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Certificate Program in Practice-Based Research Methods (PBRMCert)

Translational Research in Practice-Based Research Networks

April 13, 2017



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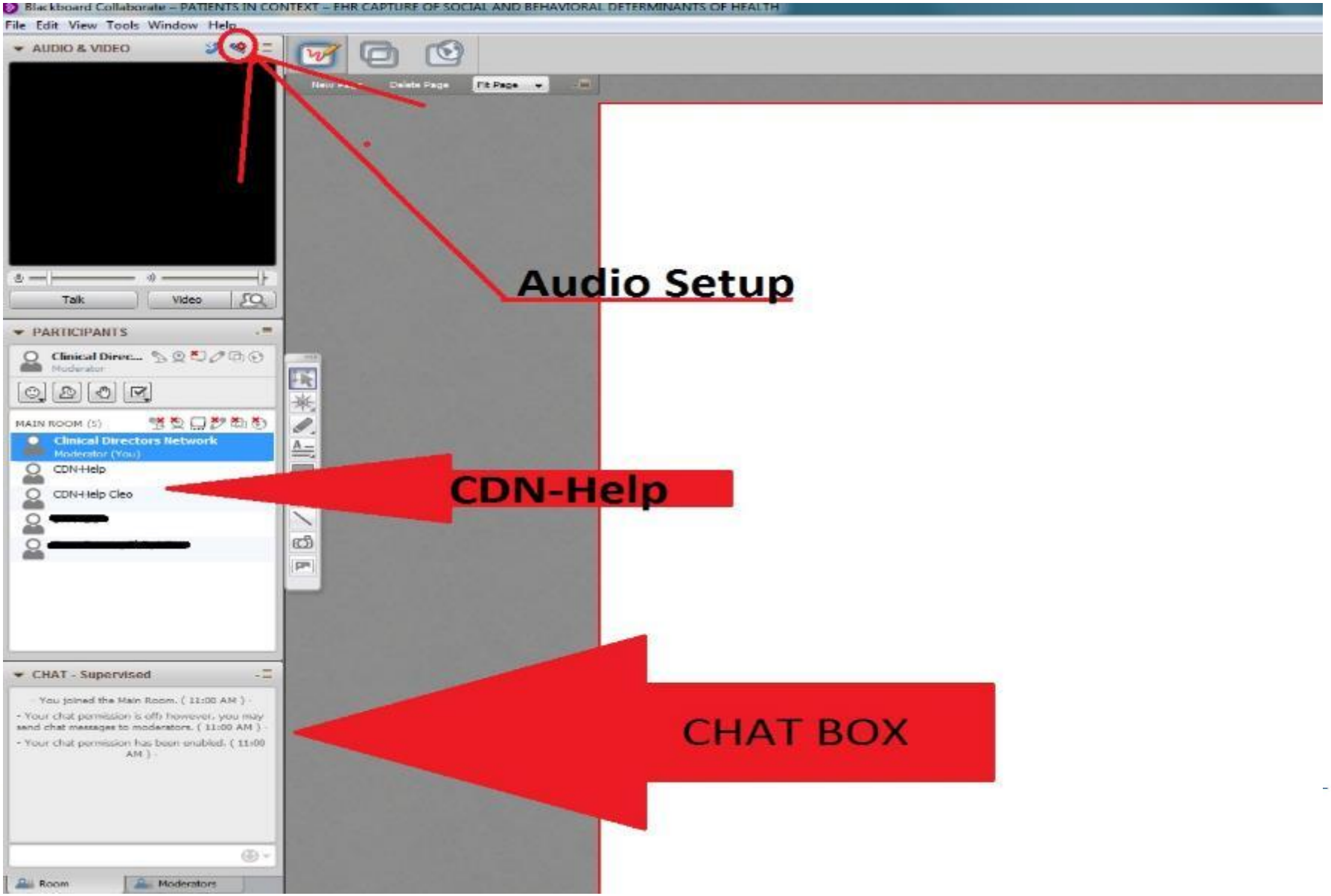

Speakers:

Jonathan N. Tobin, PhD, FAHA, FACE
President/CEO
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Co-Director, Community Engaged Research CORE
The Rockefeller University Center for Clinical & Translational Science

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Translational Research and its Relevance to Practice-Based Research Networks

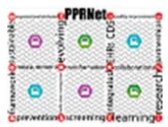
Steven H. Woolf, MD, MPH
Department of Family Medicine and Population Health
Virginia Commonwealth University



Visibility of Translational Research

- CTSA program
- Foundations
- Industry
- Disease-related organizations
- Hospitals and health systems
- Journals





What is “translational research”?



The traditional NIH view

NIH Roadmap FOR MEDICAL RESEARCH

Re-engineering the Clinical Research Enterprise

- Overview
- Implementation Group Members
- Funding Opportunities
- Funded Research
- Meetings
- Presentations

TRANSLATIONAL RESEARCH

OVERVIEW

To improve human health, scientific discoveries must be translated into practical applications. Such discoveries typically begin at "the bench" with basic research—in which scientists study disease at a molecular or cellular level—then progress to the clinical level, or the patient's "bedside."

Scientists are increasingly aware that this bench-to-bedside approach to translational research is really a two-way street. Basic scientists provide clinicians with new tools for use in patients and for assessment of their impact, and clinical researchers make novel observations about the nature and progression of disease that often stimulate basic investigations.

Translational research has proven to be a powerful process that drives the clinical research engine. However, a stronger research infrastructure could strengthen and accelerate this critical part of the clinical research enterprise. The NIH Roadmap attempts to catalyze translational research in various ways, including:



“Bench to Bedside”

Translational Research? →

Translational Research, Classically Defined

- "…effective translation of the new knowledge, mechanisms, and techniques generated by advances in basic science research into new approaches for prevention, diagnosis, and treatment of disease is essential for improving health"

Source: Fontanarosa PB, DeAngelis CD. Basic science and translational research in JAMA. JAMA 2002;287:1728.





EXAM GLOVES


COCONET
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access
mentor
diversity
preventive medicine
Meta-LARC
MOSAIC
PPRNet
PRIME Net

AHRQ (circa 2000)

Agency for Healthcare Research and Quality • 2101 East Jefferson Street • Rockville, MD 20852

In September 2000, the Agency for Healthcare Research and Quality (AHRQ) funded 13 new projects to evaluate different strategies for translating research findings into

quality of health care. What has been learned in the research setting often is not implemented into daily clinical practice. A 1998 review of published studies on the quality of care received

Translating Research into Practice (TRIP)

- Improving access
- Reorganizing and coordinating systems of care
- Helping clinicians and patients to change behaviors and make more informed choices
- Reminders, point-of-care decision support tools
- Strengthening the clinician-patient relationship


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The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

The Quality of Health Care Delivered to Adults in the United States

Elizabeth A. McGlynn, Ph.D., Steven M. Asch, M.D., M.P.H., John Adams, Ph.D., Joan Keesey, B.A., Jennifer Hicks, M.P.H., Ph.D., Alison DeCristofaro, M.P.H., and Eve A. Kerr, M.D., M.P.H.

ABSTRACT

BACKGROUND

We have little systematic information about the extent to which standard processes involved in health care — a key element of quality — are delivered in the United States.

METHODS

We telephoned a random sample of adults living in 12 metropolitan areas in the United States and asked them about selected health care experiences. We also received written

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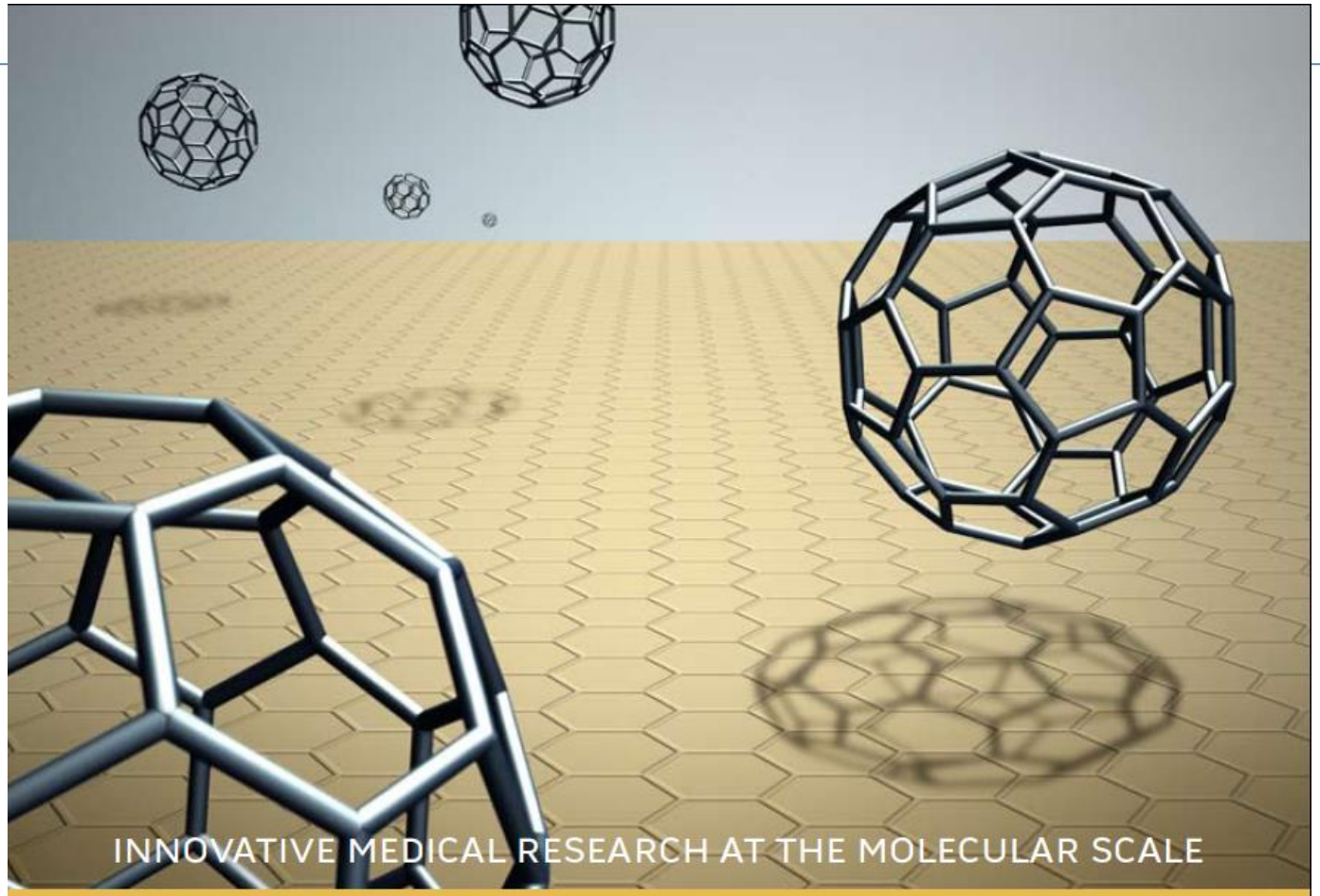
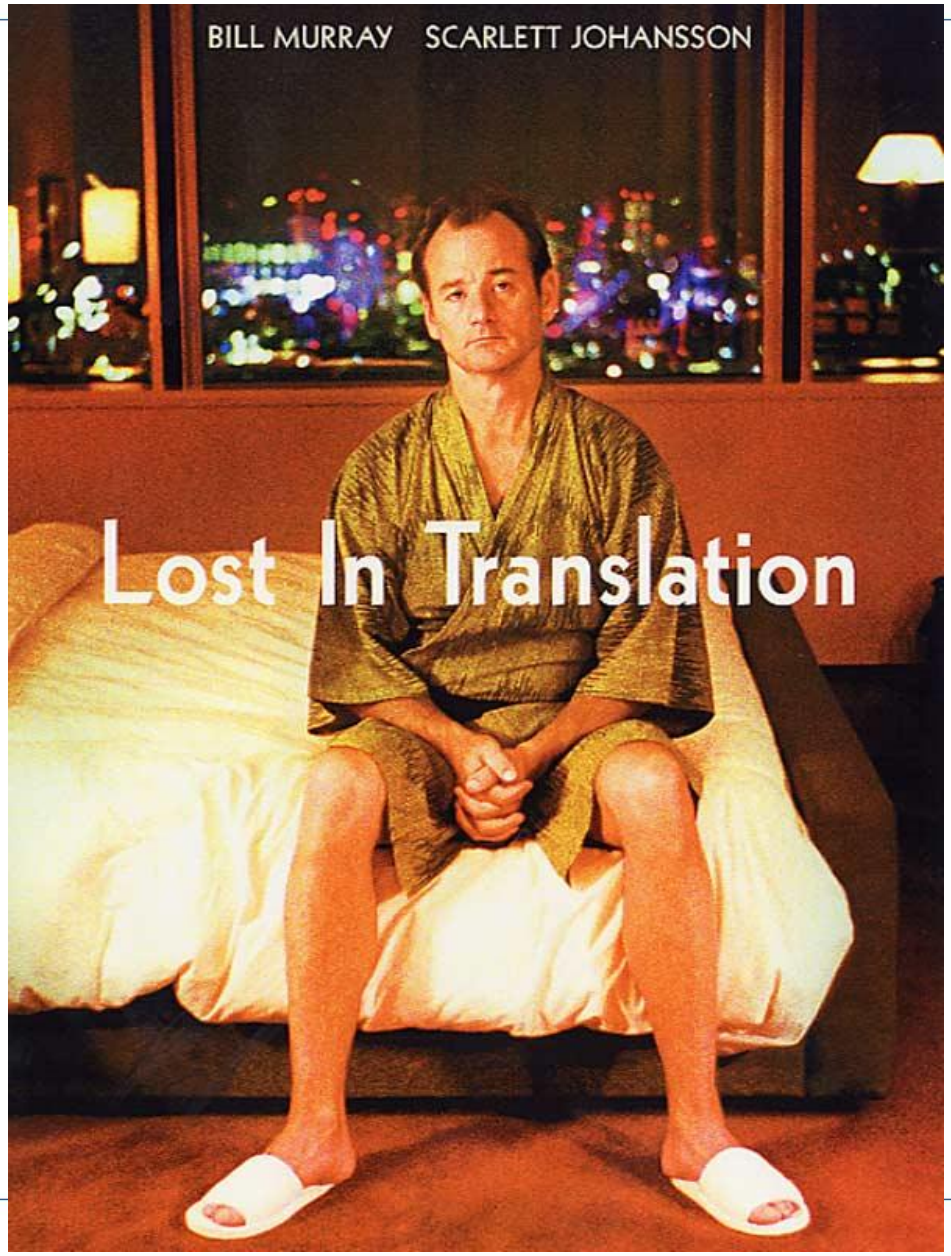


