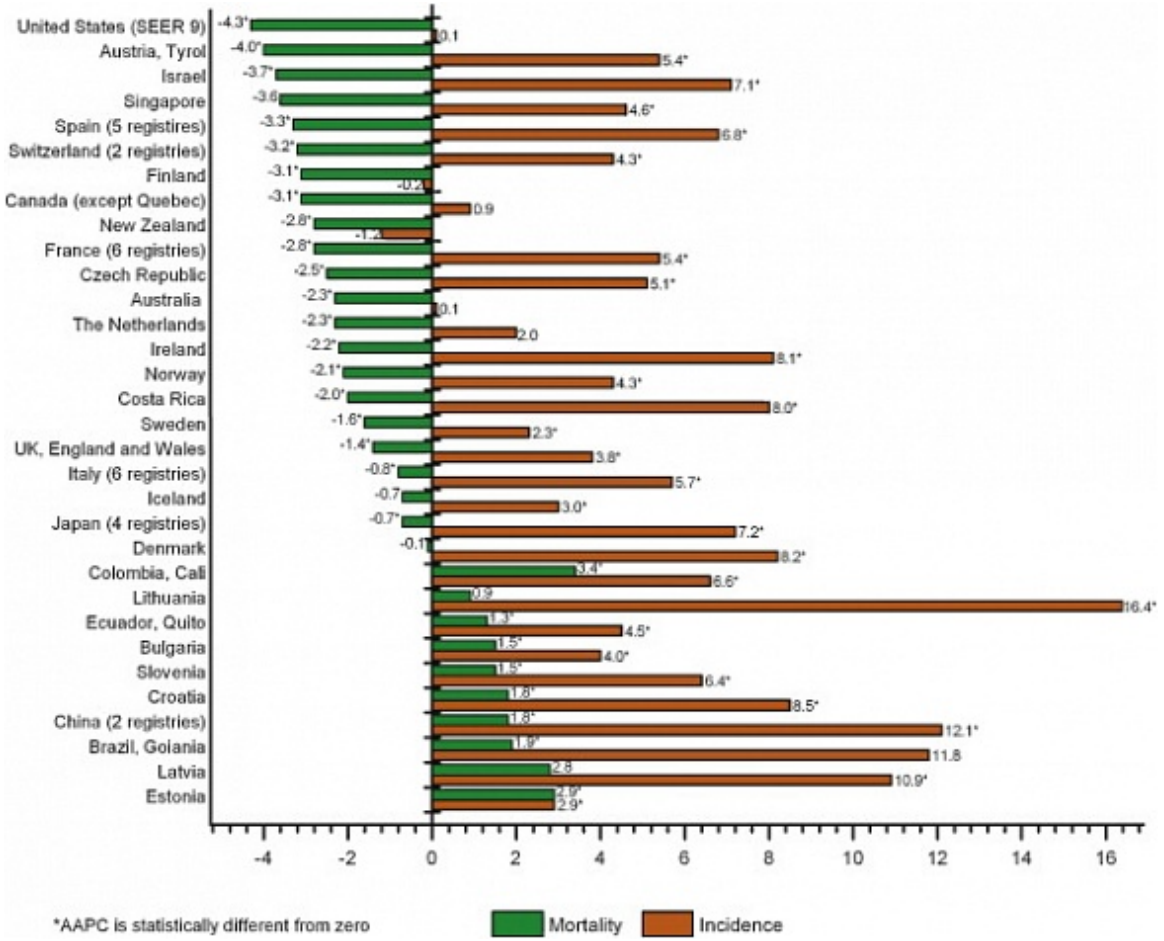
World Cancer Report 2014

PROSTATE CANCER AVERAGE ANNUAL PERCENT CHANGE (AAPC) IN INCIDENCE AND MORTALITY RATES FOR THE LAST 10 YR OF AVAILABLE DATA.

SEER=Surveillance Epidemiology and End Results.*AAPC is statistically different from zero.



doi:10.1016/j.eururo.2012.02.054

These trends strongly suggest a substantial benefit from screening, but the prevailing academic thinking has increasingly questioned the value of screening.

What are the factors fueling controversy about the value of screening?

Factor 1

There’s been a change in the science of how we judge the value of a preventive care intervention.

There’s now a greater appreciation of the potential harms associated with screening, including a relatively new concept – overdiagnosis.

OVERDIAGNOSIS

Three potential definitions:

1. A cancer with no biologic potential to cause harm
2. A cancer that is very unlikely to cause harm within the predicted life expectancy of the individual
3. Any cancer case where the individual dies before the cancer causes harm

MEASURING OVERDIAGNOSIS

- Excess number of cancers detected in the screening arm compared to the control arm.
  - Effective screening should detect more cancers earlier than no screening.
  - Cancers detected through usual care should catch-up with time.
  - If there is over-diagnosis the usual care group will never catch up.

MEASURING OVERDIAGNOSIS

- The natural history of cancers may be longer than we suspected.
- Usual care group may take many years to catch up.
- 15 to 25 years of measurement are needed to accurately measure over-diagnosis.

Factor 2

Lack of clarity about the goals of a cancer screening guideline.

LACK OF CLARITY

- This is perhaps the leading source of controversy.
- On one extreme, there is the view that screening should be recommended for anyone with even a small chance of avoiding a premature cancer death.

The more conventional view of a screening guideline is an intervention that:

- Must clearly add value to the health of a population.
- Should be applied only to the population with a high likelihood of benefit.
- Must be affordable and feasible for population-wide implementation.

Factor 3

Heightened appreciation of the concept of societal and personal values.

BALANCING OF BENEFITS AND HARMS

- Modern day guideline groups are asked to consider an evidence review and then make a recommendation based on the balance of benefits and harms.
- There is no evidence-based balance scale.

A NEW CATEGORY OF RECOMMENDATION

- Promote screening – Benefits clearly outweigh harms on a population basis.
- **Recommend a shared decision – Balance of benefits and harms is close.**
- Recommend against screening.
- Insufficient evidence.

SHARED DECISION MAKING

- While appealing on the surface, shared decision making is not universally accepted … and it's quite difficult to implement.
- To some degree, it's a response to attempts to marry the competing views of the purpose of a guideline.

SHARED DECISION MAKING

- Almost impossible to incorporate into large population based screening programs – such as programs that are run by the government or a health plan.
- Shared or informed decision making requires that primary care clinicians are integral to cancer screening.

RECOMMENDED IN BREAST, PROSTATE AND LUNG CANCER SCREENING

- Informed decision making is now recommended in breast cancer screening regarding age to start and interval.
- It’s recommended for all prostate and lung cancer screening.

Factor 4

Screening guidelines are big news, and controversy sells.

“HIGH LEVEL OF AGREEMENT BETWEEN DIFFERENT GUIDELINES”

This is not a headline you should expect to see.

GUIDELINES AND THE MEDIA

It’s not the media’s fault that there are actual differences between guidelines, but the media does fuel the perception of controversy – and creates the sense that organizations are competing, not cooperating.

THE ACS NEW BREAST CANCER GUIDELINE.

- One of JAMA's top 5 articles of the year
- One of the top 100 health stories of 2015
- 3,500+ media hits
- 72 million impressions
- The earned media equivalent of buying $7mm+ in advertising

New mammogram guidelines spark controversy

Mammograms later, less often: Breast cancer screening advice 'sowing massive confusion'

New mammography guidelines could cloud decision-making, doctors say

American Cancer Society says start mammograms at 45, not 40

AP

While some patient advocates are upset, the change reflects growing concern that the benefits of the breast cancer test may have been oversold.

BY LINDSEY TANNER THE ASSOCIATED PRESS

The New York Times

The changes reflect increasing evidence that mammography is imperfect, that it is less useful in younger women, and that it has serious drawbacks, like false-positive results that lead to additional testing, including biopsies.

