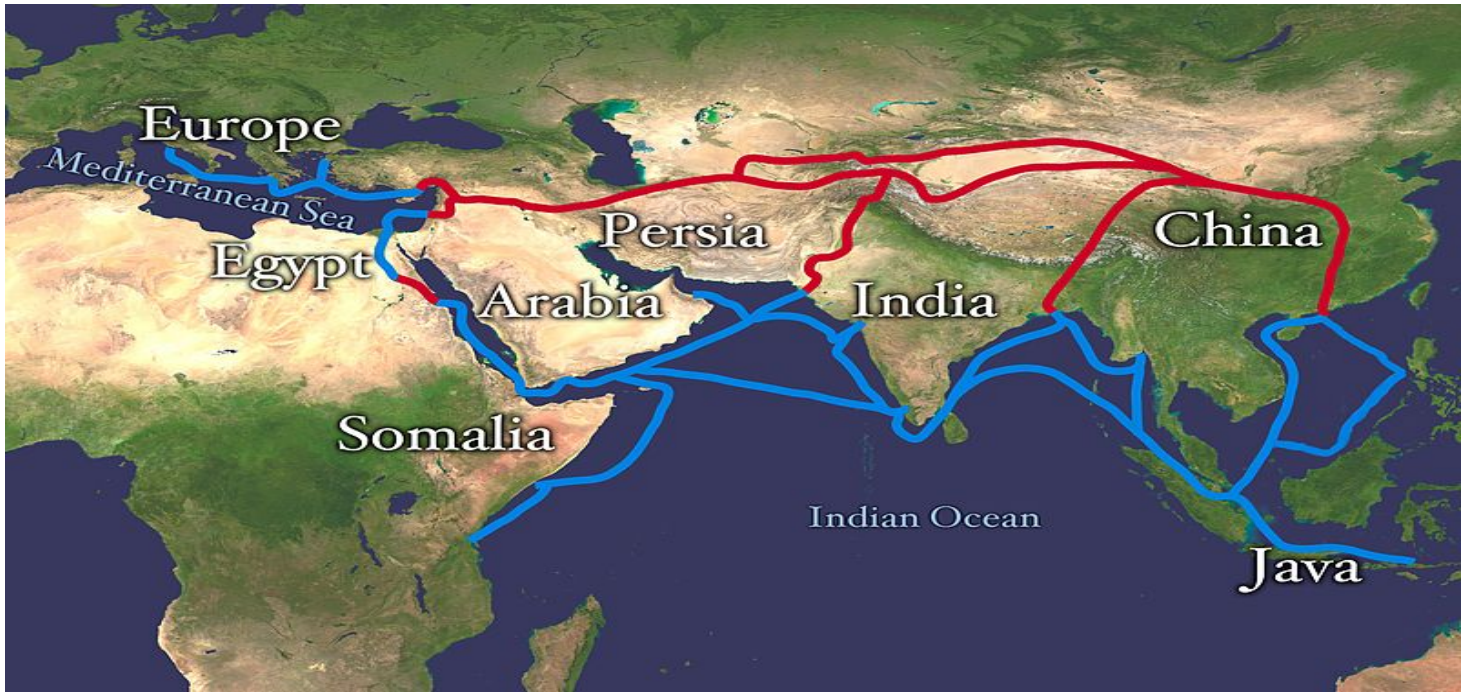
Biomedical science and public health: Intersecting on the silk road



Irma E. Arispe, PhD.
Associate Director, Analysis and Epidemiology
National Center for Health Statistics
Centers for Disease Control and Prevention
Presentation to NIH SMRB, June 11, 2013

There are many pathways from research to outcome (and back)

Bench to bedside

- Data from RCTs provide evidence
- Body of evidence informs clinical recommendations; Evidence based recommendations are diffused into clinical practice
- Improved clinical practice results in better care and better outcomes

Beside to community

- Public health data captures incidence and prevalence
- Clinical performance measures capture provider actions
- Patient and population data document behavior and health status
- Multiple measures track outcomes, changes over time.

National Center for Health Statistics

What We Do:

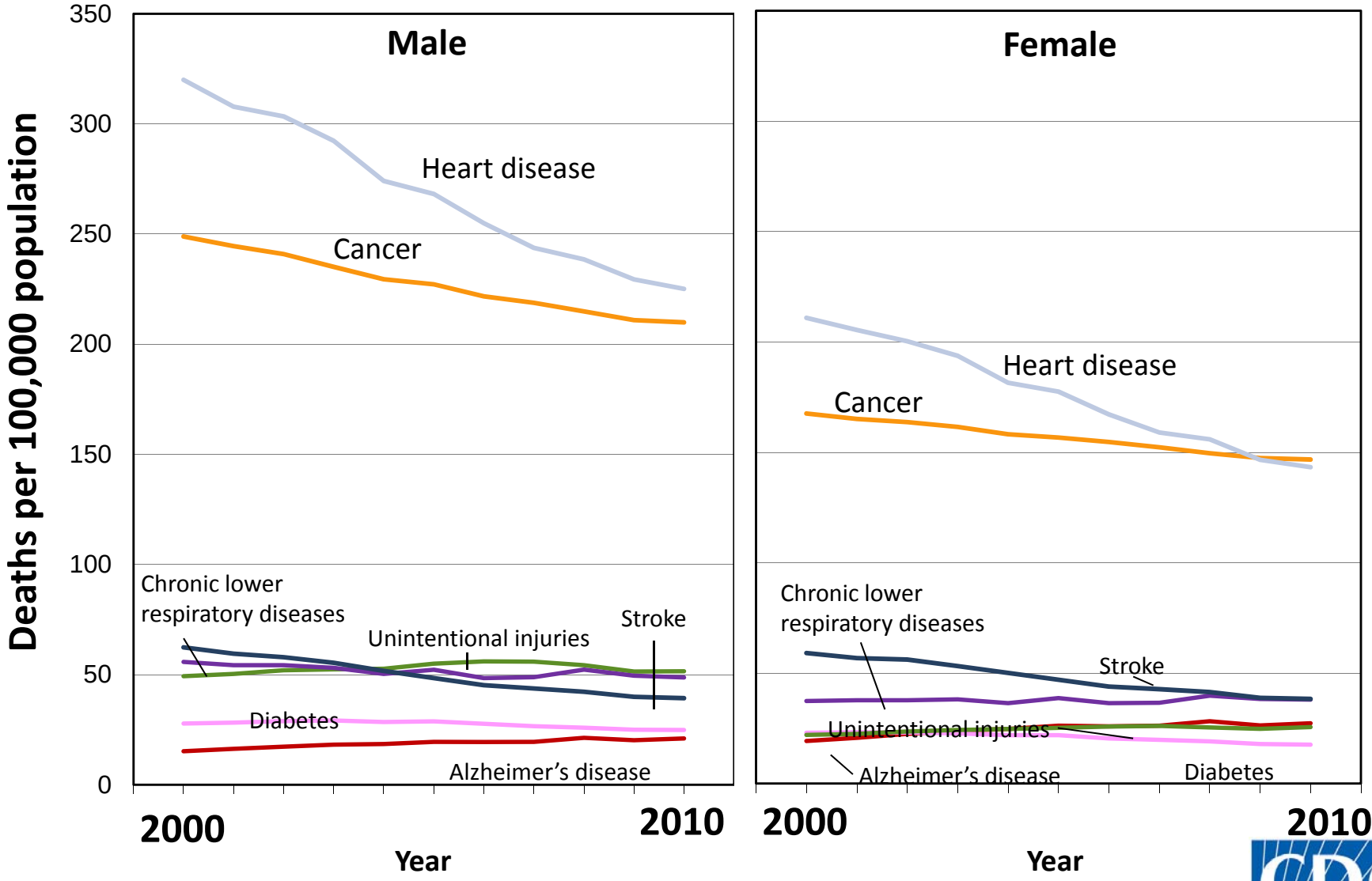
Monitor the nation's health by collecting, analyzing and disseminating health data

- Compare across time, populations, providers and geographic areas
- Identify health problems, risk factors, and disease patterns
- Inform actions and policies to improve the health of the American people

NCHS Data Collection Systems and Surveys Use These Sources ...