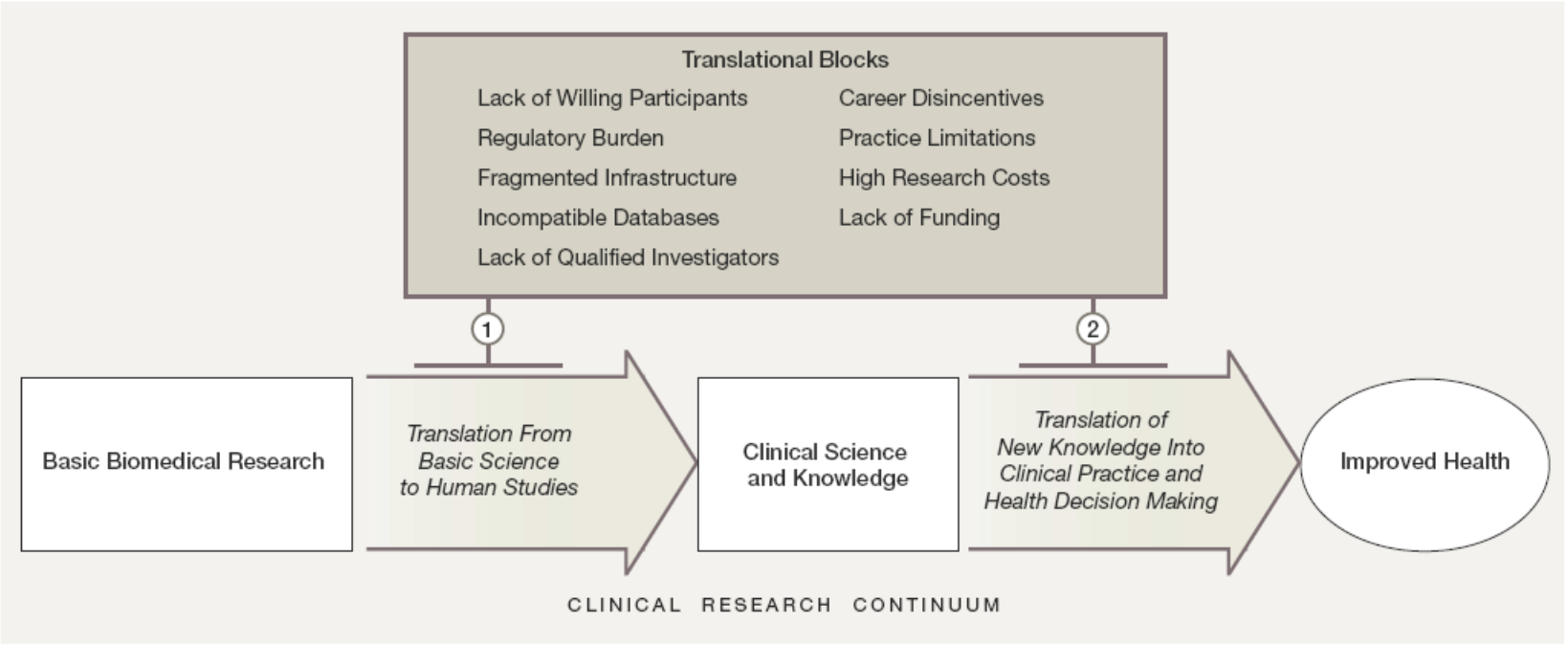
Nanotechnology

AT THE NATIONAL INSTITUTES OF HEALTH


BILL MURRAY SCARLETT JOHANSSON
Lost In Translation

IOM Clinical Research Roundtable

Figure 1. The 2 Translational Blocks in the Clinical Research Continuum



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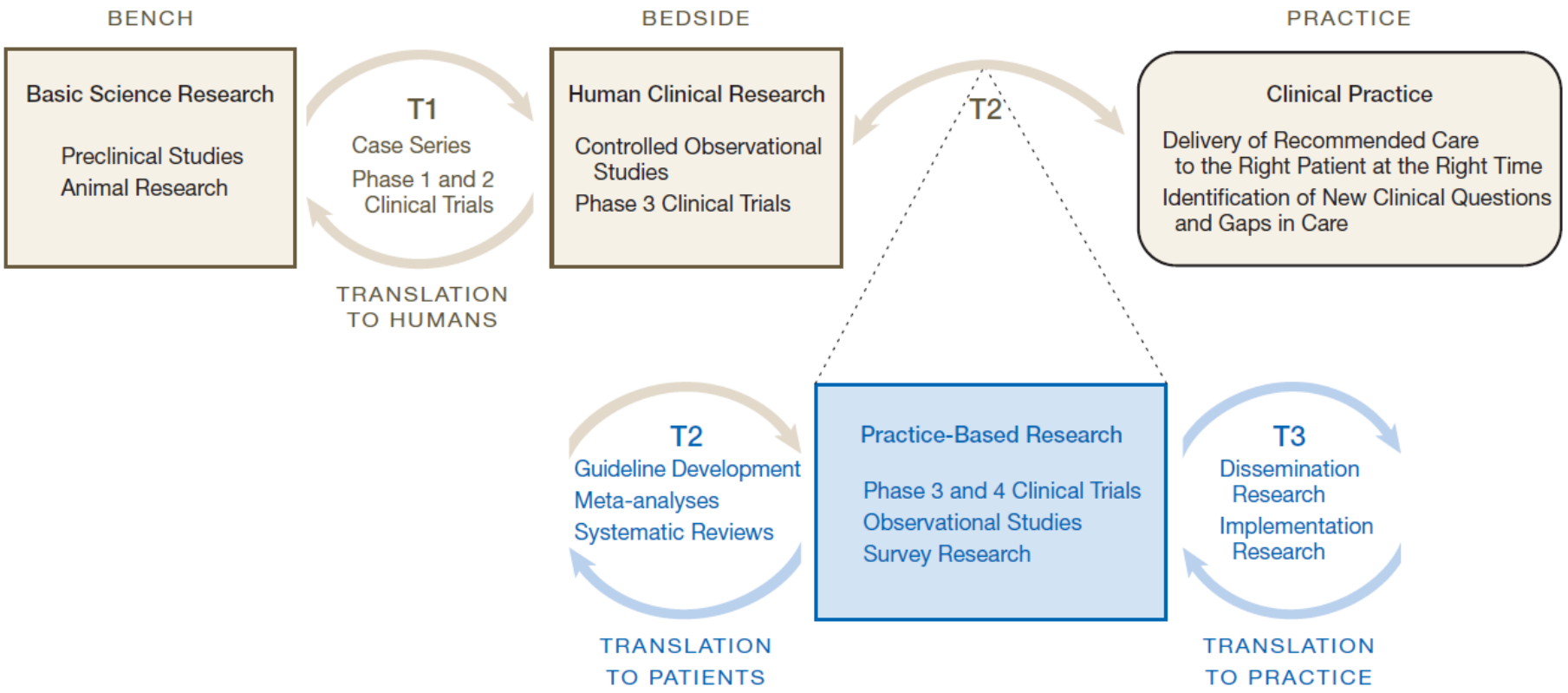
The Blue Highways model

Figure. "Blue Highways" on the NIH Roadmap



Westfall, Mold, and Fagnan. *JAMA.* 2007;297(4):403-406




T1 and T2

- T1: "The transfer of new understandings of disease mechanisms gained in the laboratory into the development of new methods for diagnosis, therapy, and prevention and their first testing in humans."

- T2: "The translation of results from clinical studies into everyday clinical practice and health decision making."