THE WALL STREET JOURNAL.

In a recognition that breast cancer screening can bring both benefits and harms, the American Cancer Society issued new guidelines saying women should start have mammograms later and less often than it previously recommended. But the group also acknowledged that one recommendation doesn't fit all.

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USING IOM RECOMMENDATIONS

- Increasingly, major guideline organizations are following the same process that was recommended by the Institute of Medicine.
- These guidelines require an independent evidence review, use of a system to evaluate and describe level of evidence, and explicit value based judgments balancing risks and harms of screening.

MORE OR LESS EVIDENCE-BASED?

Individuals and organizations often contend that guidelines that aren't consistent with their own opinions are less evidence-based than the guidelines with which they agree.

The bottom line: Statements that one or another organization is more or less evidence based are not helpful and rarely correct.

GUIDELINE GROUPS COOPERATE

- Major guideline groups, while debating and disagreeing, do not perceive other organizations as being more or less evidence based.
- Specifically, the ACS Guidelines Committee and the USPSTF have a mutually respectful, friendly, cooperative relationship.

GUIDELINE GROUPS COOPERATE

- ACS and USPSTF provide extensive feedback on guideline drafts and the final products are modified in response to this feedback.
- Neither organization believes that the differences emerge from one or the other organization being more or less evidence based.

BREAST CANCER SCREENING

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THE NEW ACS BREAST CANCER SCREENING GUIDELINE – MADE SIMPLE

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THE EVIDENCE SUMMARY

- The USPSTF and the ACS both conducted independent evidence reviews.
  - Ours was performed by Duke University.
  - USPSTF by University of Oregon
- **Good news:** Both evidence reviews found the same evidence and came to the same conclusions.

THE EVIDENCE SUMMARY

1. Mammography is equally effective in every age group tested.
2. Regular mammography reduces breast cancer mortality by 20 to 45% in every age group studied.
   - Randomized trials find 20% reduction.
   - Modern day observational trials find 40 to 45% reduction.

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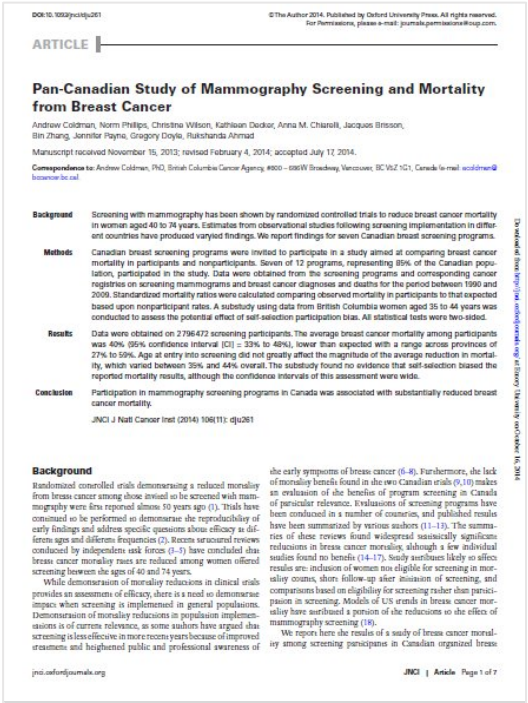
PAN-CANADIAN STUDY OF MAMMOGRAPHY SCREENING

- Comparison of breast cancer screening among exposed (2.8 million) and non-exposed women, 1990-2009.
- **7 of 12 Canadian breast cancer programs, representing 85% of the population.**
- SMRs were calculated comparing observed mortality in participants to that expected based upon nonparticipant rates.



DOI:10.1093/jnci/dju261

ARTICLE

Pan-Canadian Study of Mammography Screening and Mortality from Breast Cancer

Andrew Coldman, Norm Phillips, Christina Wilson, Kathleen Decker, Anna M. Chiarelli, Jacques Brisson, Bin Zhang, Jennifer Payne, Gregory Doyle, Rukshanda Ahmad

Manuscript received November 15, 2013; revised February 4, 2014; accepted July 17, 2014.

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Background Screening with mammography has been shown by randomized controlled trials to reduce breast cancer mortality in women aged 40 to 74 years. Estimates from observational studies following screening implementation in different countries have produced varyied findings. We report findings for seven Canadian breast screening programs.

Methods Canadian breast screening programs were invited to participate in a study aimed at comparing breast cancer mortality in participants and nonparticipants. Seven of 12 programs, representing 85% of the Canadian population, participated in the study. Data were obtained from the screening programs and corresponding cancer registries on screening mammograms and breast cancer diagnoses and deaths for the period between 1990 and 2009. Standardized mortality ratios were calculated comparing observed mortality in participants to that expected based upon nonparticipant rates. A substudy using data from British Columbia women aged 35 to 44 years was conducted to assess the potential effect of self-selection participation bias. All statistical tests were two-sided.

Results Data were obtained on 2796472 screening participants. The average breast cancer mortality among participants was 40% (95% confidence interval [CI] = 33% to 48%), lower than expected with a range across provinces of 27% to 59%. Age at entry into screening did not greatly affect the magnitude of the average reduction in mortality, which varied between 35% and 44% overall. The substudy found no evidence that self-selection biased the reported mortality results, although the confidence intervals of this assessment were wide.

Conclusion Participation in mammography screening programs in Canada was associated with substantially reduced breast cancer mortality.

JNCI J Natl Cancer Inst (2014) 106(11): dju261

Background

Randomized controlled trials demonstrating a reduced mortality from breast cancer among those invited to be screened with mammography were first reported almost 30 years ago (1). Trials have continued to be performed to demonstrate the reproducibility of early findings and address specific questions about efficacy in different ages and different frequencies (2). Recent structured reviews conducted by independent task forces (3–5) have concluded that breast cancer mortality rates are reduced among women offered screening between the ages of 40 and 74 years.

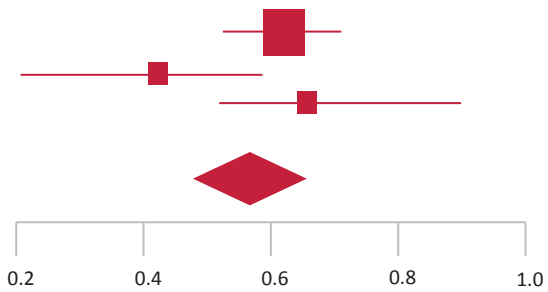
While demonstration of mortality reductions in clinical trials provides an assessment of efficacy, there is a need to demonstrate impact when screening is implemented in general populations. Demonstration of mortality reductions in population implementations is of current relevance, as some authors have argued that screening is less effective in more recent years because of improved treatments and heightened public and professional awareness of the early symptoms of breast cancer (6–8). Furthermore, the lack of mortality benefit found in the two Canadian trials (9,10) makes an evaluation of the benefits of program screening in Canada of particular relevance. Evaluations of screening programs have been conducted in a number of countries, and published results have been summarized by various authors (11–13). The summaries of these reviews found widespread statistically significant reductions in breast cancer mortality, although a few individual studies found no benefit (14–17). Study attributes likely to affect results are: inclusion of women not eligible for screening in mortality counts, short follow-up after initiation of screening, and comparisons based on eligibility for screening rather than participation in screening. Models of US trends in breast cancer mortality have attributed a portion of the reductions to the effect of mammography screening (18).

We report here the results of a study of breast cancer mortality among screening participants in Canadian organized breast

STANDARDIZED MORTALITY RATIOS (SMRS) BY CANADIAN PROVINCE FOR AGES AT ENTRY: SUMMARY ESTIMATES ARE BASED UPON RANDOM EFFECTS MODELS. ALL STATISTICAL TESTS WERE TWO-SIDED.