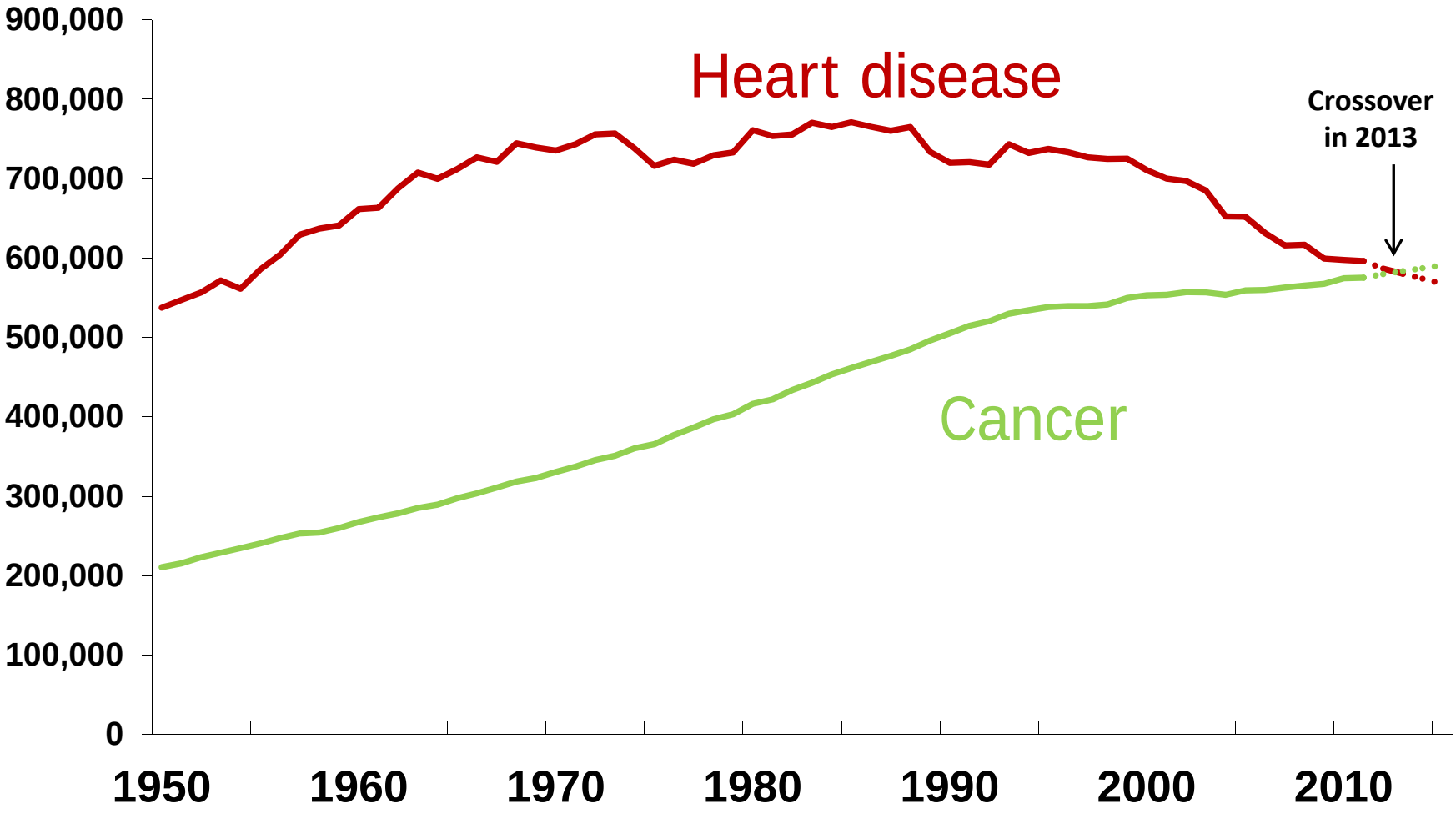
- **Birth and death records** (National Vital Statistics System)
- **Personal interviews** in the home and via phone (National Health Interview Survey, National Survey of Family Growth, State and Local Area Integrated Telephone Survey)
- **Physical examinations and laboratory testing** in mobile exam centers (National Health and Nutrition Examination Survey)
- **Medical records** from hospitals, emergency rooms, outpatient clinics, physicians' offices, nursing homes and hospice and home care agencies (National Health Care Surveys)
- **Interviews with health care providers** in hospitals, physicians' offices and long term care agencies (National Health Care Surveys)

Age-adjusted death rates for selected causes of death for all ages, by sex: United States, 2000–2010



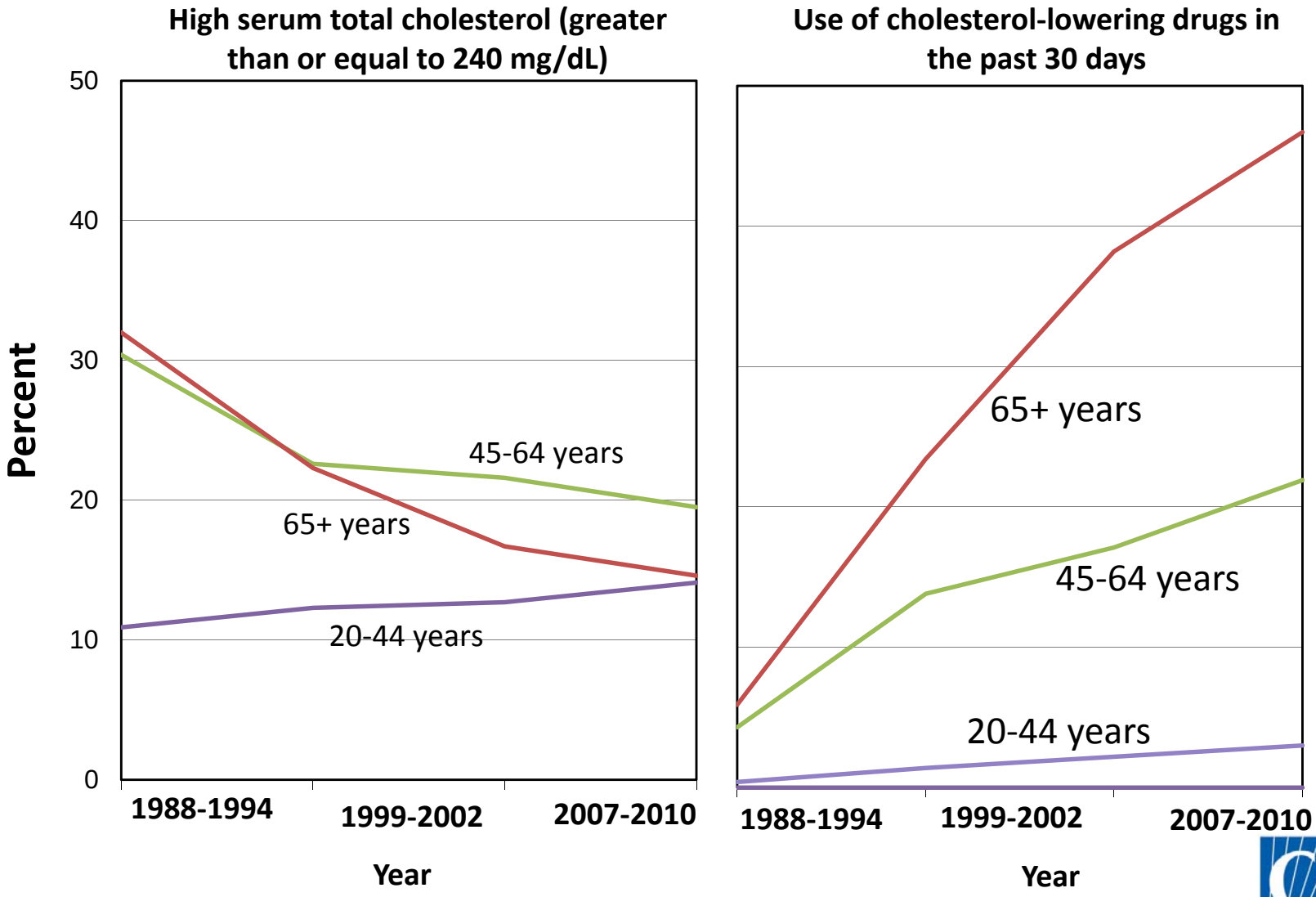
SOURCE: CDC/NCHS, *Health, United States*. Data from the National Vital Statistics System.

