

# PROSPR: Population-based Research Optimizing Screening through Personalized Regimens (with CDC)

Stephen Taplin, MD, MPH

Carrie Klabunde, PhD

Nancy Potischman, PhD

Emily Dowling, MHS

Rachel Ballard-Barbash, MD, MPH

Robert T. Croyle, PhD

# Support as a Scientific Priority

- USPSTF controversy on breast cancer screening
  - Need studies of digital mammography and MRI in practice
- NIH State of the Science Conference on CRC screening use (2/10)
  - Monitor the impact of screening
- Health care reform passed and supports efforts consistent with PROSPR
  - Comparative effectiveness, prevention services, development of quality metrics
- 2010 Think Tank review with leading investigators
  - Need comprehensive data on risks and benefits of screening in practice

Clinical Guidelines

**Effects of Mammography Screening Under Different Screening Schedules: Model Estimates of Potential Benefits and Harms**

Jeanne S. Mandelblatt, MD, MPH; Kathleen A. Cronin, PhD; Stephanie Bailey, PhD; Donald A. Berry, PhD; Harry J. de Koning, MD, PhD; Gerrit Draisma, PhD; Hui Huang, MS; Sandra J. Lee, DSc; Mark Munsell, MS; Sylvia K. Plevritis, PhD; Peter Ravdin, MD, PhD; Clyde B. Schechter, MD, MA; Bronislava Sigal, PhD; Michael A. Stoto, PhD; Natasha K. Stout, PhD; Nicolien T. van Ravesteijn, MSc; John Venier, MS; Marvin Zelen, PhD; Eric J. Feuer, PhD; and for the Breast Cancer Working Group of the Cancer Intervention and Surveillance Modeling Network (CISNET)\*

Author Affiliations

Abstract

**Background:** Despite trials of mammography and widespread use, optimal screening policy is controversial.

**Objective:** To evaluate U.S. breast cancer screening strategies.

**Design:** 6 models using common data elements.

**Data Sources:** National data on age-specific incidence, competing mortality, mammography characteristics, and treatment effects.

**Target Population:** A contemporary population cohort.

**Time Horizon:** Lifetime.

**Perspective:** Societal.

« Previous | Next Article »  
Table of Contents

This Article

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Abstract FREE

Figures

Full Text

Full Text (PDF)

Correction

Summary for Patients

Services

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Top

Abstract

Methods

Results

Discussion

Article and Author Information

References

Prev Med. 2010 Jan-Feb;50(1-2):74-80. Epub 2009 Sep 8.

**Psychosocial predictors of adherence to risk-appropriate cervical cancer screening guidelines: a cross sectional study of women in Ohio Appalachia participating in the Community Awareness Resources and Education (CARE) project.**

Paskett ED, McLaughlin JM, Reiter PL, Lehman AM, Rhoda DA, Katz ML, Hade EM, Post DM, Ruffin MT.

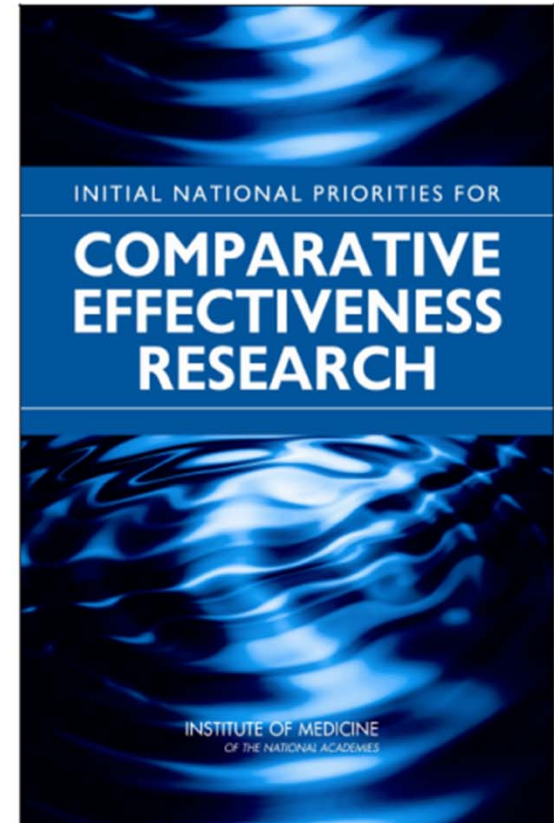
College of Public Health, The Ohio State University, Columbus, OH 43210, USA. Electra.Paskett@osumc.edu