40-49

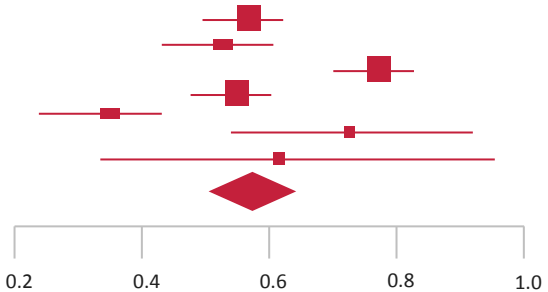
44% fewer deaths



Region	SMR	95% CI
British Columbia	0.58	0.51 to 0.65
New Brunswick	0.42	0.26 to 0.59
Nova Scotia	0.66	0.47 to 0.85
Summary (random)	**0.56**	**0.45 to 0.67**

50-59

40% fewer deaths

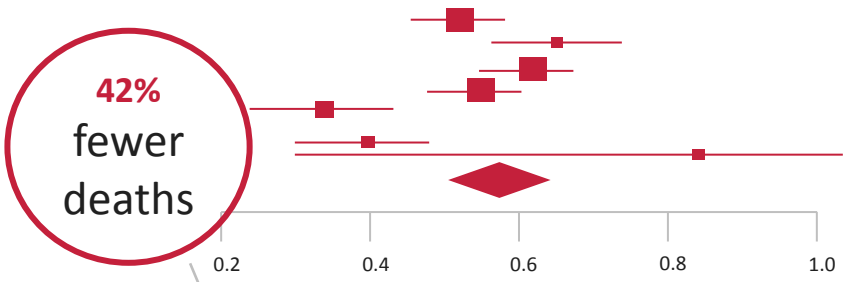


Region	SMR	95% CI
British Columbia	0.57	0.51 to 0.64
Manitoba	0.54	0.44 to 0.63
Ontario	0.78	0.71 to 0.85
Quebec	0.57	0.51 to 0.63
New Brunswick	0.37	0.25 to 0.48
Nova Scotia	0.75	0.57 to 0.92
Newfoundland & Labrador	0.65	0.34 to 0.97
Summary (random)	**0.60**	**0.49 to 0.70**

JNCI 2014;106(11)

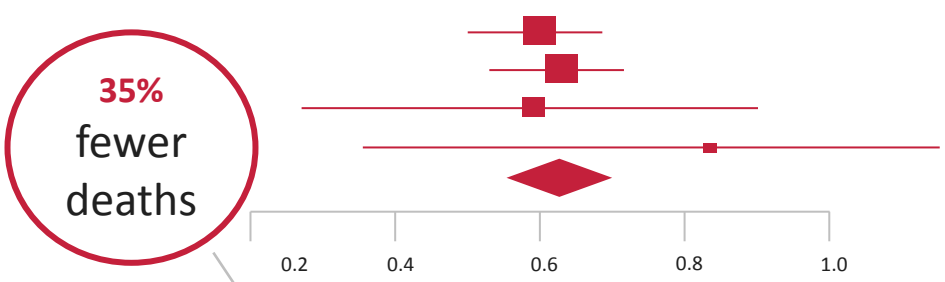
STANDARDIZED MORTALITY RATIOS (SMRS) BY CANADIAN PROVINCE FOR AGES AT ENTRY: SUMMARY ESTIMATES ARE BASED UPON RANDOM EFFECTS MODELS. ALL STATISTICAL TESTS WERE TWO-SIDED.

60-69



Region	SMR	95% CI
British Columbia	0.57	0.49 to 0.64
Manitoba	0.70	0.55 to 0.85
Ontario	0.69	0.62 to 0.77
Quebec	0.63	0.56 to 0.71
New Brunswick	0.39	0.27 to 0.52
Nova Scotia	0.45	0.30 to 0.60
Newfoundland & Labrador	0.69	0.30 to 1.09
Summary (random)	**0.58**	**0.50 to 0.67**

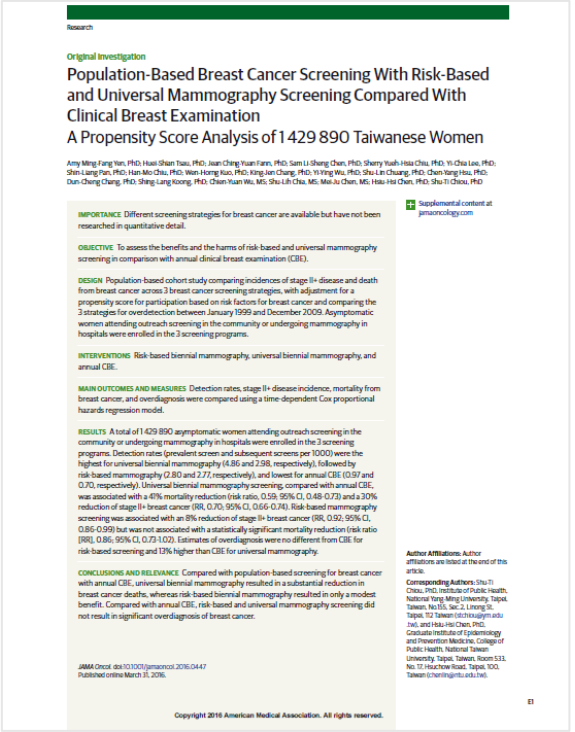
70-79



Region	SMR	95% CI
British Columbia	0.63	0.49 to 0.76
Ontario	0.66	0.52 to 0.79
New Brunswick	0.63	0.30 to 0.96
Nova Scotia	0.84	0.36 to 1.31
Summary (random)	**0.65**	**0.56 to 0.74**

TAIWAN STUDY

- Population-based cohort study assessed benefits and harms of risk-based and universal mammography screening compared with annual CBE.
- Compared incidences of stage II+ disease and death from breast cancer across 3 breast cancer screening strategies.



Research

Original Investigation

Population-Based Breast Cancer Screening With Risk-Based and Universal Mammography Screening Compared With Clinical Breast Examination

A Propensity Score Analysis of 1 429 890 Taiwanese Women

Amy Ming-Fang Yen, PhD; Huai-Shian Tsau, PhD; Jean Ching-Yuan Fann, PhD; Sam Li-Sheng Chen, PhD; Sherry Yueh-Hsia Chiu, PhD; Yi-Chia Lee, PhD; Shin-Liang Pan, PhD; Han-Mo Chiu, PhD; Wen-Horng Kuo, PhD; King-Jan Chang, PhD; Yi-Ying Wu, PhD; Shu-Lin Chuang, PhD; Chen-Yang Hsu, PhD; Dun-Cheng Chang, PhD; Shing-Lung Koong, PhD; Chen-Yuan Wu, MS; Shu-Lih Chia, MS; Mei-Ju Chan, MS; Hsiu-Hsi Chen, PhD; Shu-Ti Chiou, PhD

IMPORTANCE Different screening strategies for breast cancer are available but have not been researched in quantitative detail.

OBJECTIVE To assess the benefits and the harms of risk-based and universal mammography screening in comparison with annual clinical breast examination (CBE).

DESIGN Population-based cohort study comparing incidences of stage II+ disease and death from breast cancer across 3 breast cancer screening strategies, with adjustment for a propensity score for participation based on risk factors for breast cancer and comparing the 3 strategies for overdetection between January 1999 and December 2009. Asymptomatic women attending outreach screening in the community or undergoing mammography in hospitals were enrolled in the 3 screening programs.

INTERVENTIONS Risk-based biennial mammography, universal biennial mammography, and annual CBE.

MAIN OUTCOMES AND MEASURES Detection rates, stage II+ disease incidence, mortality from breast cancer, and overdiagnosis were compared using a time-dependent Cox proportional hazards regression model.