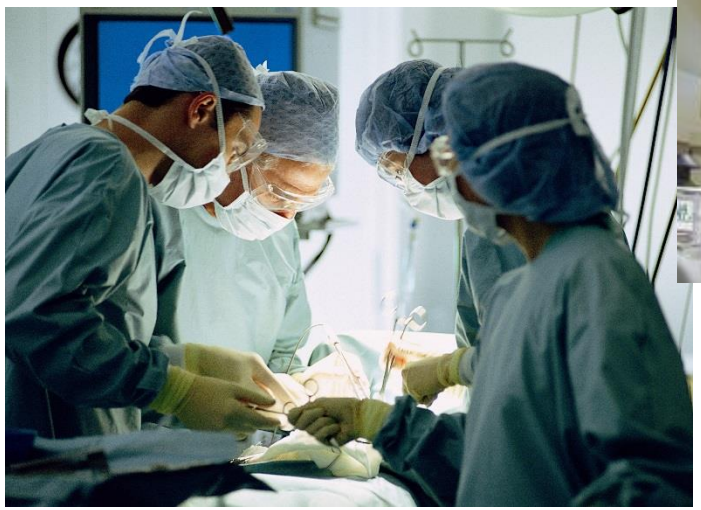
[redacted]

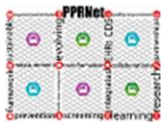
T1 and T2:
Translational Research Alike in Name Only

- Goals
- Settings
- Study designs
- Investigators



The Laboratory of T1





The "Laboratory" of T2

COCONet · COIN · Meta-LARC · MOSAIC · PPRNet · PRIME Net

Resources Needed for T1

- Mastery of molecular biology, genetics, and other basic sciences
- Appropriately trained clinical scientists
- Strong laboratories
- Cutting-edge technology
- Supportive infrastructure within the institution


TIME
THERE IS NEW AMMUNITION IN THE WAR AGAINST CANCER.
THESE ARE THE BULLETS.
Revolutionary new pills like GLEEVEC combat cancer by targeting only the diseased cells. Is this the breakthrough we've been waiting for?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PPRNet
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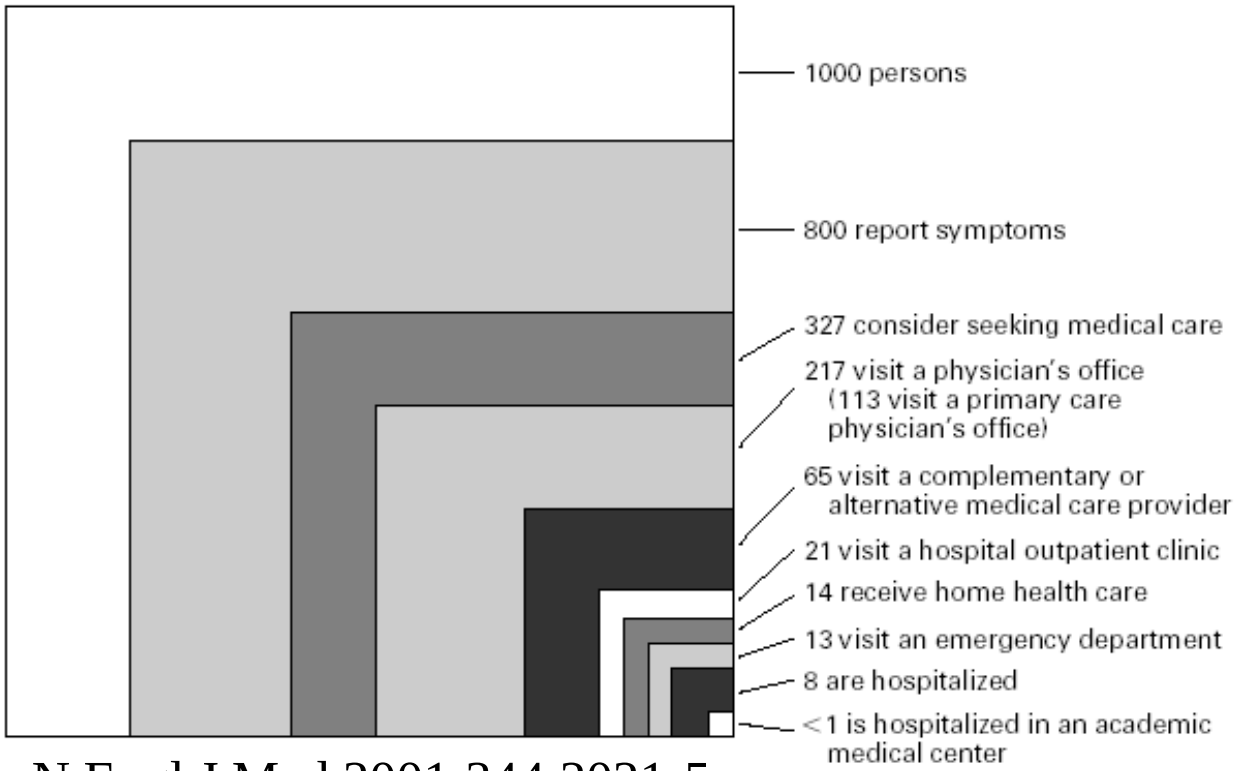
screening
learning
research


PRIME Net

The "Ecology" of Medical Care



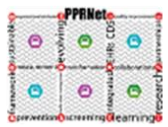
Green LA, et al. N Engl J Med 2001;344:2021-5.

Resources Needed for T2

"Implementation science": evaluating interventions in real-world settings

- Clinical epidemiology and evidence synthesis
- Communication theory
- Behavioral science
- Public policy
- Financing
- Organizational theory
- System redesign
- Informatics
- Mixed methods/qualitative research



The Dominant Challenges

- Biological and technological mysteries
- Trial recruitment
- Regulatory concerns

- Human behavior
- Organizational inertia
- Infrastructure and resource constraints
- Messiness of “moving targets” and conditions that investigators cannot fully control

The Conventional "Afferent" Model

Community practitioners

Subject recruitment

Clinical Trials

Bidirectional Collaborative Research

Formulating research questions

Generalizable populations

Evaluations of effectiveness

Evaluation of systems for delivering interventions

Translational Research and its Relevance to Practice-Based Research Networks

Jonathan N. Tobin, PhD, FAHA, FACE

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Clinical Directors Network, Inc (CDN)
Co-Director, Community Engaged Research CORE
The Rockefeller University Center for Clinical & Translational Science
New York, NY
JNTobin@CDNetwork.org

PBRMCert Training Session April 13, 2017

Clinical Directors Network, Inc.

A Practice-based Research Network (PBRN) that works with
Primary Health Care Safety-net Practices

Research Infrastructure to build a Learning Healthcare System




CDN N²: Building a Network of Safety Net PBRNs
AHRQ Center of Excellence for Practice-based Research and Learning

- A collaboration among:
  - Access Community Health Network (ACCESS)
  - Alliance of Chicago (ALLIANCE)
  - Association of Asian Pacific Community Health Organization (AAPCHO)
  - Center for Community Health Education Research and Service (CCHERS)
  - **Clinical Directors Network (CDN) [LEAD PBRN]**
  - Community Health Applied Research Network (CHARN)
  - Fenway Institute (FENWAY)
  - New York City Research and Improvement Group (NYCRING)
  - Oregon Community Health Information Network (OCHIN)
  - South Texas Ambulatory Research Network (STARNet)

Funded by AHRQ Grant: P30 HS 021667

Principal Investigator: Jonathan N. Tobin, PhD (CDN)
Project Officer: Rebecca A. Roper, MS, MPH Director, AHRQ PBRN Initiative

AHRQ N² PBRN

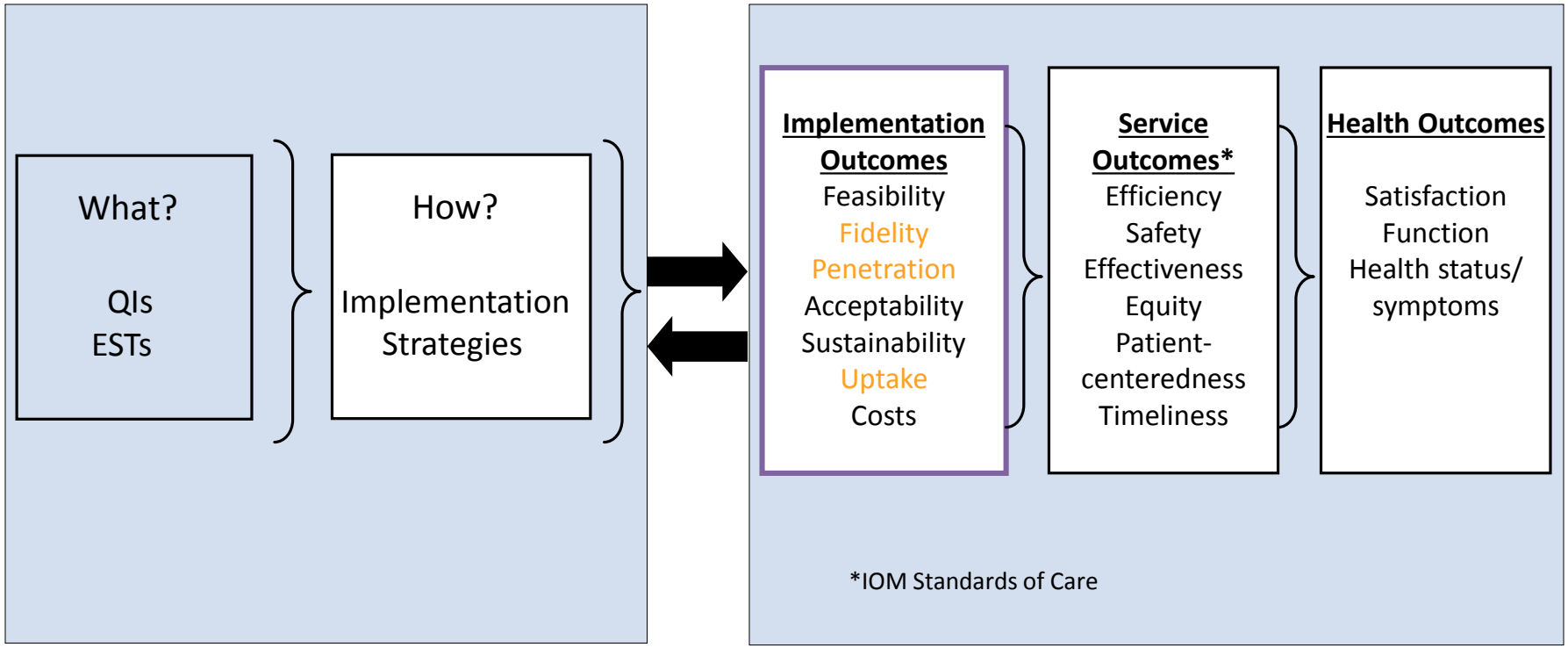
Types of Research Conducted in PBRNs

- Descriptive
- Observational
- **Experimental – Randomized Controlled Trials (RCTs) [including: cluster, individual & pragmatic]**
- Dissemination & Implementation (D&I)
- Quality Improvement Projects



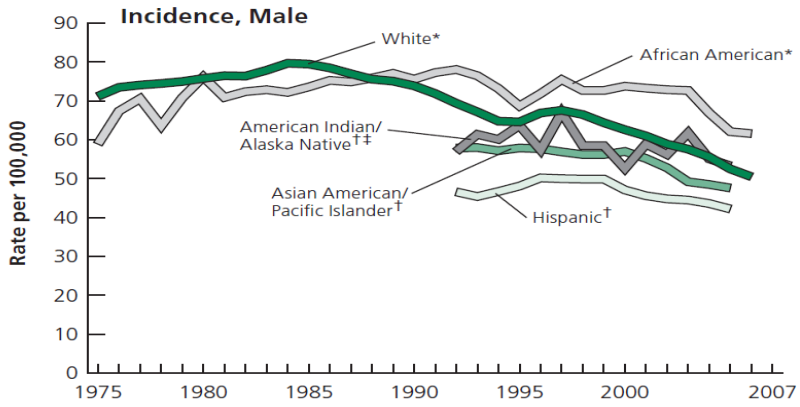
Studying Implementation

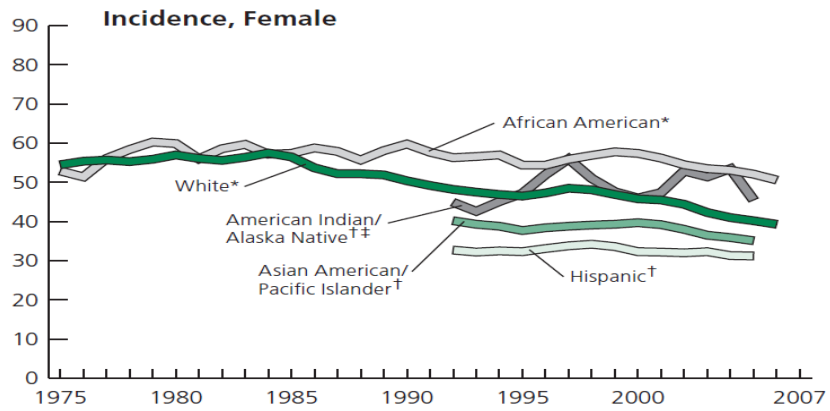
Proctor et al 2009 *Admin. & Pol. in Mental Health & Mental Health Services Research*
(Adapted from : David Chambers, DPhil Associate Director, NIMH D&I Research
American College of Epidemiology D&I Research Workshop 2014)