Abstract

**OBJECTIVE:** We describe factors, in the context of smears within risk-appropriate guidelines (i.e., of developing cervical cancer). **METHODS:** Cross-sectional study of health clinics in Ohio Appalachia pertaining to adherence to risk-appropriate cervical cancer screening guidelines. **RESULTS:** Of 562 women with a



Enhancing Use and Quality of Colorectal Cancer Screening



Ann Intern Med. 2008 Nov 4;149(9):659-69. Epub 2008 Oct 6.

**Evaluating test strategies for colorectal cancer screening: a decision analysis for the U.S. Preventive Services Task Force.**

Zauber AG, Lansdorp-Vogelaar I, Knudsen AB, Wilschut J, van Ballegooijen M, Kuntz KM.

Memorial Sloan-Kettering Cancer Center, New York, New York 10065, USA. zauber@mskcc.org.

Comment in:

Ann Intern Med. 2008 Nov 4;149(9):680-2.

Ann Intern Med. 2009 Mar 3;150(5):359; author reply 359-60.

Summary for patients in:

Ann Intern Med. 2008 Nov 4;149(9):1-44.

Abstract

**BACKGROUND:** The U.S. Preventive Services Task Force requested a decision analysis to inform their updated recommendations for colorectal cancer screening. **OBJECTIVE:** To assess life-years gained and colonoscopy rates for colorectal cancer screening strategies and identify a set of recommendable screening strategies. **DESIGN:** Decision analysis using 2 colorectal cancer microsimulation models from the Cancer Intervention and Surveillance Modeling Network.

Cancer Epidemiol Biomarkers Prev. 2010 Jan;19(1):201-10.

**Randomized trial of a lay health advisor and computer intervention to increase mammography screening in African American women.**

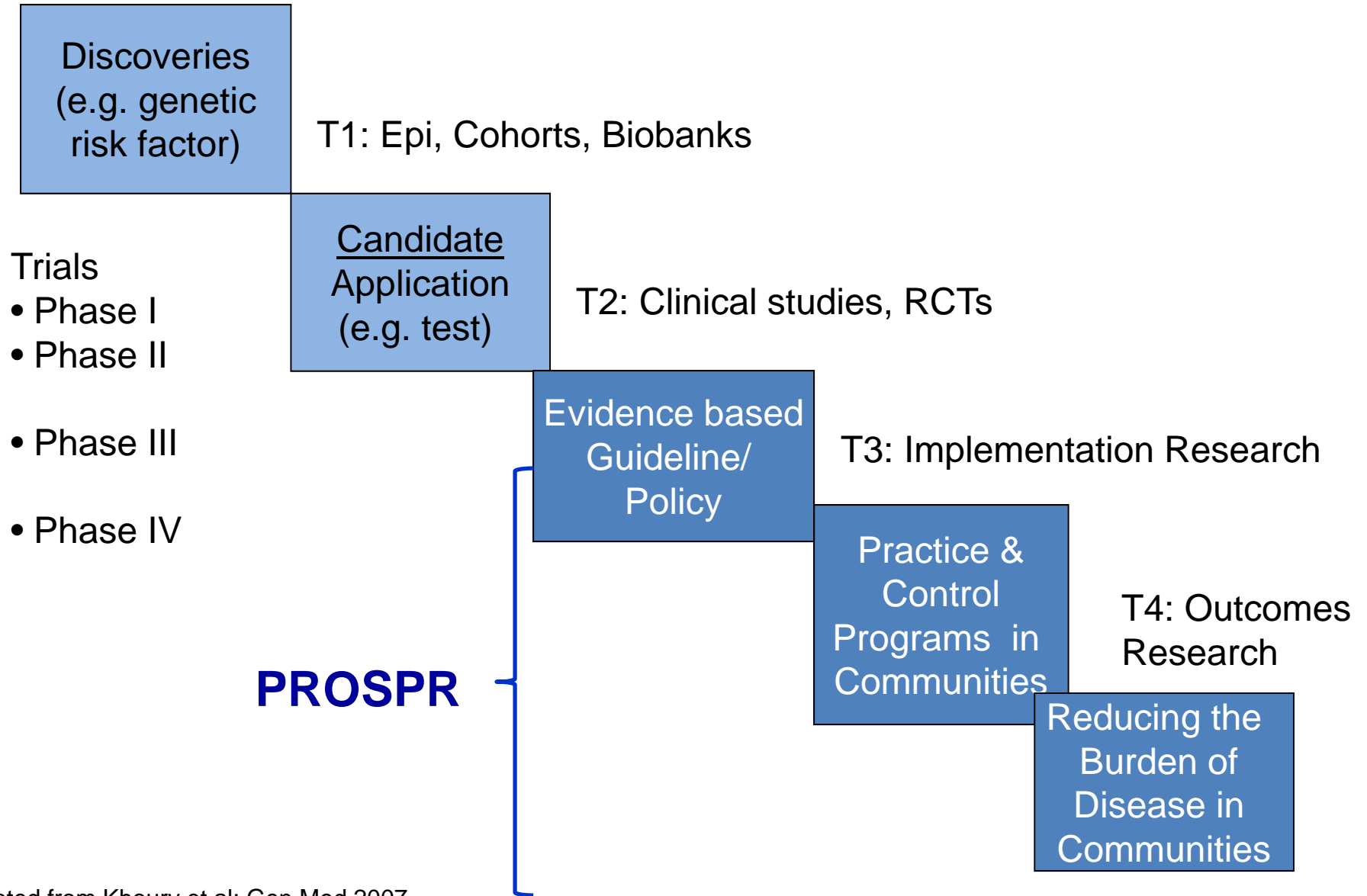
Russell KM, Champion VL, Monahan PO, Millon-Underwood S, Zhao Q, Spacey N, Rush NL, Paskett ED.