RESULTS A total of 1 429 890 asymptomatic women attending outreach screening in the community or undergoing mammography in hospitals were enrolled in the 3 screening programs. Detection rates (prevalent screen and subsequent screens per 1000) were the highest for universal biennial mammography (4.86 and 2.98, respectively), followed by risk-based mammography (2.80 and 2.77, respectively), and lowest for annual CBE (0.97 and 0.70, respectively). Universal biennial mammography screening, compared with annual CBE, was associated with a 41% mortality reduction (risk ratio, 0.59; 95% CI, 0.48-0.73) and a 30% reduction of stage II+ breast cancer (RR, 0.70; 95% CI, 0.66-0.74). Risk-based mammography screening was associated with an 8% reduction of stage II+ breast cancer (RR, 0.92; 95% CI, 0.86-0.99) but was not associated with a statistically significant mortality reduction (risk ratio [RR], 0.86; 95% CI, 0.73-1.02). Estimates of overdiagnosis were no different from CBE for risk-based screening and 13% higher than CBE for universal mammography.

CONCLUSIONS AND RELEVANCE Compared with population-based screening for breast cancer with annual CBE, universal biennial mammography resulted in a substantial reduction in breast cancer deaths, whereas risk-based biennial mammography resulted in only a modest benefit. Compared with annual CBE, risk-based and universal mammography screening did not result in significant overdiagnosis of breast cancer.

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doi:10.1001/jamaoncol.2016.0447

TAIWAN STUDY RESULTS

- A total of 1,429,890 asymptomatic women attending outreach screening in the community or undergoing mammography in hospitals were enrolled in the 3 screening programs.
- Universal mammography: **41% mortality reduction compared to CBE**
- Risk-based mammography: **14% mortality reduction, (not statistically significant)**

DIFFERENT RECOMMENDATIONS FOR DIFFERENT AGE GROUPS RESULTS FROM CONSIDERING TWO SETS OF DATA

- The incidence and attributable mortality of breast cancer in different age groups – increases with age.
- The aggressiveness of breast cancer before and after menopause.

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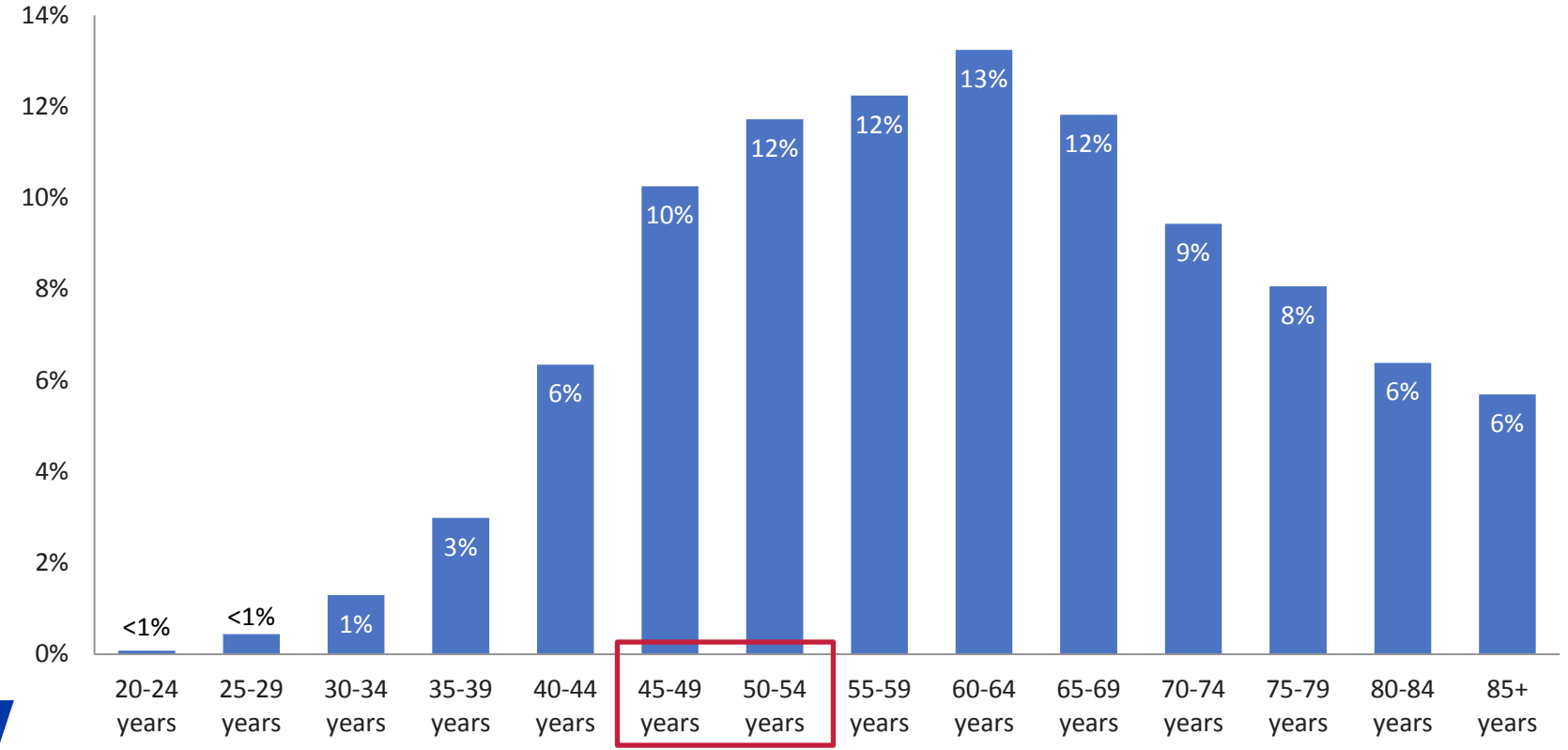
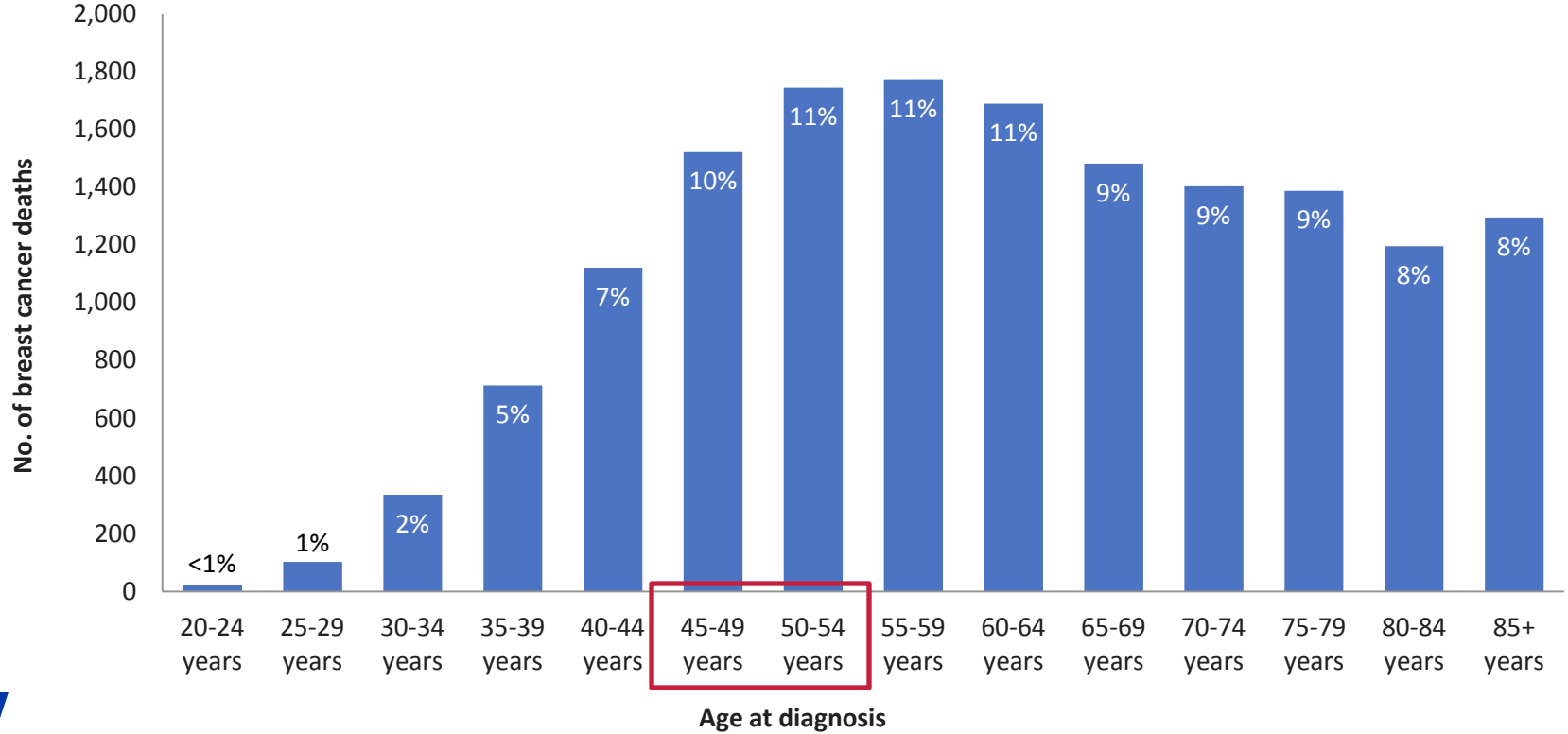
AGE DISTRIBUTION OF INVASIVE FEMALE BREAST CANCER CASES, 2007-2011