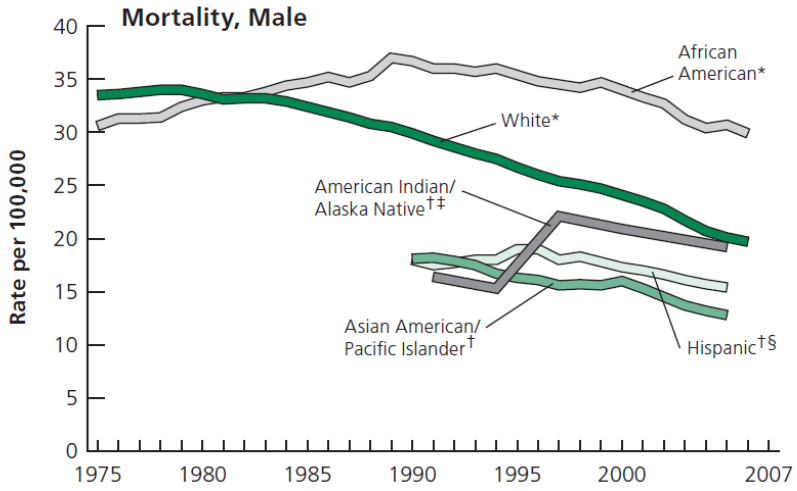


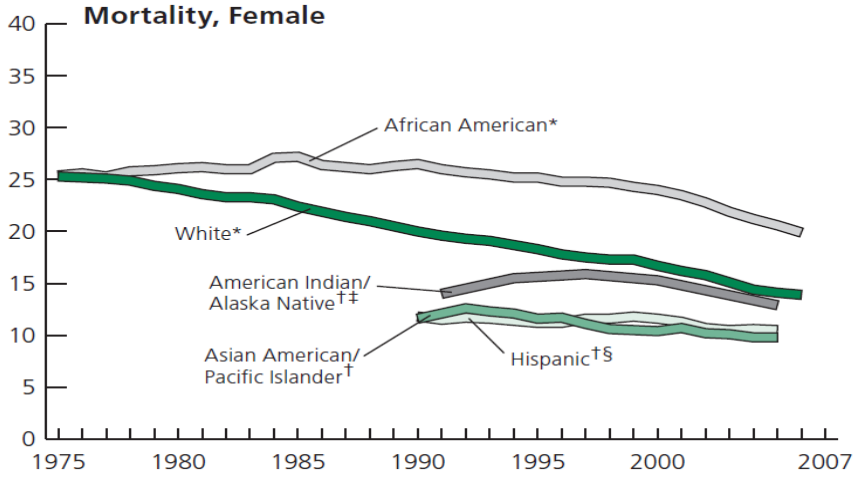
Implementation Research Methods

Trends in Colorectal Cancer Incidence & Mortality Rates by Race/Ethnicity and Sex, 1975-2007

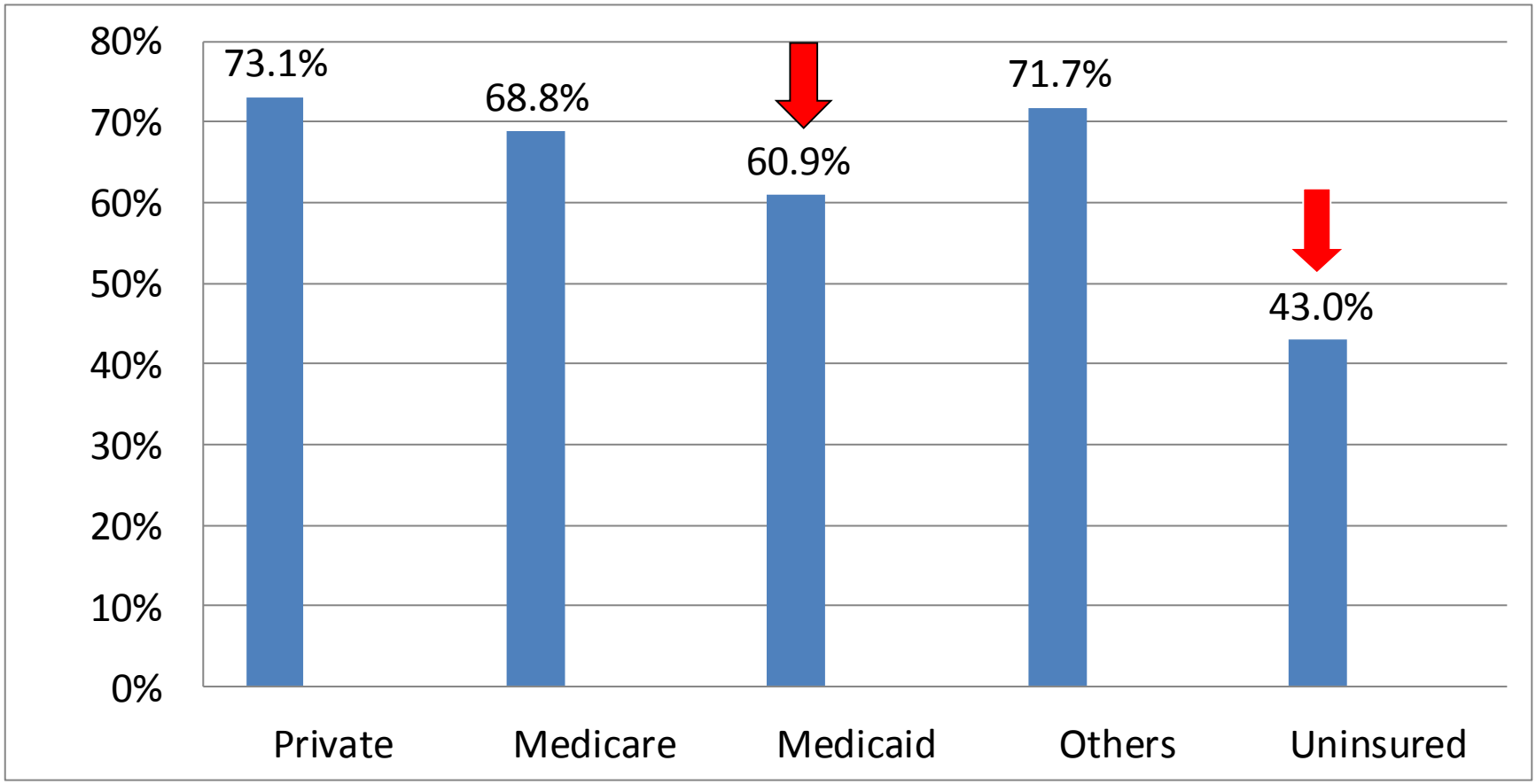








Colonoscopy Screening Rate by Health Insurance, NYC, 2010



Background

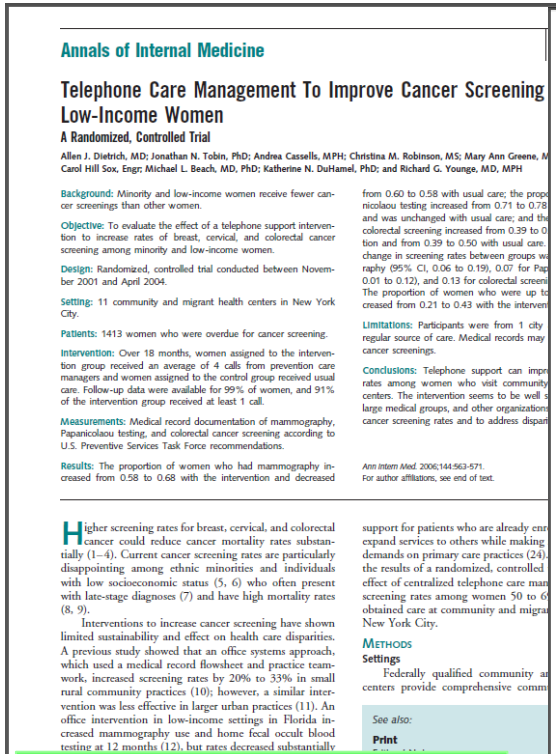
- We describe the results from three previous NCI-funded RCTs conducted in NYC Federally Qualified Health Centers (FQHCs) and Medicaid Managed Care Organizations (MMCOs) as the transition **from Efficacy to Effectiveness to Dissemination & Implementation**

- These three RCTs conducted with FQHCs and Medicaid Managed Care Organizations informed our current patient-centered outcomes research (PCOR) study comparing two evidence-based care management (CM) strategies **to improve mental health and cancer screening outcomes for low-income women who receive primary care from Bronx NY Community Health Centers (CHCs)**
  - "Cancer Prevention Care Management " (PCM) alone
  - PCM with added "Depression Collaborative Care Intervention" (CCI)



Prevention Care Management (PCM)

RCTs (2000-2012)



Annals of Internal Medicine

Telephone Care Management To Improve Cancer Screening Low-Income Women

A Randomized, Controlled Trial

Allen J. Dietrich, MD; Jonathan N. Tobin, PhD; Andrea Cassells, MPH; Christina M. Robinson, MS; Mary Ann Greene, M
Carol Hill Sox, Engr; Michael L. Beach, MD, PhD; Katherine N. DuHamel, PhD; and Richard G. Younge, MD, MPH

Background: Minority and low-income women receive fewer cancer screenings than other women.

Objective: To evaluate the effect of a telephone support intervention to increase rates of breast, cervical, and colorectal cancer screening among minority and low-income women.

Design: Randomized, controlled trial conducted between November 2001 and April 2004.

Setting: 11 community and migrant health centers in New York City.

Patients: 1413 women who were overdue for cancer screening.

Intervention: Over 18 months, women assigned to the intervention group received an average of 4 calls from prevention care managers and women assigned to the control group received usual care. Follow-up data were available for 99% of women, and 91% of the intervention group received at least 1 call.

Measurements: Medical record documentation of mammography, Papanicolaou testing, and colorectal cancer screening according to U.S. Preventive Services Task Force recommendations.

Results: The proportion of women who had mammography increased from 0.58 to 0.68 with the intervention and decreased from 0.60 to 0.58 with usual care; the propo nicolaou testing increased from 0.71 to 0.78 and was unchanged with usual care; and the colorectal screening increased from 0.39 to 0 tion and from 0.39 to 0.50 with usual care. change in screening rates between groups wa raphy (95% CI, 0.06 to 0.19), 0.07 for Pap 0.01 to 0.12), and 0.13 for colorectal screeni The proportion of women who were up to creased from 0.21 to 0.43 with the interven

Limitations: Participants were from 1 city regular source of care. Medical records may cancer screenings.