Number of Deaths Due to Heart Disease and Cancer: United States, 1950-2015



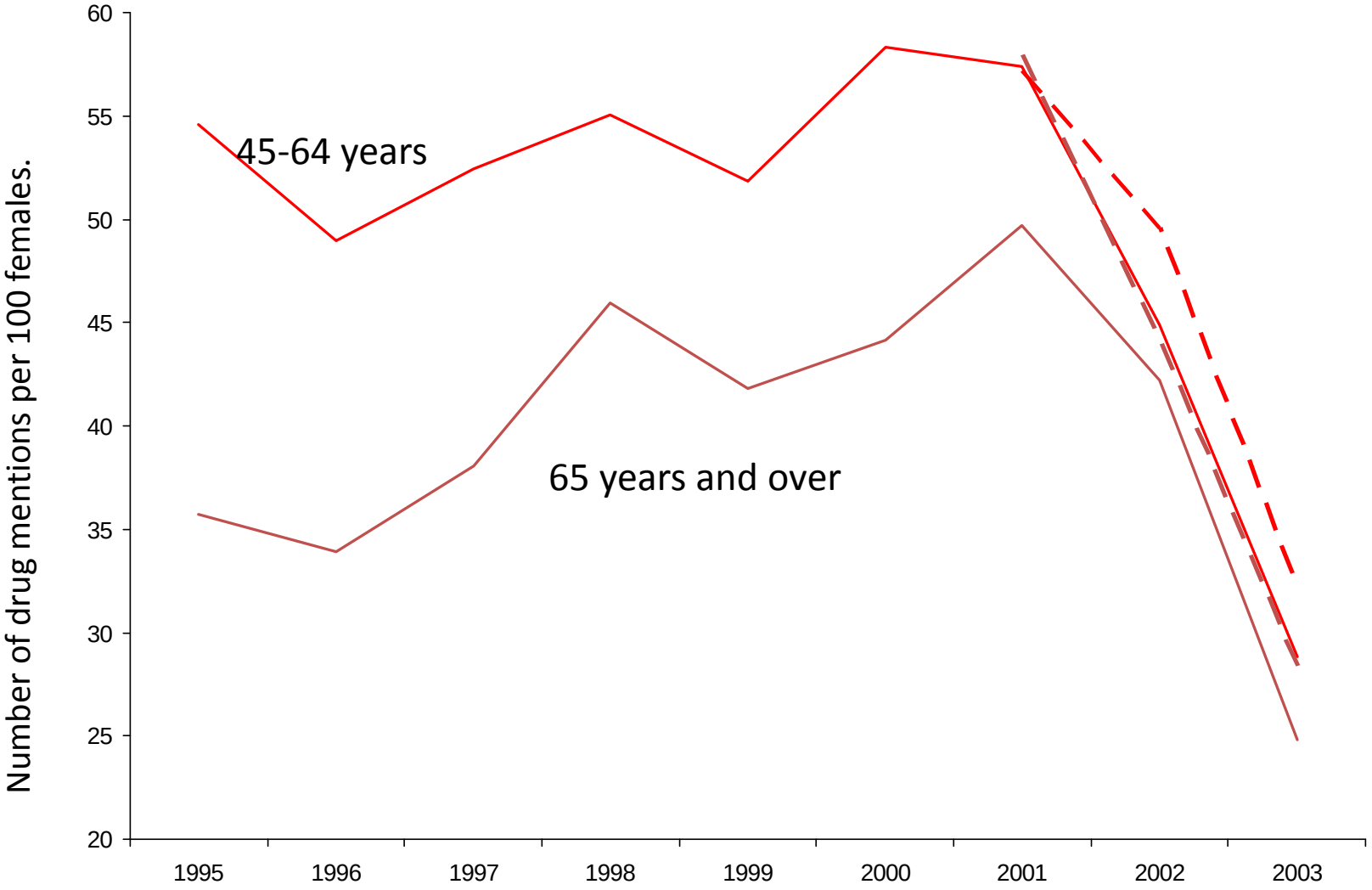
NOTE: Data for 2011 are preliminary data from the National Vital Statistics System. Data for 2012-2015 are based on a simple linear projection of data for 2008-2011.

High serum total cholesterol and use of cholesterol-lowering drugs: 1988-1994 through 2007-2010



SOURCE: CDC/NCHS, *Health, United States*. Data from the National Health and Nutrition Examination Survey.

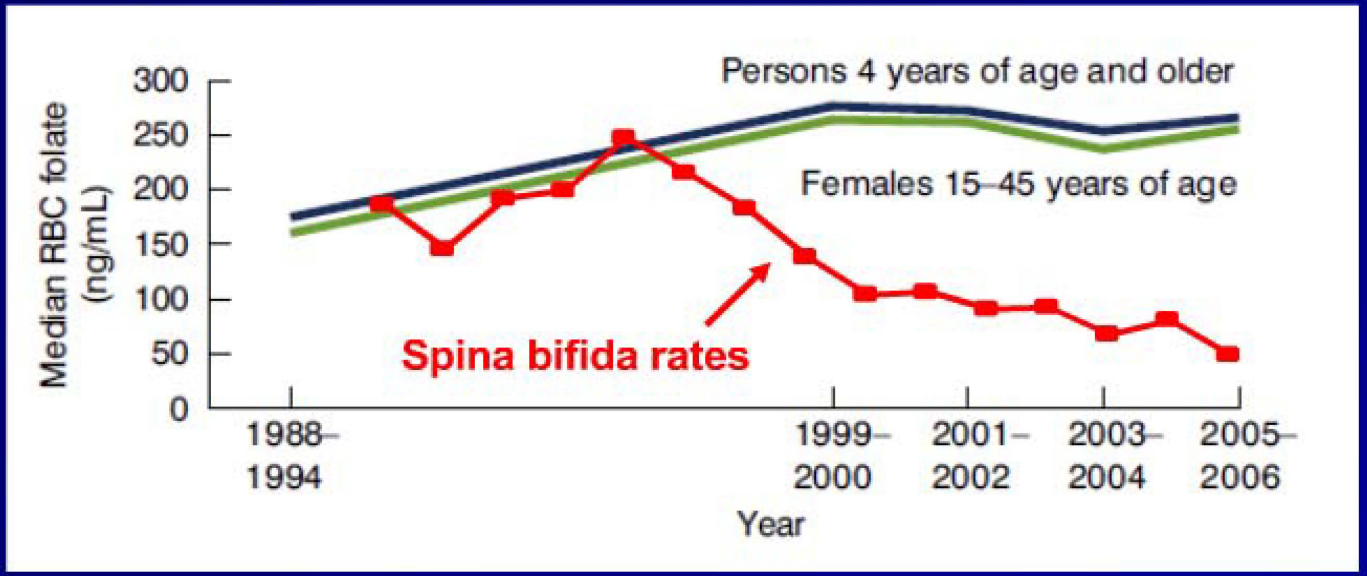
Trends in estrogen/progestin drug mention population rates at physician office visits by patient's age: United States, 1995-2003



NOTES: Rates based on visits made by females. Trend for 65 years and over 1995-2000 is significant. All trends for 2001-2003 are significant ($p<0.05$). Rate computed with revised 2001-03 weight indicated by dotted line; original weight indicated by solid line. The revised weight includes adjustment for variation in the typical number of weeks worked annually and for variation in visit volume in a work week, whereas the weights for 2000 and earlier do not.