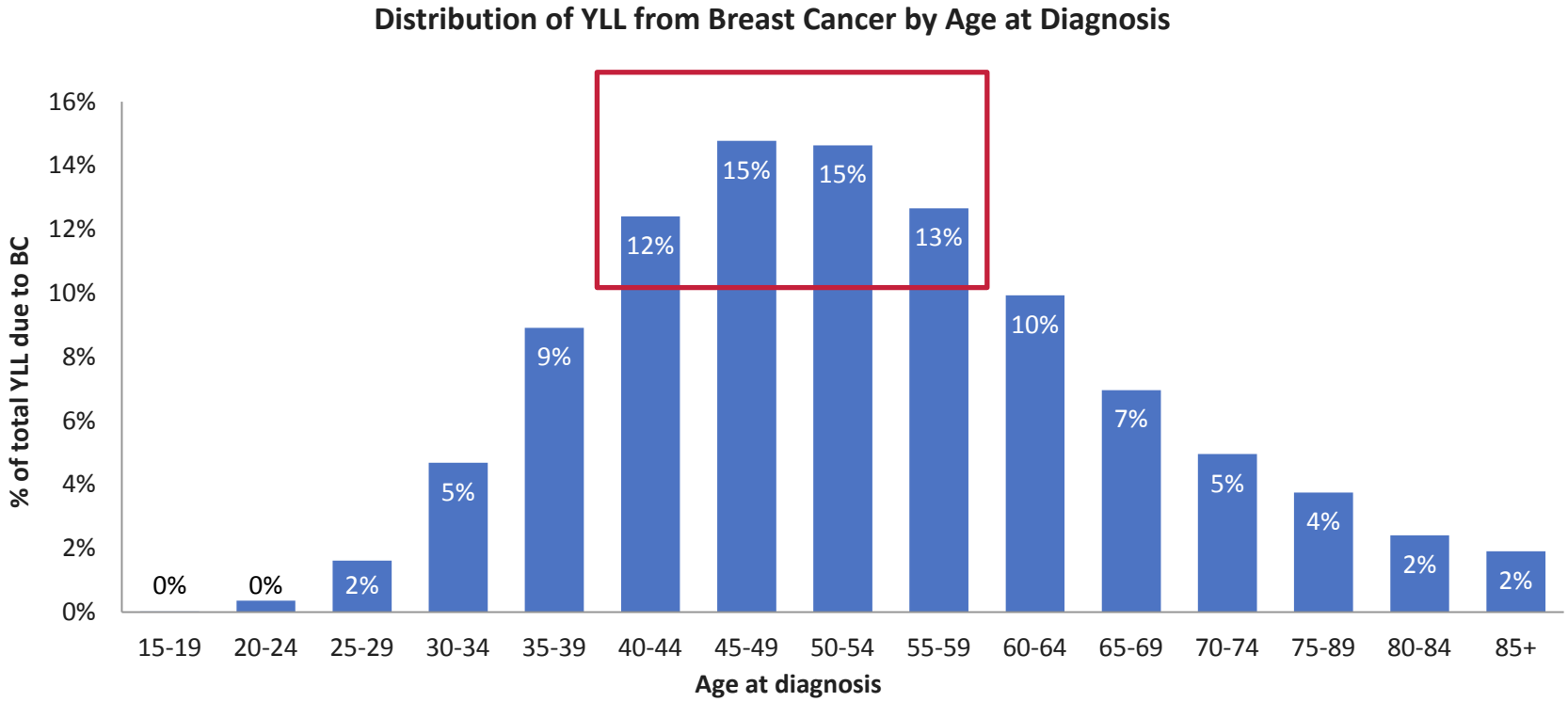
Source: SEER 18 registries.

DISTRIBUTION OF BREAST CANCER DEATHS BY AGE AT DIAGNOSIS, 2007-2011



Source: SEER 9 registries, patients followed for 15 years after diagnosis.

DISTRIBUTION OF YEARS OF LIFE LOST DUE TO DEATH FROM BREAST CANCER BY AGE AT DIAGNOSIS



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SUPPLEMENTAL ANALYSIS ON THE SCREENING INTERVAL FROM NCI-FUNDED BREAST CANCER SURVEILLANCE CONSORTIUM

- Miglioretti D, et al. Risk of less-favorable breast tumor characteristics with biennial versus annual mammography by age and menopausal status

SUPPLEMENTAL ANALYSIS ON THE SCREENING INTERVAL FROM NCI-FUNDED BREAST CANCER SURVEILLANCE CONSORTIUM

- **Main finding:** Among premenopausal women, biennial screeners had higher proportions of tumors with advanced stage (relative risk [RR]=1.28), larger size (RR=1.21), and any less-favorable prognostic characteristic (RR=1.11) compared with annual screeners [all RR were statistically significant].

RR (95% CI) OF LESS-FAVORABLE INVASIVE CANCER CHARACTERISTICS FOR BIENNIAL VERSUS ANNUAL SCREENERS

Tumor Prognostic Characteristics

	Stage IIB, III, or IV vs. 1 or IIA	Tumor size >15 mm vs. <=15 mm	Lymph node positive vs. negative	Less- vs. more-favorable prognostic characteristics
Menopausal Status				
Premenopausal	**1.28 (1.01, 1.63)**	**1.21 (1.07, 1.37)**	1.15 (0.96, 1.38)	**1.11 (1.00, 1.22)**
Postmenopausal, without HT use	0.95 (0.79, 1.15)	**1.11 (1.00, 1.22)**	0.89, (0.77, 1.04)	1.03 (0.95, 1.12)
Postmenopausal, with HT use	1.14 (0.89, 1.47)	1.13 (0.98, 1.31)	1.18 (0.98, 1.42)	1.12 (1.00, 1.25)
Estrogen plus progestogen used	1.01 (0.94, 1.08)	**1.38 (1.04, 1.82)**	0.95 (0.64, 1.41)	1.16 (0.91, 1.47)
Estrogen only used	1.19 (0.78, 1.83)	1.19, (0.95, 1.50)	1.26 (0.90, 1.77)	1.14 (0.94, 1.37)

THE ACS BREAST CANCER GUIDELINE – A PRACTICAL APPROACH

- **Starting at age 40,** all women should be offered screening mammography.
- Recommending that they be screened at this age is perfectly fine!
- BUT – we do feel that women should understand that they are very unlikely to prevent a breast cancer death and are very likely to have a false positive result.