Conclusions: Telephone support can impr rates among women who visit community centers. The intervention seems to be well s large medical groups, and other organizations cancer screening rates and to address dispar

Ann Intern Med. 2006;144:563-571.
For author affiliations, see end of text.

Higher screening rates for breast, cervical, and colorectal cancer could reduce cancer mortality rates substantially (1–4). Current cancer screening rates are particularly disappointing among ethnic minorities and individuals with low socioeconomic status (5, 6) who often present with late-stage diagnoses (7) and have high mortality rates (8, 9).

Interventions to increase cancer screening have shown limited sustainability and effect on health care disparities. A previous study showed that an office systems approach, which used a medical record flowsheet and practice teamwork, increased screening rates by 20% to 33% in small rural community practices (10); however, a similar intervention was less effective in larger urban practices (11). An office intervention in low-income settings in Florida increased mammography use and home fecal occult blood testing at 12 months (12), but rates decreased substantially

support for patients who are already enr expand services to others while making demands on primary care practices (24). the results of a randomized, controlled effect of centralized telephone care man screening rates among women 50 to 6 obtained care at community and migra New York City.

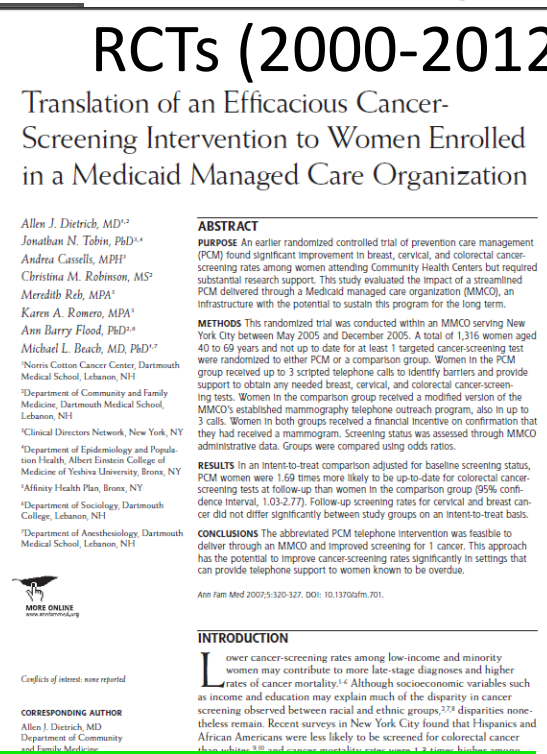
Methods

Settings

Federally qualified community a centers provide comprehensive comm

See also:

Print



Translation of an Efficacious Cancer-Screening Intervention to Women Enrolled in a Medicaid Managed Care Organization

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Conflicts of interest: none reported

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ABSTRACT

PURPOSE An earlier randomized controlled trial of prevention care management (PCM) found significant improvement in breast, cervical, and colorectal cancer-screening rates among women attending Community Health Centers but required substantial research support. This study evaluated the impact of a streamlined PCM delivered through a Medicaid managed care organization (MMCO), an infrastructure with the potential to sustain this program for the long term.

METHODS This randomized trial was conducted within an MMCO serving New York City between May 2005 and December 2005. A total of 1,316 women aged 40 to 69 years and not up to date for at least 1 targeted cancer-screening test were randomized to either PCM or a comparison group. Women in the PCM group received up to 3 scripted telephone calls to identify barriers and provide support to obtain any needed breast, cervical, and colorectal cancer-screening tests. Women in the comparison group received a modified version of the MMCO's established mammography telephone outreach program, also in up to 3 calls. Women in both groups received a financial incentive on confirmation that they had received a mammogram. Screening status was assessed through MMCO administrative data. Groups were compared using odds ratios.

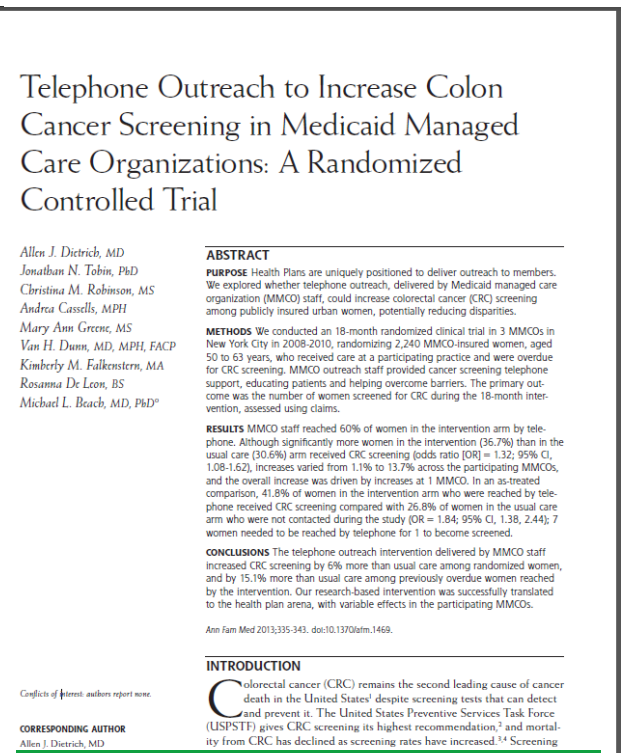
RESULTS In an intent-to-treat comparison adjusted for baseline screening status, PCM women were 1.69 times more likely to be up-to-date for colorectal cancer-screening tests at follow-up than women in the comparison group (95% confidence interval, 1.03-2.77). Follow-up screening rates for cervical and breast cancer did not differ significantly between study groups on an intent-to-treat basis.

CONCLUSIONS The abbreviated PCM telephone intervention was feasible to deliver through an MMCO and improved screening for 1 cancer. This approach has the potential to improve cancer-screening rates significantly in settings that can provide telephone support to women known to be overdue.

Ann Fam Med 2007;5:320-327. DOI: 10.1370/afm.701.

INTRODUCTION

Lower cancer-screening rates among low-income and minority women may contribute to more late-stage diagnoses and higher rates of cancer mortality.[1-6] Although socioeconomic variables such as income and education may explain much of the disparity in cancer screening observed between racial and ethnic groups,[2,7,8] disparities nonetheless remain. Recent surveys in New York City found that Hispanics and African Americans were less likely to be screened for colorectal cancer



Telephone Outreach to Increase Colon Cancer Screening in Medicaid Managed Care Organizations: A Randomized Controlled Trial

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Andrea Cassells, MPH
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Kimberly M. Falkenstern, MA
Rosanna De Leon, BS
Michael L. Beach, MD, PhD

ABSTRACT

PURPOSE Health Plans are uniquely positioned to deliver outreach to members. We explored whether telephone outreach, delivered by Medicaid managed care organization (MMCO) staff, could increase colorectal cancer (CRC) screening among publicly insured urban women, potentially reducing disparities.

METHODS We conducted an 18-month randomized clinical trial in 3 MMCOs in New York City in 2008-2010, randomizing 2,240 MMCO-insured women, aged 50 to 63 years, who received care at a participating practice and were overdue for CRC screening. MMCO outreach staff provided cancer screening telephone support, educating patients and helping overcome barriers. The primary outcome was the number of women screened for CRC during the 18-month intervention, assessed using claims.

RESULTS MMCO staff reached 60% of women in the intervention arm by telephone. Although significantly more women in the intervention (36.7%) than in the usual care (30.6%) arm received CRC screening (odds ratio [OR] = 1.32; 95% CI, 1.08-1.62), increases varied from 1.1% to 13.7% across the participating MMCOs, and the overall increase was driven by increases at 1 MMCO. In an as-treated comparison, 41.8% of women in the intervention arm who were reached by telephone received CRC screening compared with 26.8% of women in the usual care arm who were not contacted during the study (OR = 1.84; 95% CI, 1.38, 2.44); 7 women needed to be reached by telephone for 1 to become screened.

CONCLUSIONS The telephone outreach intervention delivered by MMCO staff increased CRC screening by 6% more than usual care among randomized women, and by 15.1% more than usual care among previously overdue women reached by the intervention. Our research-based intervention was successfully translated to the health plan arena, with variable effects in the participating MMCOs.

Ann Fam Med 2013;335-343. doi:10.1370/afm.1469.

INTRODUCTION

Colorectal cancer (CRC) remains the second leading cause of cancer death in the United States[1] despite screening tests that can detect and prevent it. The United States Preventive Services Task Force (USPSTF) gives CRC screening its highest recommendation,[2] and mortality from CRC has declined as screening rates have increased.[3,4] Screening

Conflicts of interest: authors report none.

CORRESPONDING AUTHOR
Allen J. Dietrich, MD

Efficacy → **Effectiveness** → **Dissemination & Implementation**

PCM1 (2000-2004)

PCMT (2003-2005)

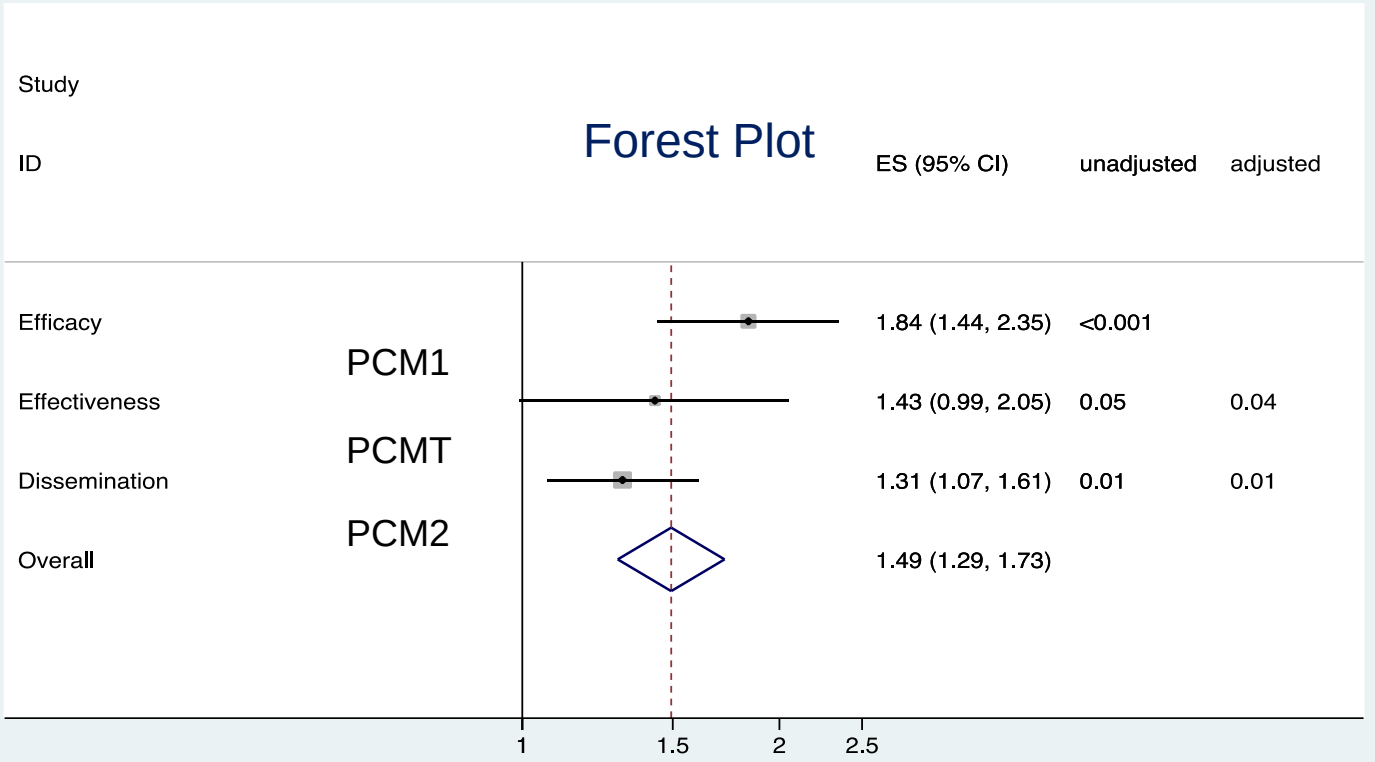
PCM2 (2006-2012)