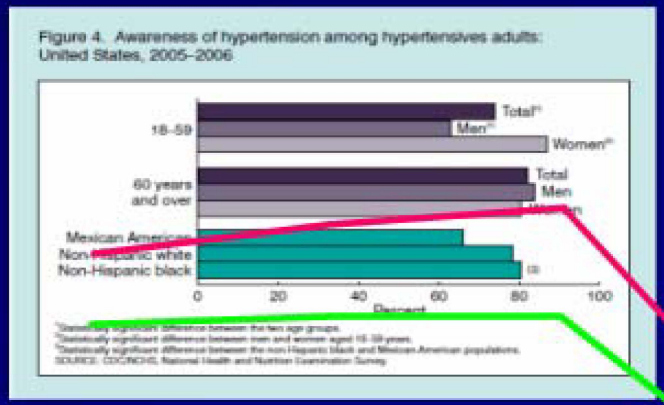
3. Evaluating Folic Acid Fortification

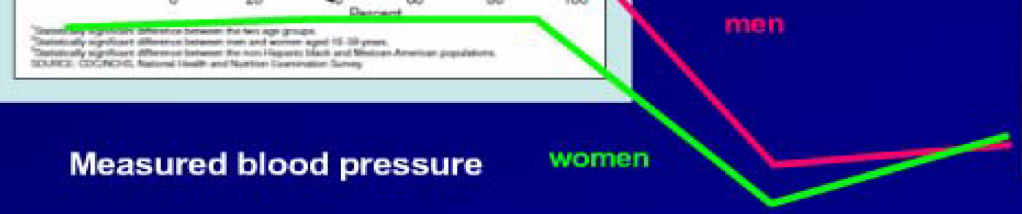
- FDA regulation to fortify grain products with folic acid (1998)
- NHANES data pre- and post- fortification showed increased blood folate levels in young women
- Vital Statistics data showed ultimate impact with declines in Spina Bifida rates
- Continuing data collection allows evaluation of fortification policy safety



10. Tracking Hypertension

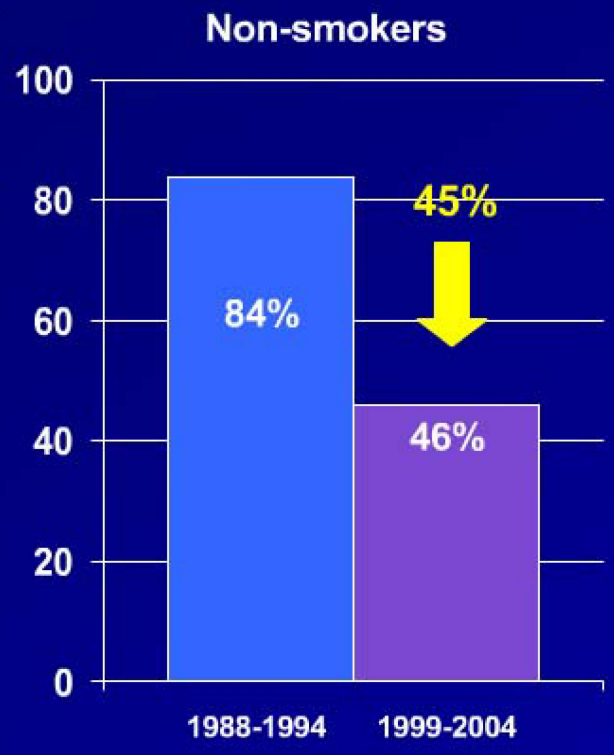
- Used to track hypertension prevalence by Joint National Committee on Detection Evaluation and Treatment of High Blood Pressure since 1980
  - Decline between 1976-80 and 1988-1994
  - Increase between 1988-94 and 1999-2000
- Since 1988-94 interview plus measured blood pressure data allow estimation of awareness, treatment, and control of hypertension



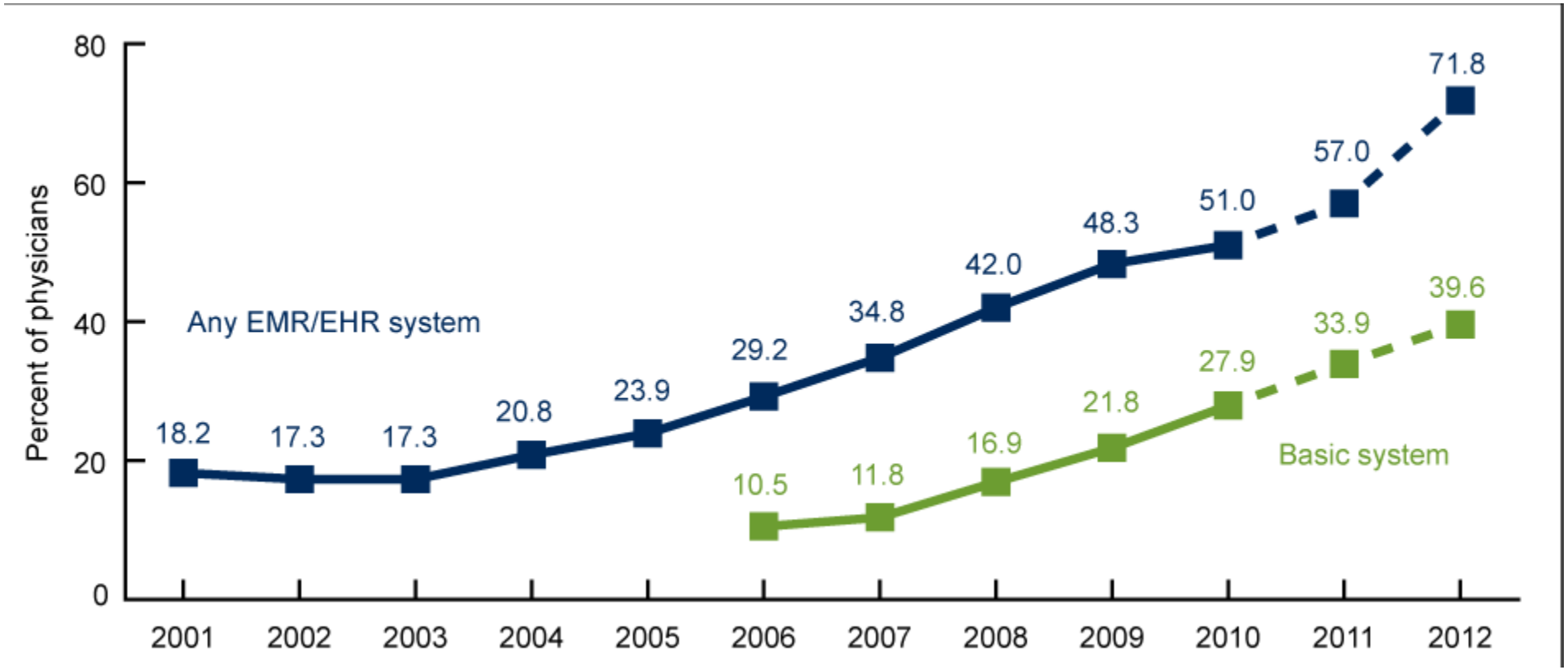


22. Elucidating Exposure to Second Hand Smoke (SHS) & Monitoring Reduction Policies

- 1st measured biological assessment of SHS in US (NHANES III)
- Documented widespread SHS exposure – 84% of non-smokers
- Trend analysis showed decline of 45% among nonsmokers between 1988-94 and 1999-2004