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FOR WOMEN 40 TO 44 – SUPPORT INDIVIDUAL CHOICES

- The ACS anticipates that most women will want to start screening sometime between 40 and 44.
- But some women want to have as few mammograms as possible – and are willing to accept a slightly higher chance of developing an incurable breast cancer.
- For these women, delaying the first mammogram until age 45 is a reasonable choice and should be supported.

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WOMEN 45 TO 54

- For women who opted not to start mammography screening before age 45, the ACS recommends that she should begin annual mammography at age 45.

FOR WOMEN AGES 55 AND OLDER

- All women should continue to have regular mammography at least every other year.
- Some women will want to continue to screen every year.
- BUT the ACS recommends that women who continue annual mammograms should understand that the likelihood of benefitting from having a mammogram every year is very small – and she'll have more mammograms and may have an extra false positive or two.

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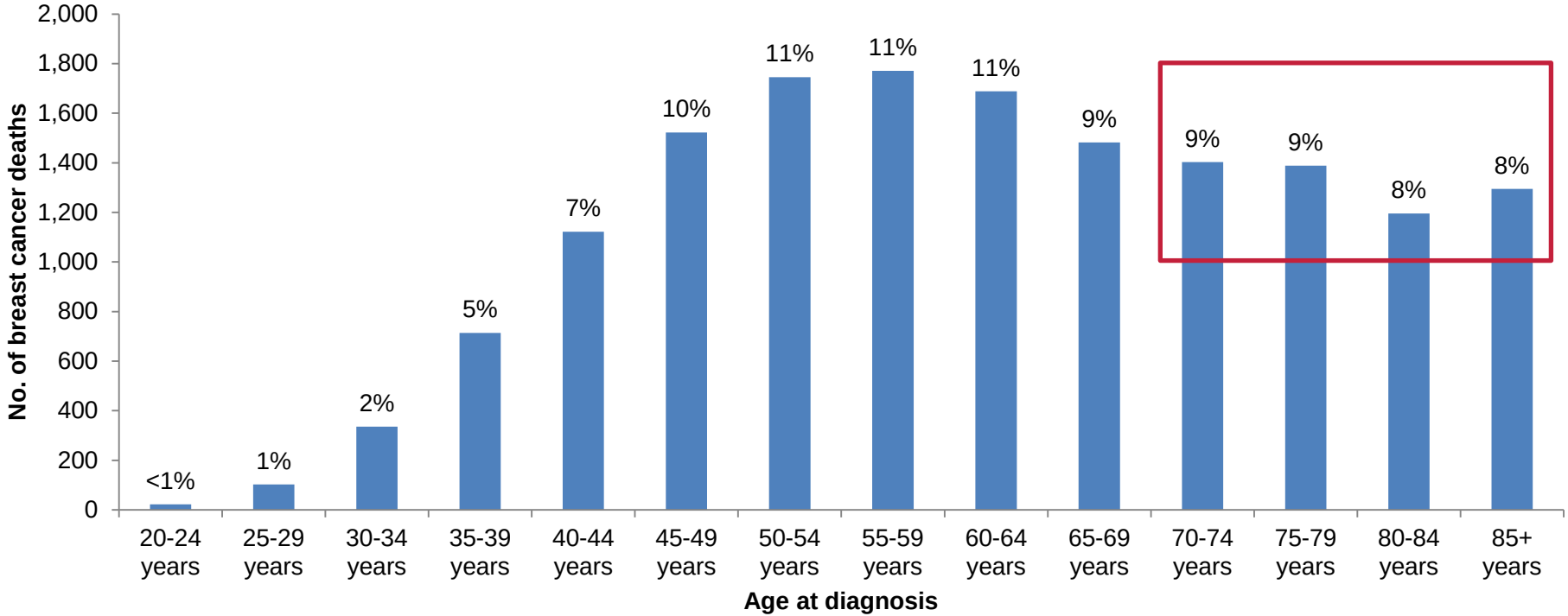
WE SHOULD GIVE MORE ATTENTION TO OFFERING SCREENING TO OLDER HEALTHY WOMEN

- Trials are never conducted in women older than age 75.
- Guideline group used inferential evidence to recommend continued screening in health older women.

DISTRIBUTION OF YEARS OF LIFE LOST DUE TO DEATH FROM BREAST CANCER BY AGE AT DIAGNOSIS



Source: SEER 9 registries, patients followed for 15 years after diagnosis.

WHAT ABOUT CLINICAL BREAST EXAMS?

- The key to early detection leading to a mortality advantage and less intense therapy is mammography.
- Clinical breast exams are not an effective form of screening for breast cancer. **Mammography is.**

BREAST CANCER SCREENING RATES ARE TOO LOW

- About one third of all women are not up to date with screening.
- The most important thing we can do to reduce breast cancer mortality is to institute systems to identify women who are not up to date with screening and navigate them into a regular screening schedule.

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BREAST CANCER SCREENING GUIDELINES – 2016

At what age should average risk women start, and how often should screening take place?

Organization	Starting Age	Screening Interval
ACS, ASBS, ASCO	45; with the option to start at 40	Annual 40-54: Biennial 55+, with option to continue annual screening
ACR, ACOG, NCCN, NCBC	40	Annual
USPSTF, AAFP, ACP	50; the decision to begin screening between ages 40-49 should be individualized based on risk and values	Biennial, 40+

ACS=American Cancer Society; ASBS=American Society of Breast Surgeons; ASCO=American Society of Surgical Oncology; USPSTF=U.S. Preventive Services Task Force; ACOG=American College of Obstetricians and Gynecologists; NCCN=National Comprehensive Cancer Network; NCBC= National Consortium of Breast Centers; AAFP=American Academy of Family Physicians; ACP=American College of Physicians;

BREAST CANCER SCREENING GUIDELINES – 2016

At what age should average risk women stop screening?	
Organization	Stopping Age
ACS, ASBS, ASCO	Continue screening as long as health is good and life expectancy is at least 10 years
ACOG	Shared decisions 75+
ACR	Continue screening as long as health is good and life expectancy is at least 5-7 years, and there is willingness to undergo additional testing
NCCN	Consider comorbidity and therapeutic decisions
USPSTF, AAFP, ACP	74; Insufficient evidence to recommend for or against screening