Indiana University School of Nursing, 1111 Middle Drive, Indianapolis, IN 46202, USA. katrusse@iupui.edu

Abstract

**BACKGROUND:** Low-income African American women face numerous barriers to mammography screening. We tested the efficacy of a combined interactive computer program and lay health advisor intervention to increase mammography screening. **METHODS:** In this randomized, single blind study, participants were 181 African American female health center patients of ages 41 to 75 years, at < or =250% of poverty level, with no breast cancer history, and with no screening mammogram in the past 15 months. They were assigned to either (a) a low-dose comparison group consisting of a culturally appropriate mammography screening pamphlet or (b) interactive, tailored computer instruction at baseline and four monthly lay health advisor counseling sessions. Self-reported screening data were collected at baseline and 6 months and verified by medical record. **RESULTS:** For

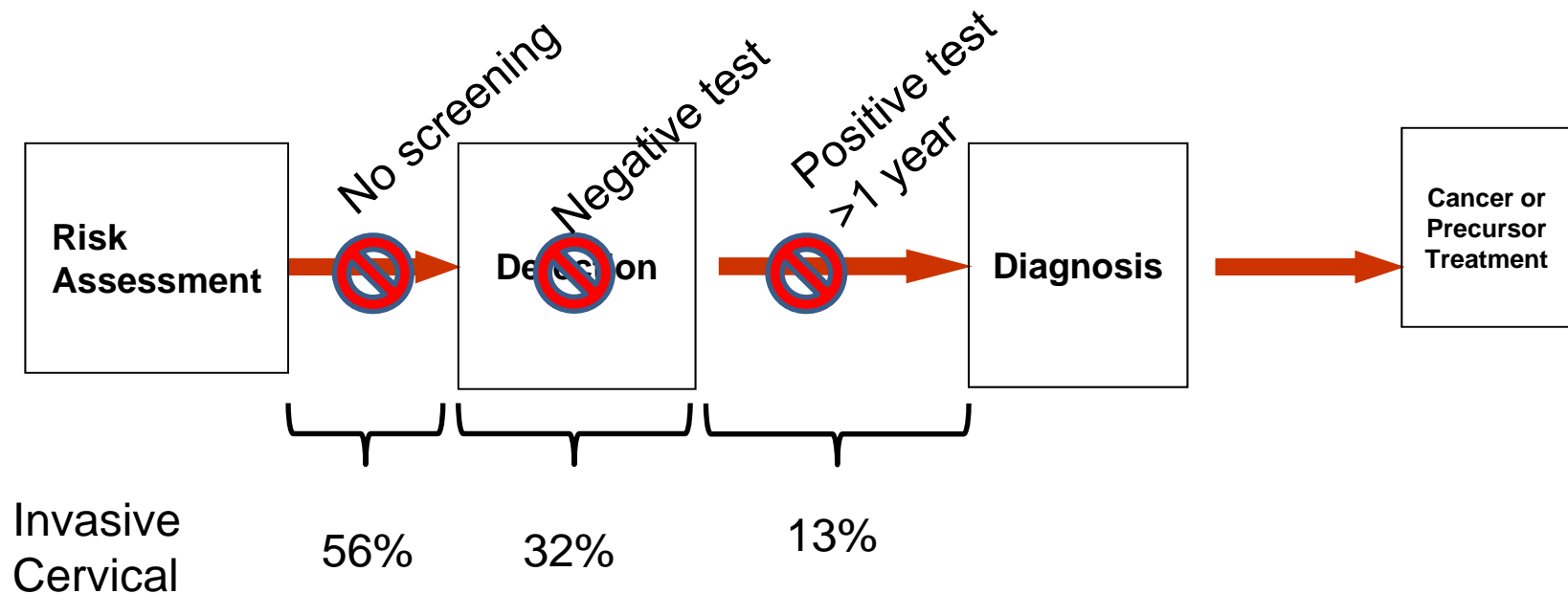
# Focus on Research Translation and Implementation



# Screening is a process that breaks down in the community

Invasive cervical cancers should not occur in populations where screening is implemented well.

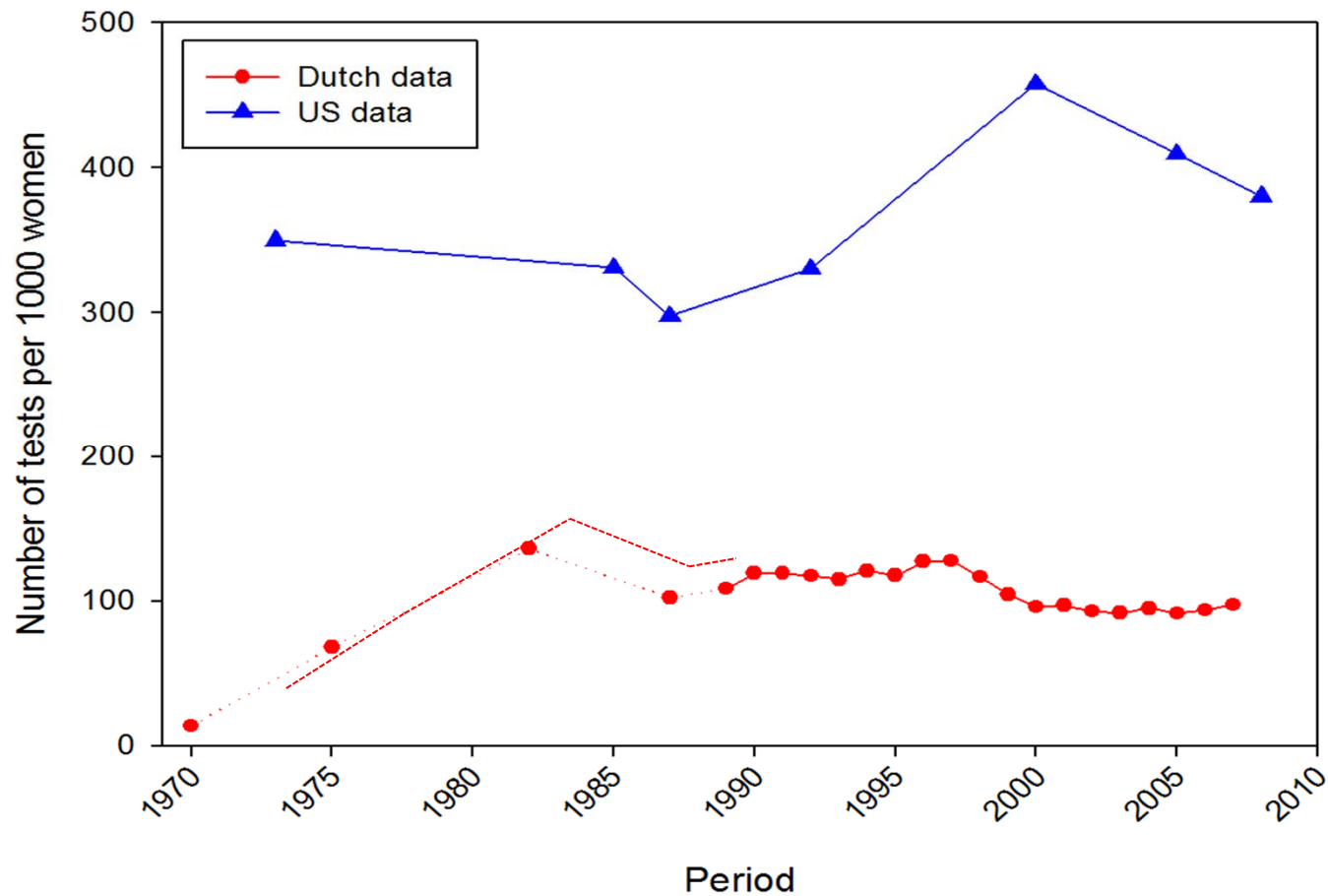
Chart audits for breakdowns in the process of screening among women with invasive cervical cancer (n =835) in 7 managed care locations with high screening rates