Funded by NCI Grants R01-CA87776 & RO1-CA119014 (A. Dietrich, PI; J.N. Tobin, Co-PI)

PCM Intervention Delivery

Intervention Components	PCM1	PCMT	PCM2	PCM3
Intervention Components				
Mail clinician recommendation letter to patient	√	–	√	√
Mail activation card to patient	√	–	√	√
Mail screening test-specific educational material to patient	√	–	√	√
Confirmed and updated screening dates	√	√	√	√
Discuss and provide support on barriers using script	√	√	√	√
Schedule screening appointments	√	–	√ (as needed)	√ (as needed)
Reminder calls	√	–	√	√
Reminder letters	√	–	√	√

Meta-analysis of Odds Ratios:
Colo-rectal Cancer Screening in 3 NCI-Funded CDN PCM RCTs

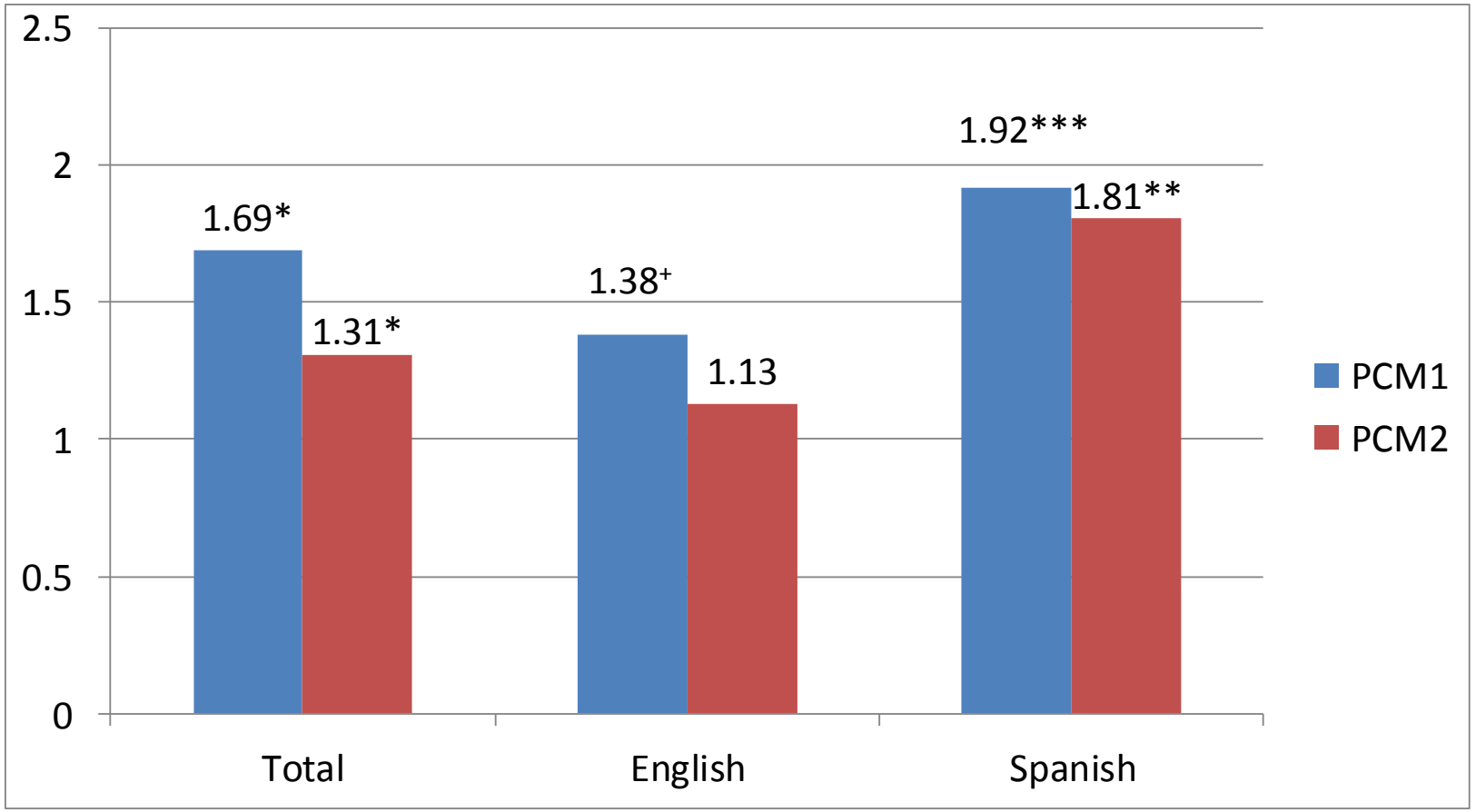


$I^2 = 54.8\%$, $p = 0.109$

Results by Language

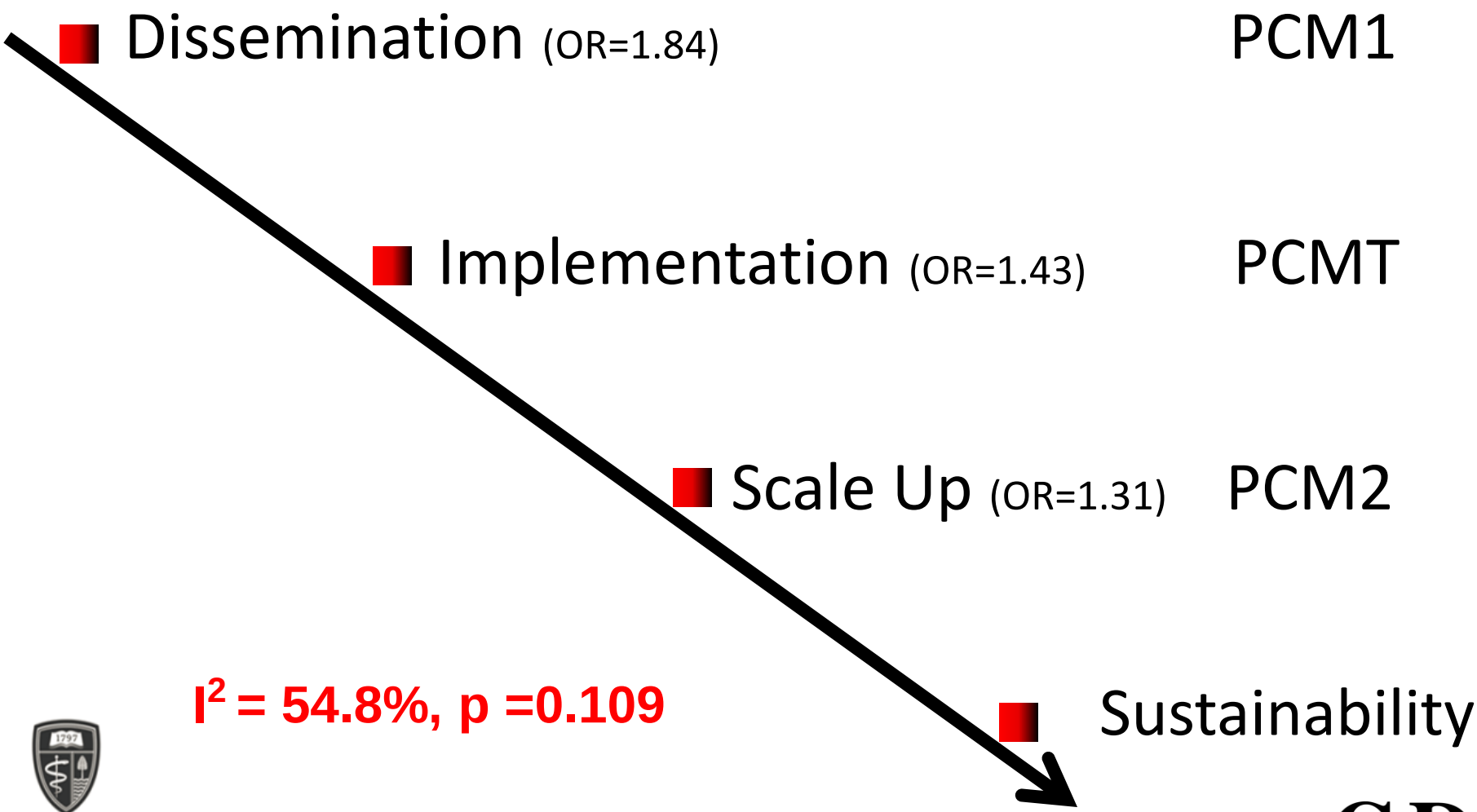
	PCM 1	PCM2	
Total	1.69 *	1.31 *	+
English	1.38 +	1.13	NS
Spanish	1.92 ***	1.81**	NS
+ P <0.10	* P < 0.05	** P <0.01	*** P<0.001

Results by Language



+ P <0.10 * P < 0.05 ** P <0.01 *** P<0.001

Enduring Resources for:



$I^2 = 54.8\%, p = 0.109$

GEISEL SCHOOL OF MEDICINE AT DARTMOUTH

CDN CLINICAL•DIRECTORS•NETWORK

Policy Implications

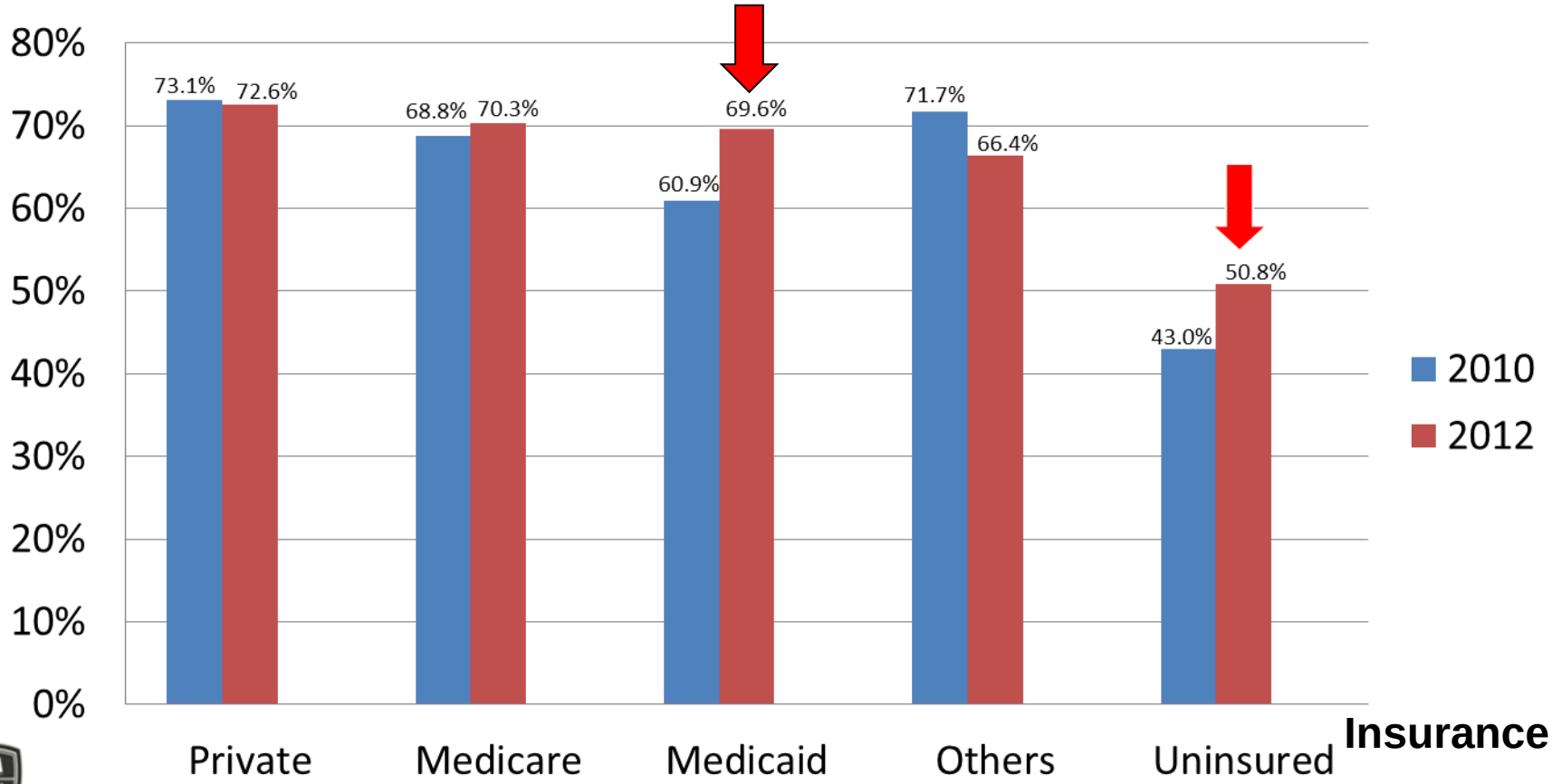
1. CHCs, DTCs, PCPs and other primary care practices with large numbers of Spanish speaking patients can benefit from the PCM intervention

2. PCM is an innovative and effective strategy that can be implemented across a multiple range of practice settings (in FQHCs, MCOs, ACOs, and PCMHs) to enhance CRC screening rates and reduce cancer health disparities

3. PCM is transferrable and can be adapted into cancer early detection Quality Improvement (QI) Initiatives

4. NEXT: Can PCM be generalized to address mental health needs of underserved populations when integrated into primary care and mental health services ?

Colonoscopy Screening Rates with Patient Navigation Program by Health Insurance, NYC, 2010 & 2012



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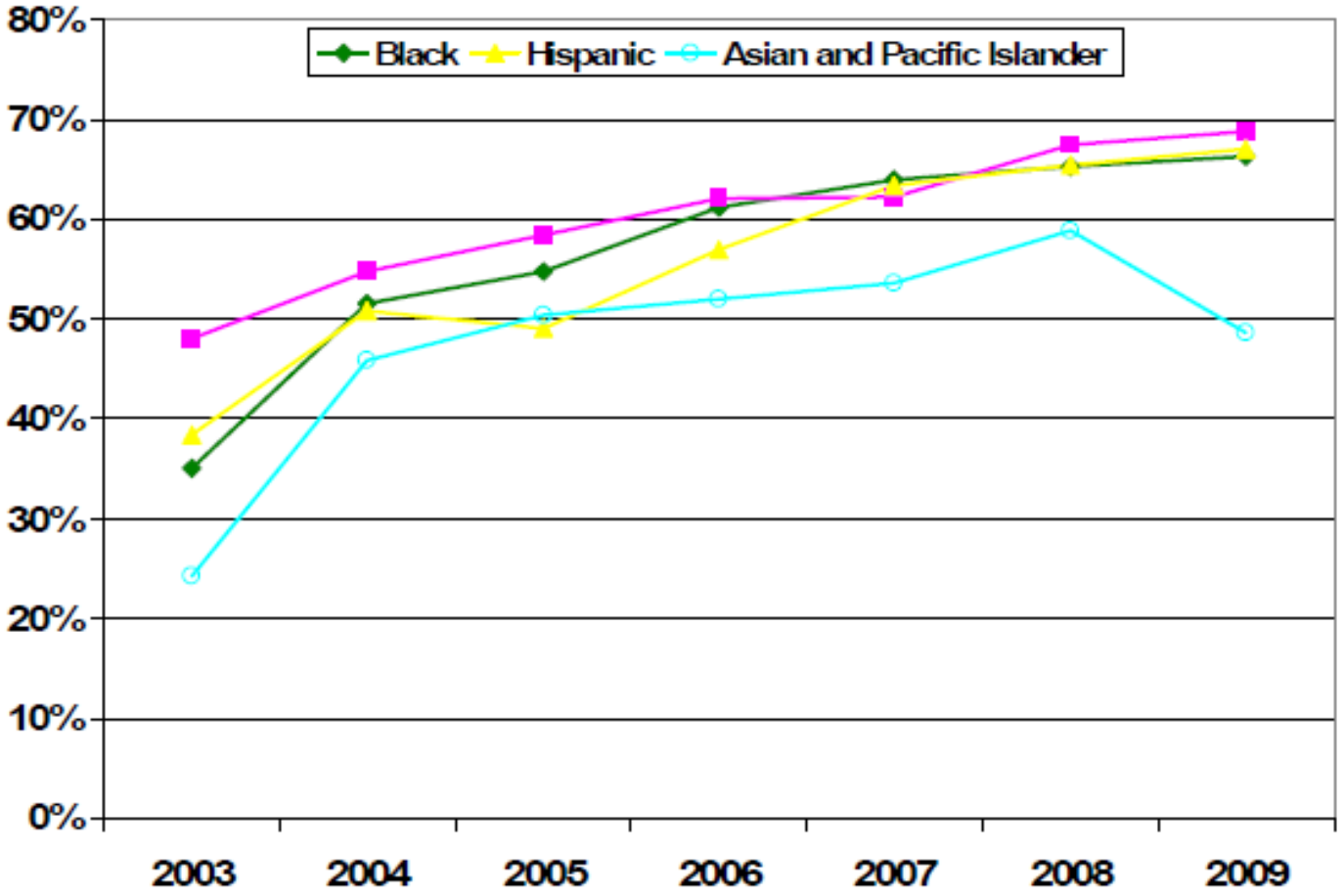
Colonoscopy Rates by Race/Ethnicity NYC, 2003-2009

Source: NYC Community Health Survey.



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Meta-LARC

MOSAIC

PPRNet

PRIME-Net

Acknowledgements

Participating Sites

- Bedford Stuyvesant Family Health Center
- Betances Health Center
- Boriken Community Health Center
- Boro Park Medical P.C.
- Brownsville Multi-Service Family Health Center
- Caribbean-American Family Health Center
- Cumberland Diagnostic & Treatment Center
- East New York Diagnostic & Treatment Center
- Family Physician Health Center
- Gouverneur HealthCare Services
- Jacobi Health Center at Tremont
- Joseph P. Addabbo Family Health Center
- Martin Luther King Jr. Health Center
- Montefiore Comprehensive Family Care Center
- Morris Heights Community Health Center
- Morrisania Diagnostic & Treatment Center
- Park Ridge Health Center
- Park Slope Family Health Center
- Physician Health Center
- Ryan-NENA Community Health Center
- Segundo Ruiz Belvis Diagnostic & Treatment Center
- Shore Road Family Health Center
- Soundview Health Center
- Sunset Park Family Health Center
- Urban Health Plan
- William F. Ryan Community Health Center
- Susan Levit Quality Care Diagnostic and Treatment Center

Participating Health Plans

Affinity, Bronx, NY
AmeriChoice, New York, NY
Health Plus, Brooklyn, NY
MetroPlus, New York, NY

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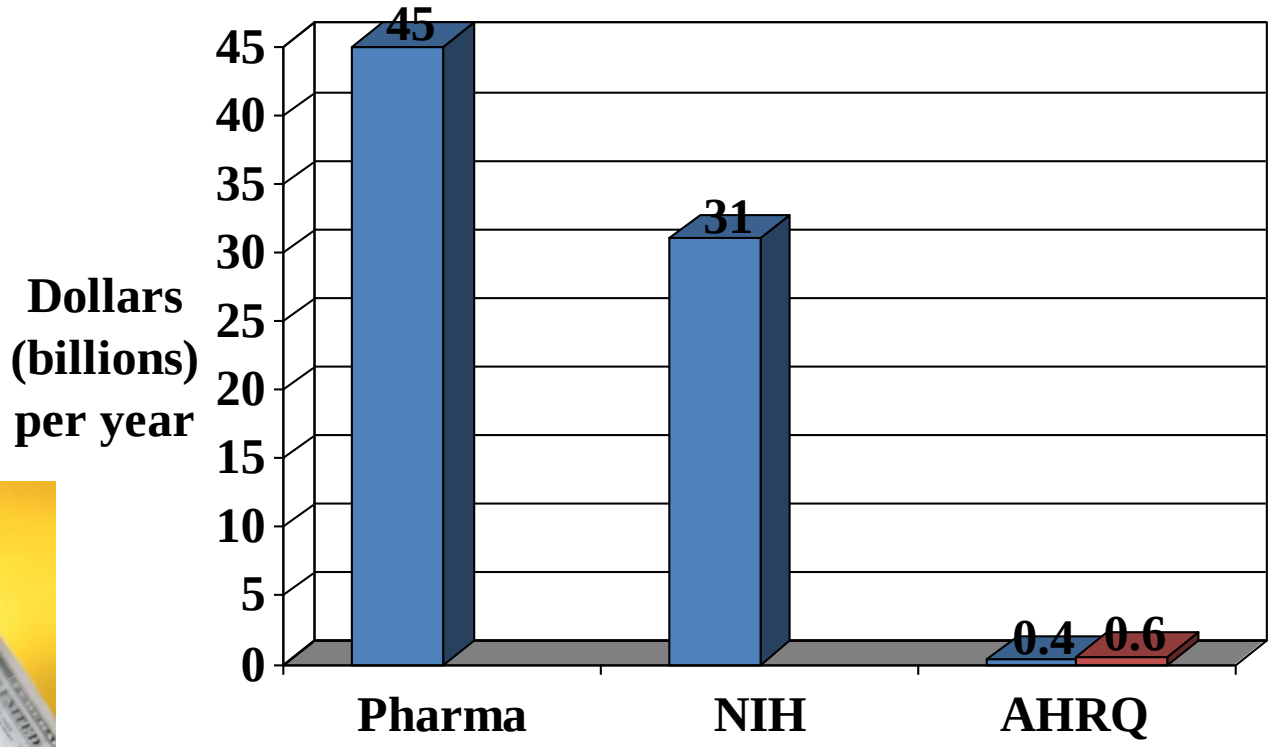
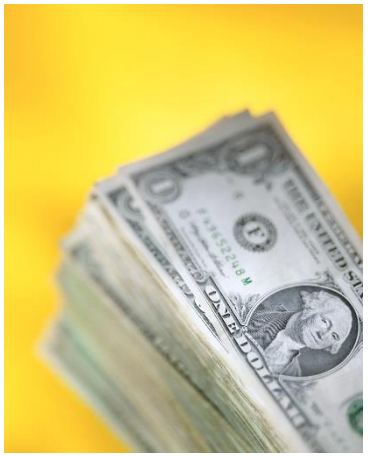
CDN CLINICAL•DIRECTORS•NETWORK