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COLORECTAL CANCER SCREENING

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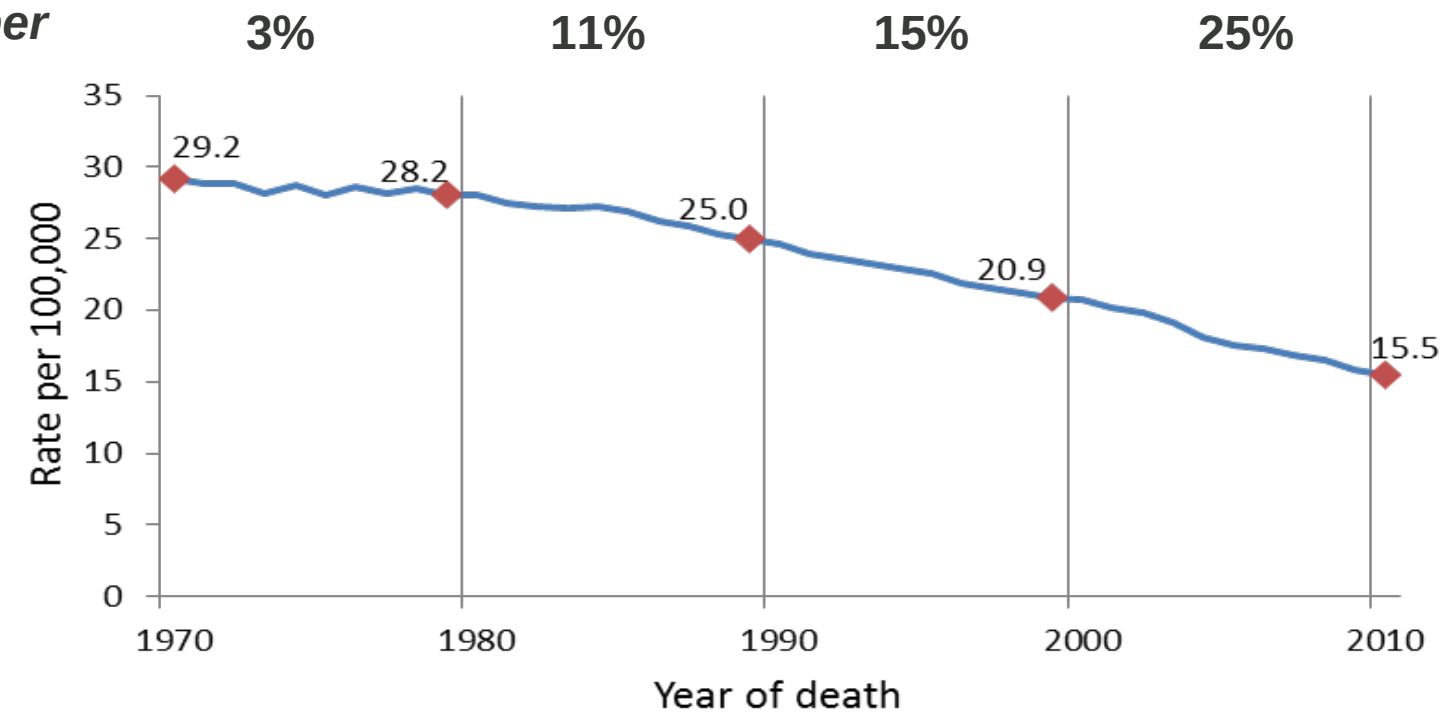
Numerous events, accomplishments, and decisions have converged.

Together, they have created an extraordinary opportunity to achieve our goal of 80% colon cancer screening rate by 2018.

WE ARE MAKING PROGRESS

Increasing Decline in Colorectal Cancer Death Rates, 1970-2010

Decline per decade:



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The nation has become energized by the goal of 80% by 2018
What will it really take to get there.

So what will it really take?

7 BASIC TRUTHS OF COLON CANCER SCREENING

Truth #1: If you only offer colonoscopy you can achieve very good but not spectacular screening rates.

COLONOSCOPY AND STOOL TESTING ARE BOTH CRITICAL STRATEGIES

Every system achieving 80% is relying on stool testing as well as colonoscopy.

Both approaches are critical.

WE MUST ENSURE ANYONE CAN BE OFFERED A HOME STOOL BLOOD TEST

- Even if you recommend colonoscopy for all, some people won’t get one, can’t get one, or shouldn’t get one.
- Using colonoscopy exclusively will, inevitably, lead to a screening gap.

STOOL BLOOD TESTING REMAINS IMPORTANT IN THE "AGE OF COLONOSCOPY"

- Colonoscopy is now the most frequently used screening test for CRC.
- However, when provided annually to average-risk patients with appropriate follow-up, stool occult blood testing with high-sensitivity tests can provide similar reductions in mortality compared to colonoscopy and some reduction in incidence.

Evaluating Test Strategies for Colorectal Cancer Screening: A Decision Analysis for the U.S. Preventive Services Task Force

MANY PATIENTS PREFER HOME STOOL TESTING

Colonoscopy recommended:	38% completed colonoscopy
FOBT recommended:	67% completed FOBT
Colonoscopy or FOBT:	69% completed a test

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Adherence to Colorectal Cancer Screening: A Randomized Clinical Trial of Competing Strategies

COLONOSCOPY FOR POSITIVE TEST IS CRITICAL

Patients who select stool blood testing must also be prepared to accept follow-up colonoscopy if the stool blood test is abnormal.

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FECAL IMMUNOCHEMICAL TESTS (FITS) SHOULD REPLACE GUAIAC FOBT

- FITs:
  - Demonstrate superior sensitivity and specificity.
  - Are specific for colon blood and are unaffected by diet or medications.
  - Some can be developed by automated readers.
  - Some improve patient participation in screening.

Allison JE, et.al. J Natl Cancer Inst. 2007; 191:1-9

Cole SR, et.al. J Med Screen. 2003; 10:117-122

FECAL IMMUNOCHEMICAL TESTS (FIT)

- FIT tests are based on the immunochemical detection of human hemoglobin (Hb) as an indicator of blood in the stool.
- Immunochemical tests use a monoclonal or polyclonal antibody that reacts with the intact globin protein portion of human hemoglobin.
- More user friendly!

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Truth #2: If you only offer screening to patients who are coming to a primary care office, you can achieve very good but not spectacular screening rates.

POPULATION MANAGEMENT IS VITAL

Every practice must have a system to assess screening gaps and conduct population outreach by letter or phone.

Truth #3: If you give out FIT or FOBT tests but do not track whether the patient returns the test and prompt them to do so, return rates will be poor.

SAMPLE LOG BOOK FOR TRACKING KITS

Patient's Name	Date given	Date received	Results recorded Yes/No

ADD A “RETURN BY” DATE

Much like setting a quit date for smoking cessation

Truth #4: If you ask a patient to schedule their colonoscopy but do not schedule it before they leave the office, only about half of them will call and schedule.

Sit down with your colonoscopist and tell them what you expect.

Truth #5: If you are “screening” patients with a stool blood test at the time of a rectal exam, it’s time to stop. This method doesn’t work.

REMEMBER: STOOL COLLECTION SHOULD BE DONE AT HOME!

- Stool collected on rectal exam may not be sufficient or sufficiently representative of stool collected from a complete bowel movement.
- There is **no evidence** that any type of stool blood testing is sufficiently sensitive when used on a stool sample collected during a rectal exam.
- Therefore, **HS-gFOBT and FIT should be completed by the patient at home, and NOT as an in-office test.**

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Truth #6: The quality of colonoscopy varies dramatically.

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THREE KEY COMPONENTS OF COLONOSCOPY QUALITY

1. Screen the right patients at the right intervals.
2. Maximize bowel prep quality and patient show rates.
3. Monitor adenoma detection rate.

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THE MOST IMPORTANT MEASURE OF QUALITY COLONOSCOPY: ADENOMA DETECTION RATE

- Definition: The percent of screening exams with at least one adenoma detected.
- Current Targets:
  - ADR should be:
  - ≥ 30% male screening patients
  - ≥ 20% female screening patients