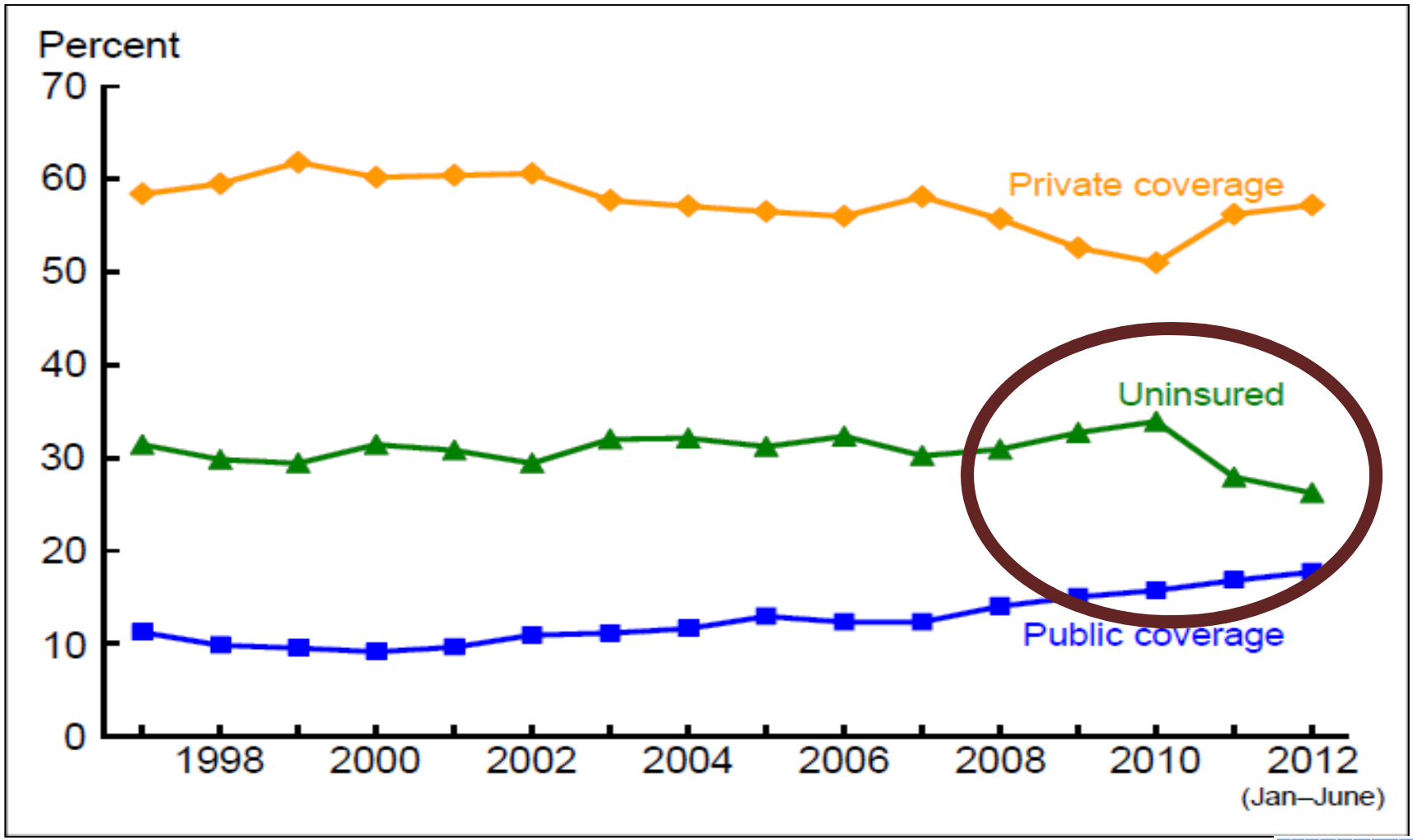


Monitoring the effects of health care policy changes
Percentage of Office-based Physicians with Electronic Medical Records



Source: National Ambulatory Medical Care Survey

Health Insurance Coverage, Ages 19–25



Source: National Health Interview Survey

NIH and NCHS partnerships

- **Collaborators** on NCHS surveys (e.g., NHANES, NHIS cancer supplement)
- **Methodological partnerships** (National Children's Study)
- **Healthy People workgroups**
  - Objective, target setting
  - Examples include heart disease and stroke, asthma, oral health, and others
- **National reporting efforts**
  - Health US
  - Aging Forum, Children's Forum

New intersections, new partnership opportunities

Vital statistics

- Electronic birth and death records

Health Care

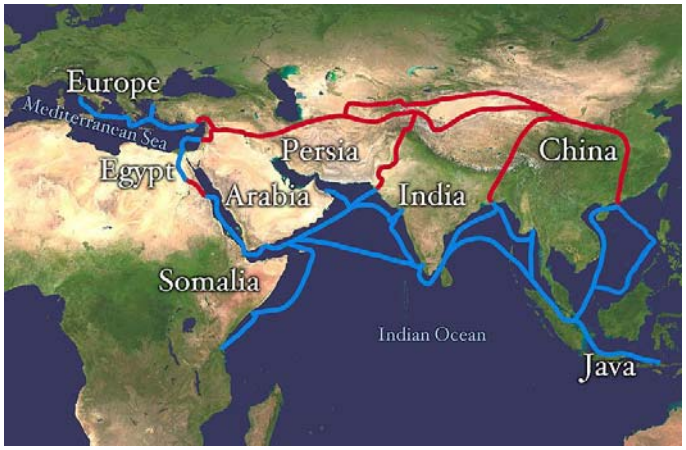
- Expansions in sample size yield state estimates
- New clinical data for EB preventive services

NHANES

- 24-hour urine collection pilot
- Health Measures at home (with NHIS)
- DNA bank

NHIS

- New LBGT data
- More state level estimates

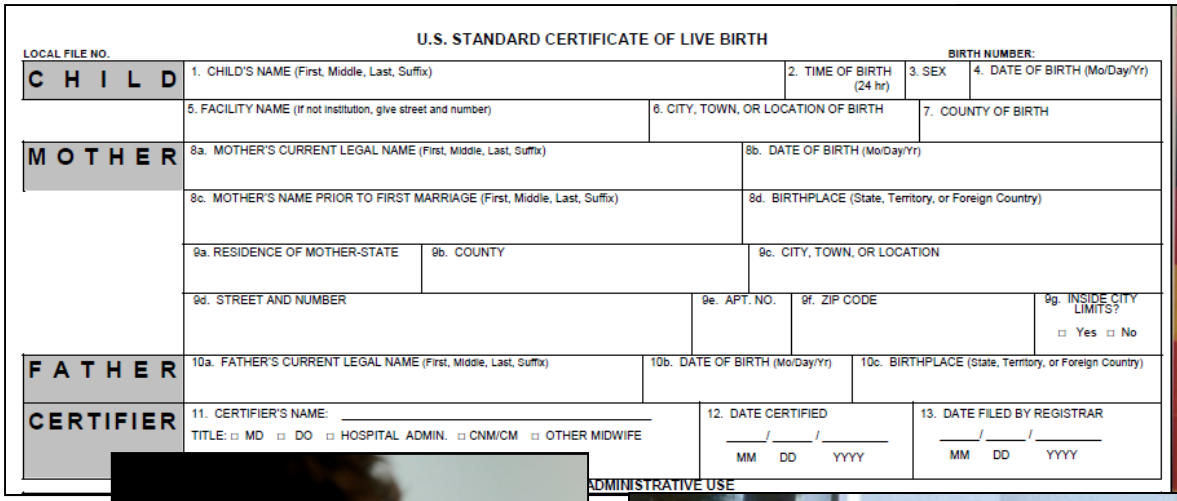


- Linked data enable broader analyses of factors that influence health and health outcomes.
- Surveys are linked with administrative data such as
  - The National Death Index;
  - Claims data from the Centers from Medicare & Medicaid Services; and
  - Supplemental Security Income data from the Social Security Administration
- Linked data are accessed through
  - Public use files
  - the NCHS Research Data Center (for restricted use files)
- OAE conducts research on linkage methods, analytic methods for using the data, and on health and health policy issues.