# Scale of Problem

- Breast, CRC, Cervical: an estimated 82 million screened each year in the U.S. (\$8.8 billion)
- But screening is not optimally applied in practice
  - 1990-2000 - \$6 billion paid for unnecessary screening
    - Greater mortality reduction possible by reaching more people
  - Additional reduction in CRC mortality
    - 9% greater by improving follow-up
    - 50% greater by improving the proportion of people screened

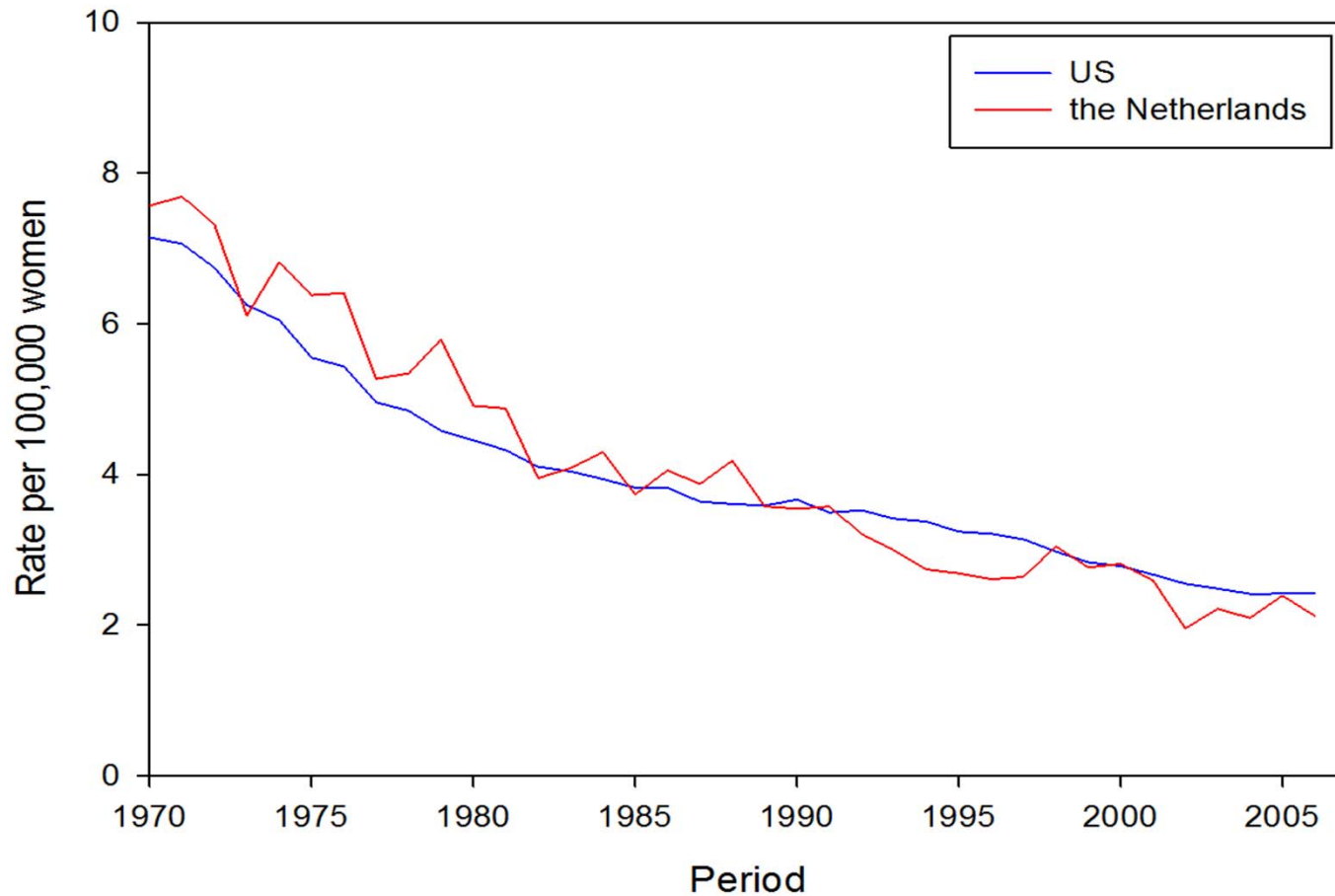
# Number of Cytological Tests per 1000 Women, standardized to U.S. 2000 pop.