Societal Preference

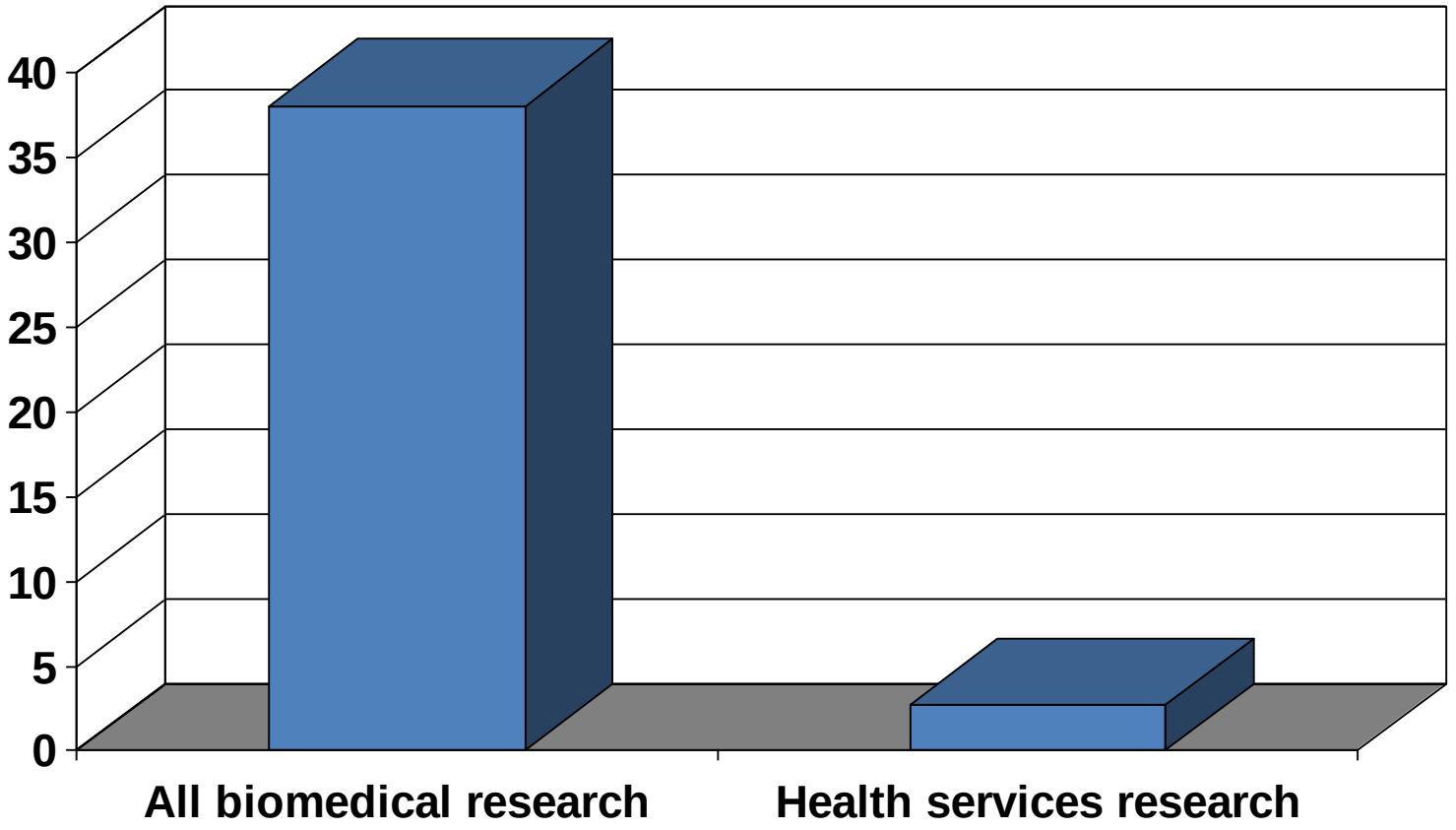




Sources: http://www.phrma.org/files/attachments/2008%20Profile.pdf; http://www.nih.gov/about/budget.htm; http://www.ahrq.gov/about/cj2011/cjweb11over.htm#Overview




Federal Spending, 2011

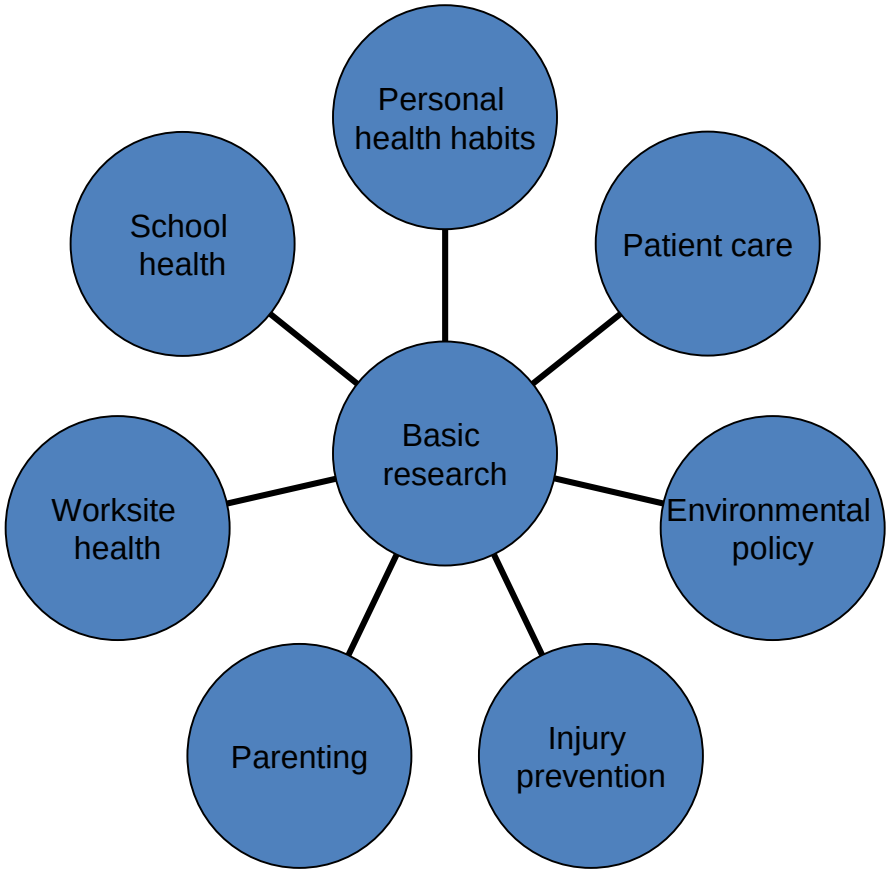


Moses et al. *JAMA*. 2015 Jan 13;313(2):174-89.

T2 Community Is Still Defining Itself

- Translational research
- Translating research into practice (TRIP)
- Dissemination science
- Health services research
- Knowledge translation
- Knowledge transfer
- Implementation science
- Quality improvement research
- Comparative effectiveness research
- Patient-centered health research

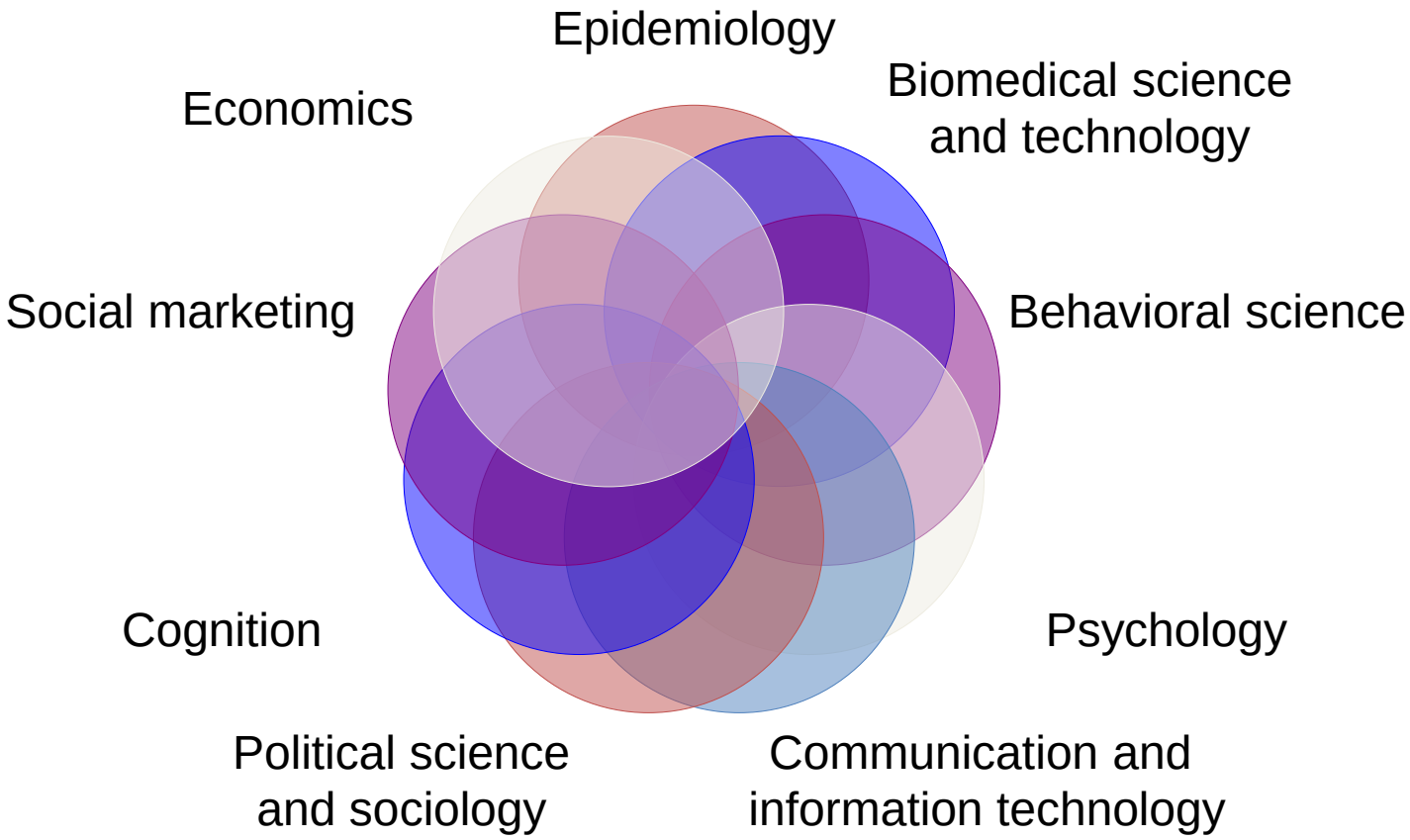
Where T2 Occurs



“Practitioners” Who Apply Evidence

- Health care professionals and hospitals
- Patients and the public
- Public health administrators
- Employers
- School officials
- Regulating bodies and policymakers
- Product designers
- Food industry

Larger Dimensions of Basic Science



What T2 Needs

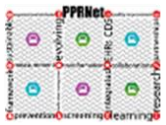
- A new name: “translational research” is too vague
- Not using the same label for T1 and T2 would reduce confusion
- New recognition and emphasis
- Policymakers need to understand distinction between inventing treatments and getting them used
- T2 salvages investment in T1 research


COCONNECT


COIN
access
collaboration
diversity prioritized
mentor
preventive medicine


Meta-LARC


education
MOSAIC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