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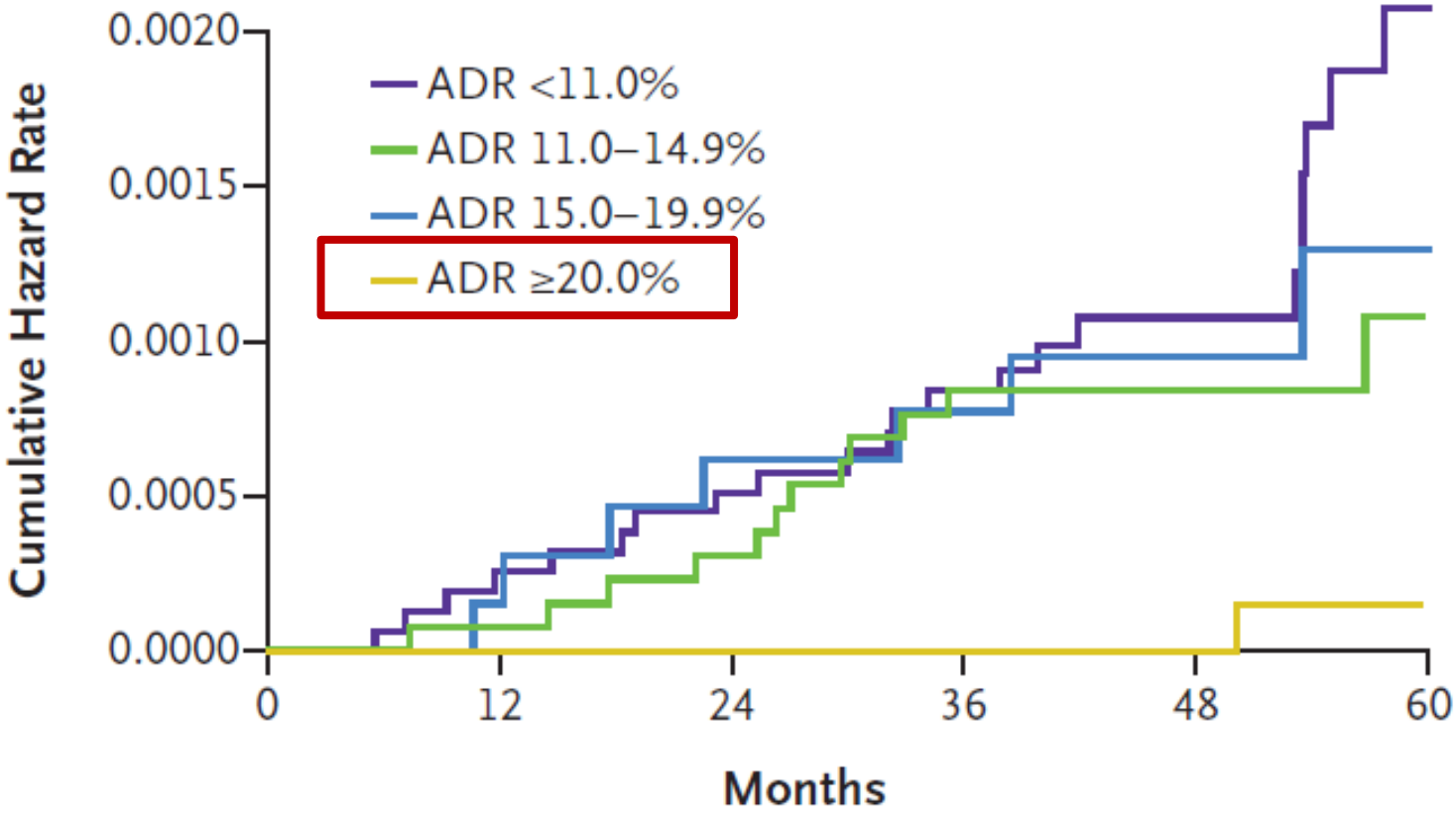
ADR AND RISK OF INTERVAL CANCER



Truth #7: Surveillance guidelines are not being followed.

UTILIZATION OF COLON SURVEILLANCE

	Surveillance in 5 yrs	≥2 Surveillance in 7 yrs
Advanced Adenoma (n = 1342)	58.4%	33.2%
≥ 3 non-advanced adenomas (n = 177)	57.5%	26.9%
1-2 non-advanced adenomas (n = 905)	46.7%	18.2%
No adenomas	26.5%	10.4%

Evidence for both over-utilization and under-utilization

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Schoen et al; Gastroenterol 2010; 138: 73-81

Know your colonoscopists. Make sure they are following national guidelines and reporting detection rates.

COLON CANCER SCREENING: SUMMARY

- A physician recommendation to undergo screening is vital.
- Either offer colonoscopy every 10 years OR sensitive FOBT/FIT annually.
  - If the FOBT/FIT is chosen, emphasize the need for annual screening.
- For individuals who won't, can't, or shouldn't have a colonoscopy, annual FOBT/FIT must be obtained.
- All positive FOBT/FIT tests, defined by any one sample testing positive, must undergo colonoscopy.
- DO NOT RELY ON DIGITAL RECTAL!

CERVICAL CANCER SCREENING

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SCREENING PERIODICITY

- Women at any age should NOT be screened annually by any screening method.
  - Not supported by evidence.
  - Leads to increased rate of harms: very large excess of unnecessary procedures and treatments.
  - Does not increase benefit: very small increment in cancers prevented.

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GUIDELINE RECOMMENDATIONS

Women <21	• No screening
Women ages 21-29	• Cytology alone every 3 years (liquid or conventional) • Recommend AGAINST annual cytology

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GUIDELINE RECOMMENDATIONS

Women ages 30-65	• HPV + cytology “cotesting” every 5 years (preferred) or • Every 3 years with cytology alone (acceptable) • Recommend AGAINST more frequent screening
Women ages >65	• Discontinue after age 65 if 3 negative cytology tests or • 2 negative HPV tests in last 10 years with most recent test in last 5 years

GUIDELINE RECOMMENDATIONS

Post-Hysterectomy	• Discontinue if for benign reason
Screening after HPV vaccination	• Follow age-appropriate recommendations (same as unvaccinated women)

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COMMENTS

- Women at any age should NOT be screened annually by any screening method.
- HPV testing should NOT be used for screening women <30 years of age.*
- Screening by HPV testing alone is not recommended for most clinical settings.*

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* See Interim Guidance, 2015

LUNG CANCER SCREENING

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LUNG CANCER

- 2015
  - Estimated new cases: 224,390
  - Estimated deaths: 158,080

THE ACS GUIDELINE

“Clinicians with access to high volume, high quality lung cancer screening and treatment centers should initiate a discussion about screening with apparently healthy patients aged 55 to 74 years who have at least a 30 pack/year smoking history and who currently smoke or have just quit within the past 15 years.”

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“A process of informed and shared decision making … should occur before any decision is made to initiate lung cancer screening.”

“Smoking cessation counseling remains a high priority for clinical attention in current smokers.”

“Where risk seems to approximate or exceed the NLST eligibility criteria in one category but not another, clinicians should consider offering the chance to screen.”

Example: A 65 yo man, who is still smoking, with a 25 year smoking history. Family history and occupational exposure also worthy of consideration.

LUNG CANCER SCREENING SHARED DECISION MAKING: BENEFITS

- Reduces death rates by at least 20%.
- Actual reduction in death rates highly likely to be greater than 20% with continued screening beyond 3 screens in a 2 year period.
- The only proven way to reduce risk of dying from lung cancer.
- Smokers who participate in lung screening are substantially more likely to quit smoking.

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LUNG CANCER SCREENING: HARMS

- Lifelong screening leads to a high likelihood of finding at least one nodule at some point.
- Finding nodules is anxiety provoking.
- Nodules require more frequent imaging and sometimes require a biopsy.
- Individuals both with and without cancer can suffer a complication during diagnostic evaluation, even – rarely – death.

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LUNG CANCER SCREENING: SHARED DECISION MAKING

- Individuals who place a high value on the opportunity to prevent a premature cancer death and are willing to accept the anxiety of finding a nodule and the risks associated with evaluating that nodule may choose to be screened.

COVERAGE FOR LOW-DOSE CT SCREENING IS A REALITY

- USPSTF B recommendation requires coverage by most commercial plans.
- On Feb. 5, CMS issued a final decision to cover screening in high risk patients.
  - Decision outlined strict requirements for what a center must provide to permit coverage.

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CMS.gov
Centers for Medicare & Medicaid Services


We have an opportunity to dramatically reduce mortality from lung cancer.

THANK YOU

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NATIONAL Colorectal Cancer ROUNDTABLE

@RichWender