Source: NHIS, Paleba



# Cervical Cancer Mortality Rates Standardized to U.S. 2000 Population



Source: SEER, CBS



# PROSPR Objectives

- **Primary**
  - Study the comparative effectiveness and outcomes of existing and emerging cancer screening processes
    - Breast
    - Colon
    - Cervical cancer.
  - Study the balance of benefits and harms of cancer screening across *recognized* cancer risk levels
- **Secondary**
  - Share data and conduct preliminary studies relevant to future innovative research to optimize the screening process.

# Examples of Potential Cancer Themes

- Strategies for estimating and communicating personalized risk, screening benefits, and harms
- Organizational and behavioral interventions to address technical and/or human factors in screening (e.g. radiologist interpretive skills, improving follow-up to abnormal tests)
- Mathematical modeling of the impact of screening improvements

## Examples of Cancer-Specific Issues

- Cervical: screening impact/age, HPV type/age, impact of HPV vaccine on HPV types
- Breast: new indicators of risk, comparative effectiveness of diagnosis by MRI, ultrasound, digital mammography
- CRC: natural history of adenomas, lesion frequencies, comparative effectiveness of FOBT, fecal DNA, CT colonography, natural history of extra-colonic lesions

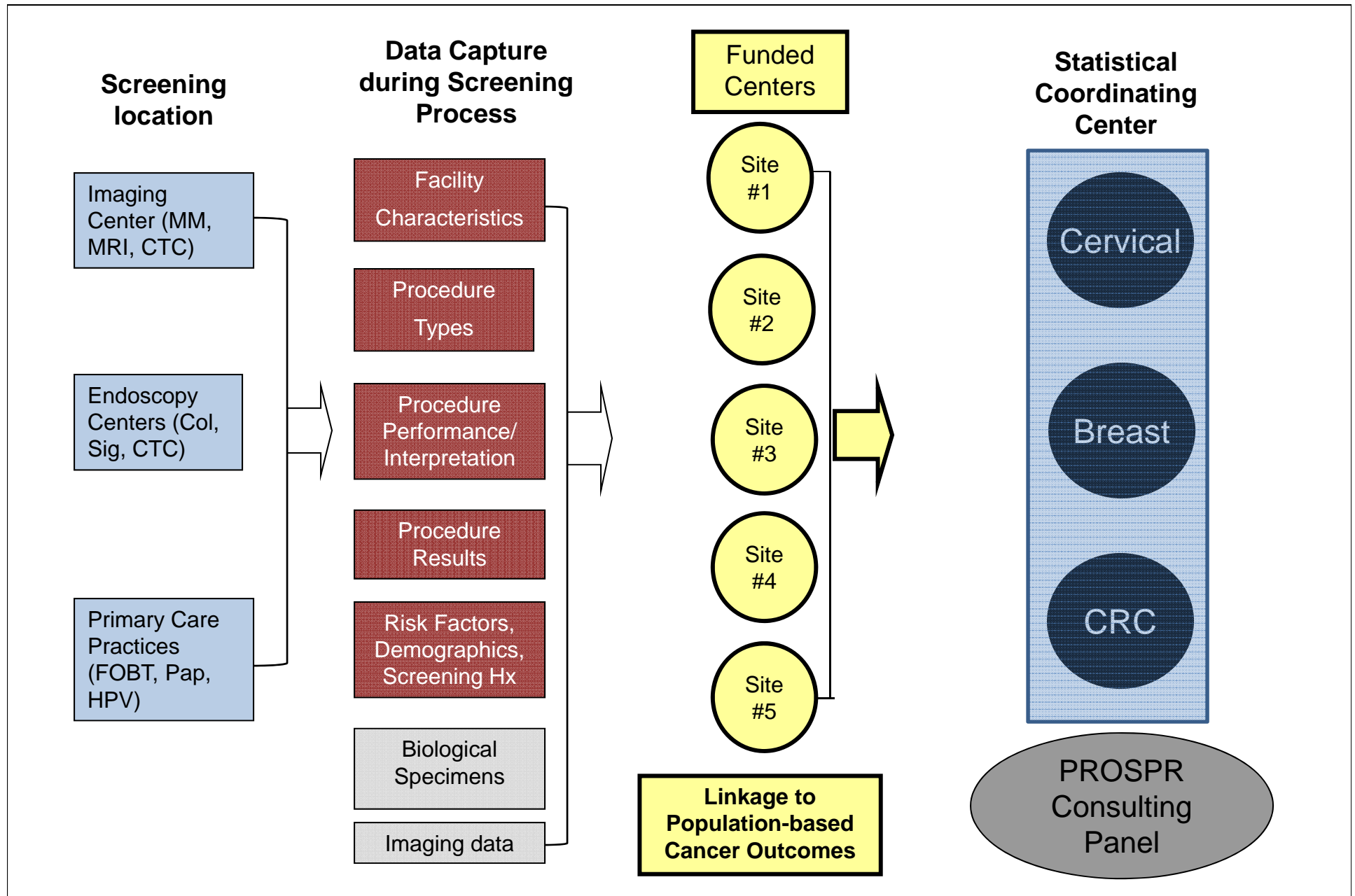
# Examples of Trans-Cancer Issues

- Standardize CER methods for evaluating the screening process
- Foster comprehensive data collection across the process of care
- Establish US community estimates of operational characteristics of screening (i.e., true and false positive rates)
- Estimate the balance of benefits and harms across screening technologies
- Identify systematic breakdowns in the screening process and comparing them across settings and cancers