NCHS Research Data Center

- Provides a mechanism for researchers to access data not released to the public because of nondisclosure or confidentiality reasons
  - Small area or micro data
  - Matches/ links to external data files
- Access is provided either on site or via a remote system
- Plans for an RDC in HHH building

Visit our website at http://www.cdc.gov/nchs



U.S. STANDARD CERTIFICATE OF LIVE BIRTH

LOCAL FILE NO. BIRTH NUMBER:

CHILD	1. CHILD'S NAME (First, Middle, Last, Suffix)	2. TIME OF BIRTH (24 hr)	3. SEX	4. DATE OF BIRTH (Mo/Day/Yr)
	5. FACILITY NAME (If not institution, give street and number)	6. CITY, TOWN, OR LOCATION OF BIRTH	7. COUNTY OF BIRTH	
MOTHER	8a. MOTHER'S CURRENT LEGAL NAME (First, Middle, Last, Suffix)	8b. DATE OF BIRTH (Mo/Day/Yr)		
	8c. MOTHER'S NAME PRIOR TO FIRST MARRIAGE (First, Middle, Last, Suffix)	8d. BIRTHPLACE (State, Territory, or Foreign Country)		
	9a. RESIDENCE OF MOTHER-STATE	9b. COUNTY	9c. CITY, TOWN, OR LOCATION	
	9d. STREET AND NUMBER	9e. APT. NO.	9f. ZIP CODE	9g. INSIDE CITY LIMITS? □ Yes □ No
FATHER	10a. FATHER'S CURRENT LEGAL NAME (First, Middle, Last, Suffix)	10b. DATE OF BIRTH (Mo/Day/Yr)	10c. BIRTHPLACE (State, Territory, or Foreign Country)	
CERTIFIER	11. CERTIFIER'S NAME: _____ TITLE: □ MD □ DO □ HOSPITAL ADMIN. □ CNM/CM □ OTHER MIDWIFE	12. DATE CERTIFIED ____/____/____ MM DD YYYY	13. DATE FILED BY REGISTRAR ____/____/____ MM DD YYYY	

ADMINISTRATIVE USE

CDC

NIH SCIENTIFIC MANAGEMENT REVIEW BOARD
VALUE OF BIOMEDICAL RESEARCH

June 4-5, 2013
Bethesda, Maryland

James W. Curran, MD, MPH
Rollins School of Public Health
Emory University

EMORY | ROLLINS SCHOOL OF PUBLIC HEALTH

Public Health

"is what we, as a society, do collectively to assure conditions in which people can be healthy…"

Institute of Medicine, 1987

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Public Health

Focus in on health of populations.

Focus is on prevention.

Main functions are: Assessment (data)
Policy Development
Assurance

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Public Health

Priority setting:

1) Numbers of persons in a population affected (or potentially affected);
2) Severity of conditions;
3) Ability to impact (1) and/or (2).

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Research Spectrum

Basic Science (Lab, Bench)	⟷	Individual	⟷	Population (Community)
		Efficacy		Effectiveness Impact
		RCT		Surveys Modeling Epidemiology Economics

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Research Priorities vs. Public Health Priorities

1) Research progress not always linear;
2) Opportunities for success may differ;
3) Time lag from research finding to implementation on wide scale;
4) Political considerations.

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Attributing Research Success in Public Health

1) Existing data sets may be inadequate:
   a) focus on disease, biomarkers, less than prevention;
   b) time lags between research and implementation;
   c) sampling may not match populations with greatest potential impact (size, focus);
   d) specialized data needs should be specified and supported early.

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Attributing Research Success in Public Health

2) Research is often collaborative in sponsorship;
3) Success (or failure) in improving health is often multifactorial;
4) Social determinants of health often ignored by policy makers (and researchers).

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Examples from HIV/AIDS:

1) Multidisciplinary collaborations
2) Research - NIH
   Other USG Agencies
   Industry
   Foundations

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Examples from HIV/AIDS:

3) Breakthroughs – Problem definition
   Etiology
   Therapy
   Impact on populations

4) Data availability for public health:
   - best in US / developed countries;
   - best for treatment / mortality;
   - less adequate – prevention, developing countries.

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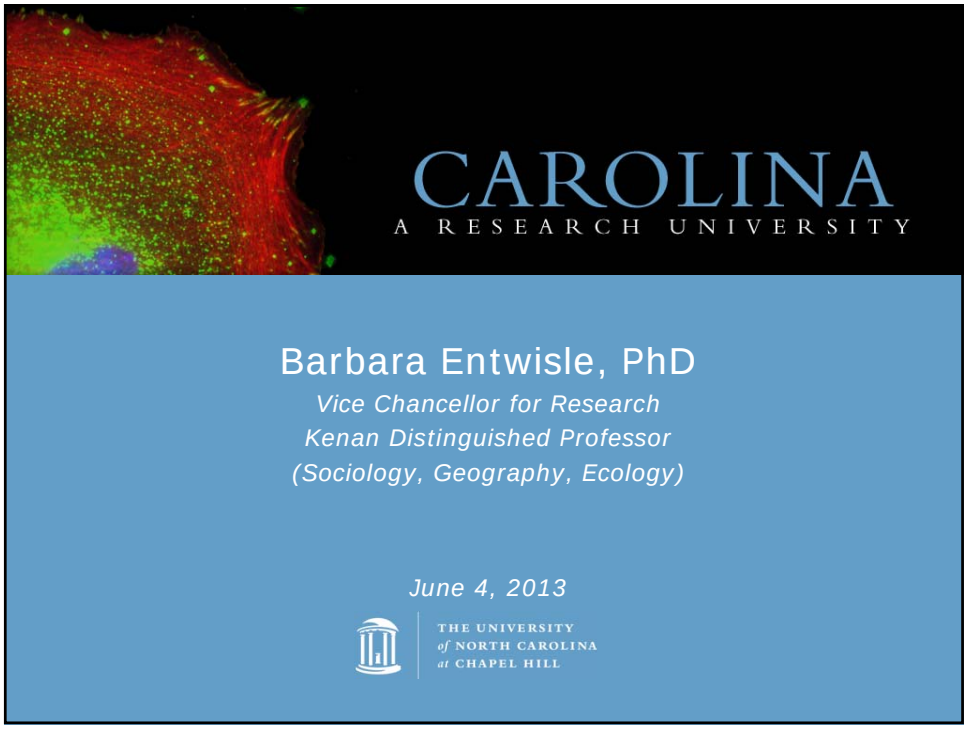

NIH Mission

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to **enhance health, lengthen life, and reduce illness and disability**.

The goals of the agency are:

- to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
- to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease;
- to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
- to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

http://www.nih.gov/about/mission.htm

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NIH Impact Statement

Our Health

Over the years, our nation has made impressive gains in health and longevity. A driving force behind that progress has been medical research supported by NIH.

Thanks in large part to NIH research, Americans are living nearly 30 years longer than they did in 1900. Not only have these gains in longevity enriched many lives, they have added an estimated $3.2 trillion annually to the U.S. economy since 1970.