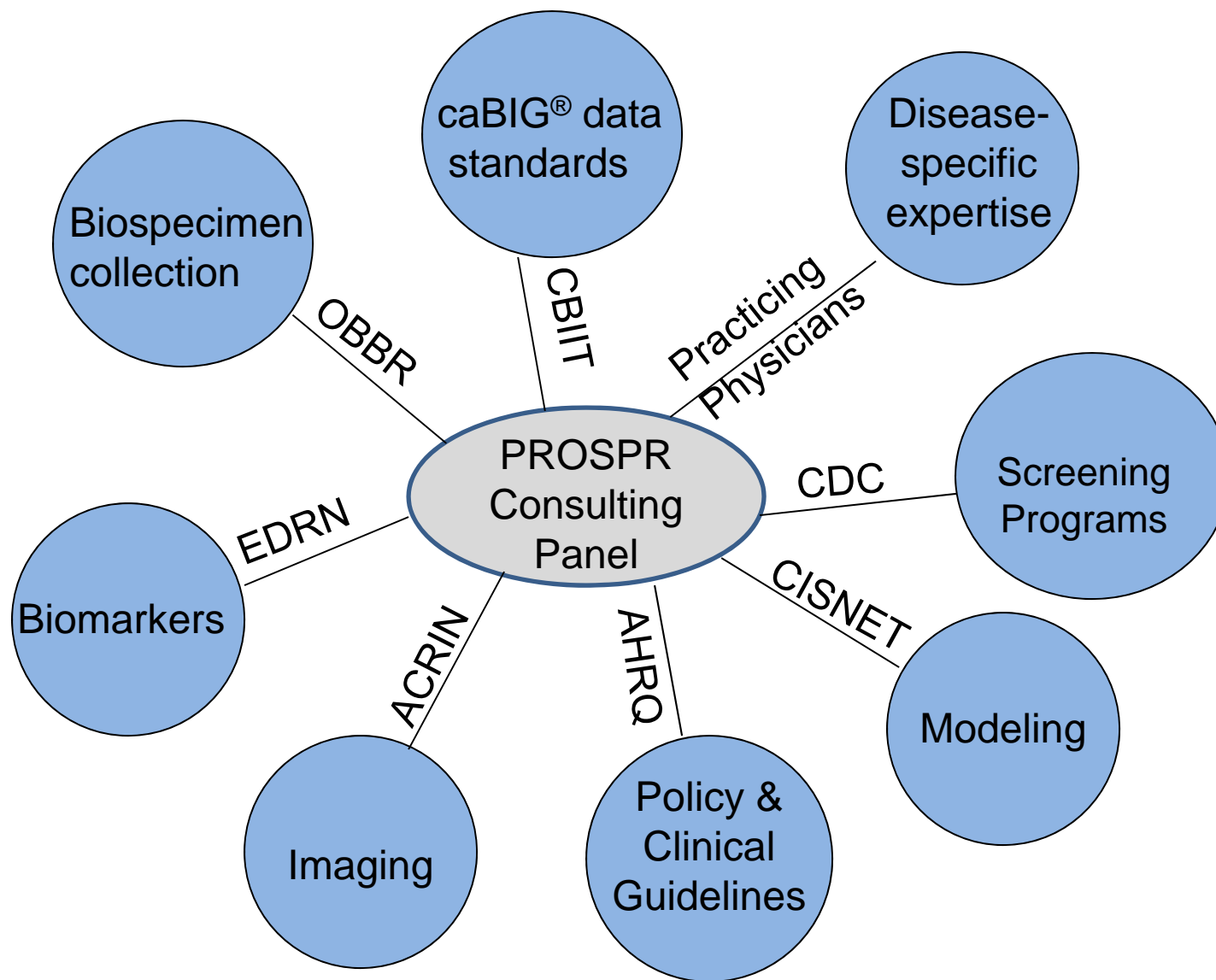
# Optimize screening to:

- Improve the screening process
  - Trans-cancer measurement of the variation across communities in the frequency of steps in the screening process
  - Improvements in recruitment
  - Improvements in follow-up
- Reduce morbidity
  - Trans-cancer measurement of morbidity (harms) of screening across ages, risk groups, communities and systems of care
  - Improvements in the screening test; comparative effectiveness of screening technologies in community practice
  - Reduction in screening frequency for some people (personalization)
  - Reduction false positive testing; center studies of alternative diagnostic strategies

# Population-based Research Optimizing Screening through Personalized Regimens (PROSPR)



# PROSPR Consulting Panel





# FY11 Budget

- Up to 5 sites per cancer (3 cancers) = \$13.5M/year (U54)
  - Establish network and common data elements/definitions
  - Collect the data in the course of care
  - Develop pilot projects and linkages to appropriate collaborators
- Statistical coordinating center = \$1.5M/year (U01)
  - Establish data quality standards, common data elements
  - Pool data and assist with analyses with these data
- Total = \$15M/year for 5 years

# Why now?

- Comparative effectiveness research is a high priority for Congress
  - 2009 Senate appropriations recommendation – “NCI should research how to apply what is known in early detection”
  - Health Care Reform mandated screening reimbursement
- There are no other multi-site research initiatives addressing the entire screening process and its results
- New screening technologies are emerging in practice
  - Breast MRI, HPV DNA testing, HPV vaccine, CT colonography
  - Optimizing the screening process affects mortality