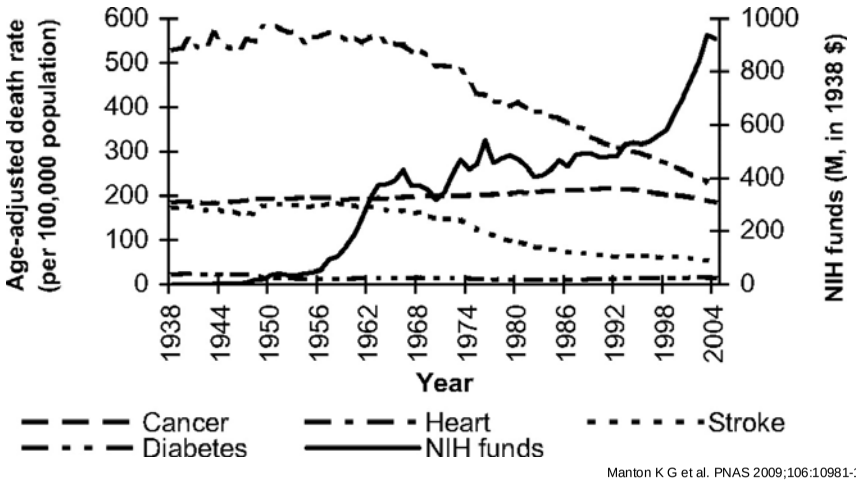
What's more, Americans are not just living longer, they are staying active longer. In the last 25 years, the proportion of older people with chronic disabilities has dropped by nearly one-third.

Such progress is made possible by NIH's support of many different types of research focused on a wide range of conditions. Here's an overview of a few of the major health advances fueled by NIH-funded research.

http://www.nih.gov/about/impact/health.htm

UNC RESEARCH

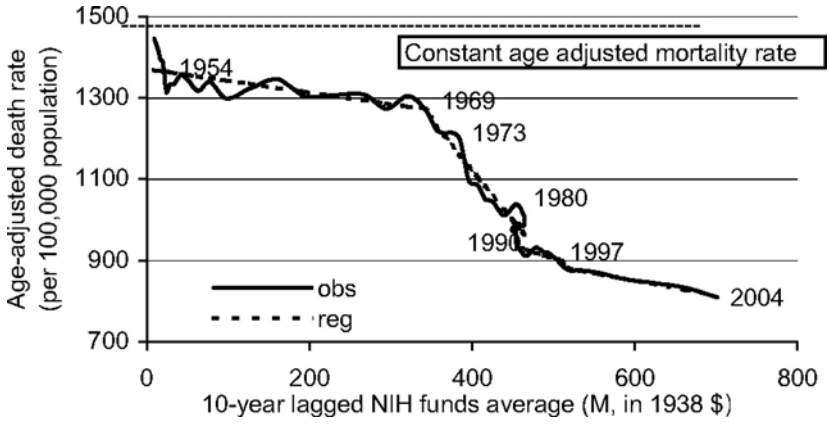
Age adjusted death rate for multiple causes and NIH funds, United States, 1938–2004.



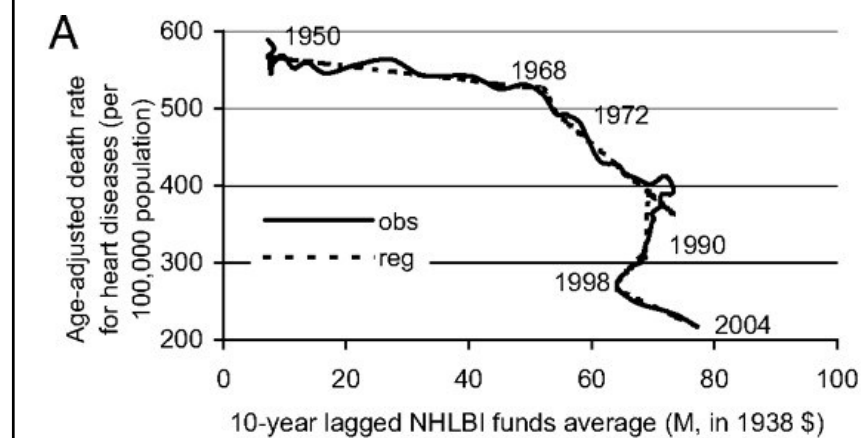
Manton K G et al. PNAS 2009;106:10981-10986

UNC RESEARCH

Age-adjusted death rates as a function of 10-year lagged NIH funds average.



Manton K G et al. PNAS 2009;106:10981-10986



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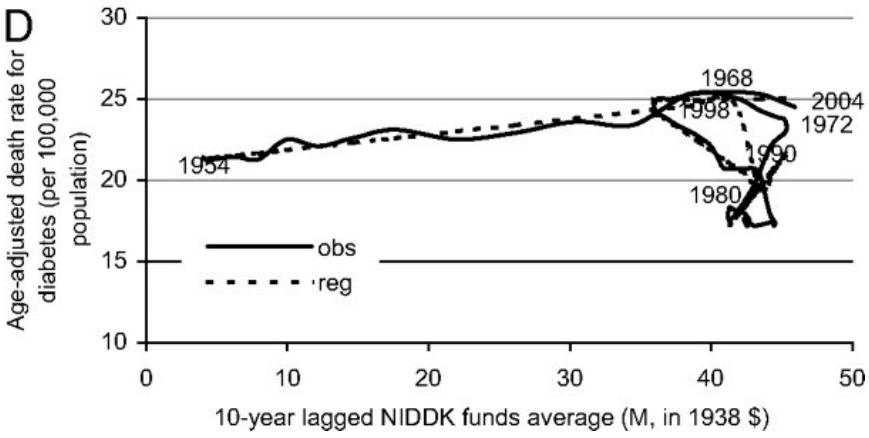

Manton K G et al. PNAS 2009;106:10981-10986

UNC RESEARCH

NIH funding trajectories and their correlations with US health dynamics, 1950-2004

Deaths (million) avoided by NIH funding

Year	Observed	Avoided	
		Total	Annual
1950-1969*	47.3	1.2	0.06
1970-1989	47.5	14.2	0.71
1990-1997	19.2	9.4	1.18
1998-2004	17.0	10.3	1.47
1950-2004	130.9	35.2	0.64

Manton K G et al. PNAS 2009;106:10981-10986

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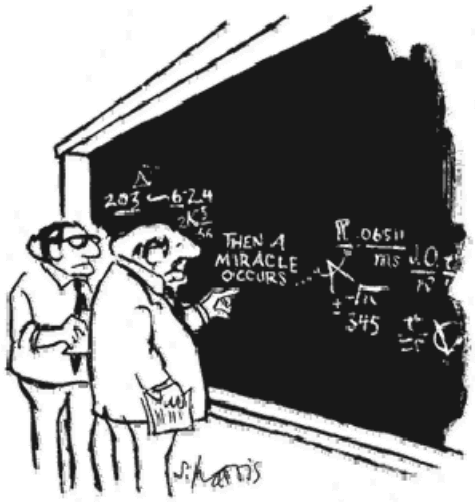
The Impact of NIH Funding on Health and Longevity



"I THINK YOU SHOULD BE MORE EXPLICIT HERE IN STEP TWO."

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- to **expand the knowledge base** in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
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http://www.nih.gov/about/mission.htm

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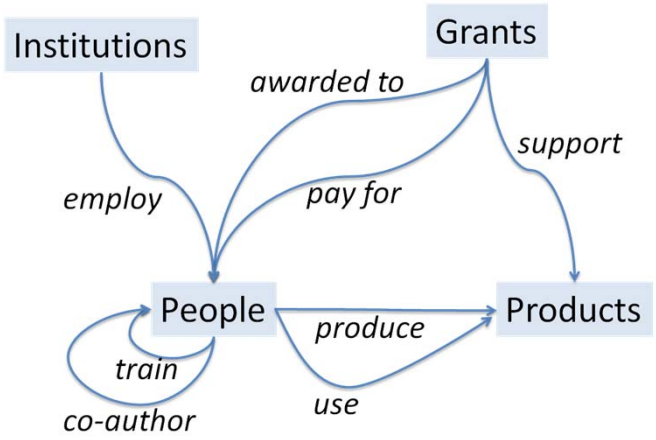
A People Centered Approach



Source: Ian Foster, University of Chicago

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Social Networks and the Creation, Dissemination, and Application of New Ideas

- Explicit project-based collaborations
- Flows of research materials
- Flows of students/postdocs
- Shared data sets
- Spatially organized "collisions"
- Overlapping panel membership
- Other personal contacts

Owen-Smith and Levenstein. 2013. "Assessing the Social and Economic Roles of Research Universities." Measuring the Results of Research Investments, University of Chicago.

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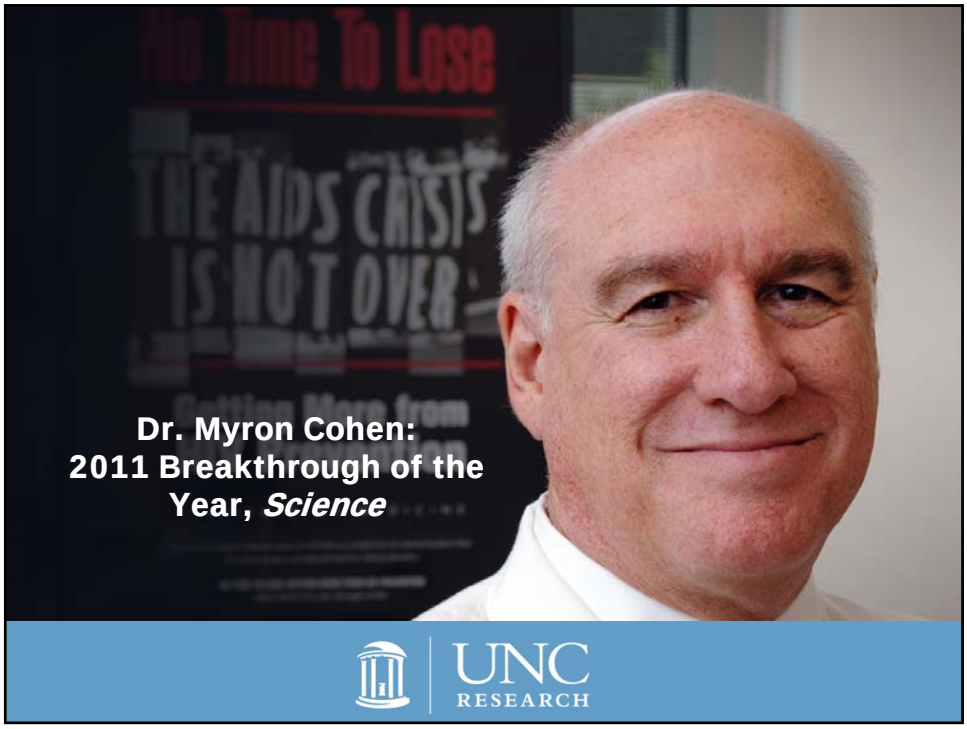
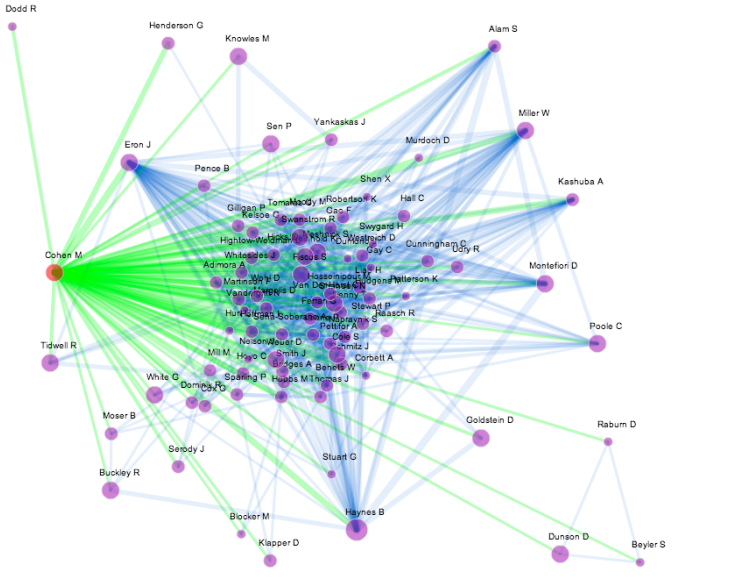


Dr. Myron Cohen's Research Network



http://reachnc.org/
http://www.experts.scival.com/reachnc/expertNetwork.asp?n=Myron+S+Cohen&u_id=704275700&oe_id=1&o_id=164

National Longitudinal Study of Adolescent Health

Add Health *Social, Behavioral, and Biological Linkages Across the Life Course*

The National Longitudinal Study of Adolescent Health (Add Health) is a longitudinal study of a nationally representative sample of adolescents in grades 7-12 in the United States during the 1994-95 school year. The Add Health cohort has been followed into young adulthood with four in-home interviews, the most recent in 2008, when the sample was aged 24-32*. Add Health combines longitudinal survey data on respondents' social, economic, psychological and physical well-being with contextual data on the family, neighborhood, community, school, friendships, peer groups, and romantic relationships, providing unique opportunities to study how social environments and behaviors in adolescence are linked to health and achievement outcomes in young adulthood. The fourth wave of interviews expanded the collection of biological data in Add Health to understand the social, behavioral, and biological linkages in health trajectories as the Add Health cohort ages through adulthood.

http://www.cpc.unc.edu/projects/addhealth

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Add Health: Contribution to Science

Add Health has become a national and global data resource for over 10,000 Add Health researchers:

Funded research grants	600+
Referee publications	2000+
Books	19
Book chapters	75
Dissertation/Theses	450+

Source: Dr. Kathleen Mullan Harris, PI

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Science of Science Policy Approach

- Need feasible, low cost and flexible approach, so use science to describe and to manage the scientific ecosystem.
- Conceptual framework: Science is done by scientists so focus on scientists and networks of scientists
- Empirical framework: New ways of collecting data so use new cybertools to capture information automatically
- Pragmatic Approach: New ways of presenting information to visualize information so public can see results of research

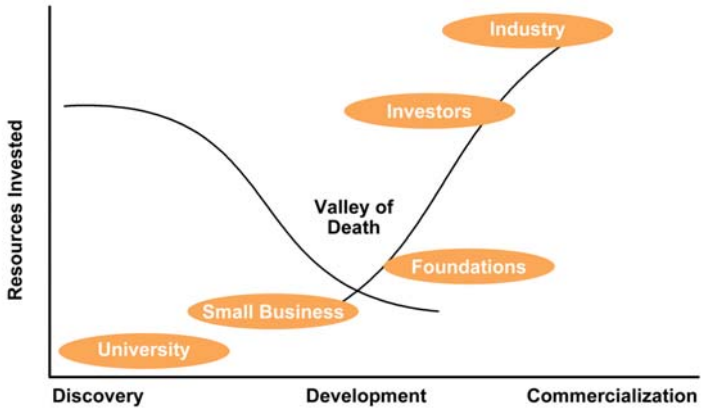
The Next Step: Discovery to Impact

Dissemination: Get the message out to those who need to know.

Implementation: Transform policy, programs, practice

Commercialization: Create commercially viable drugs, devices, diagnostics

Discovery to Commercialization



http://nciia.org/sites/default/files/u26/Anita_NSF%20Program%20Overviews.pdf

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Concluding Remarks

Measuring the impact of NIH investments on improved live expectancy is challenging

- Complex linkage between funding and health outcomes

Linking funding to projects

Linking projects to discovery:

- Projects compliment and build on each other over time
- Constructed around networks of faculty, students, postdocs, staff
- Discovery can be the product of a decade or more of work

Importance of shared infrastructure:

- Data are an important product of research
- They can be used and reused, combined and recombined over time
- Joint use creates networks of faculty, students, postdocs, staff

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Concluding Remarks

Linking discovery to projects:

- Knowledge builds
- Discovery can draw from disparate sources
- Can involve other non-NIH sources of funds

Linking discovery to health impact:

- Going beyond the bench
- A “hand-off” to industry, commercial interests, policy-makers, practioners, population
- Complex set of linkages, some of which are beyond NIH purview
- Takes time

Overall, need a scientific approach.

Attributing Value

Laurel L. Haak, PhD
Executive Director, ORCID
http://orcid.org/0000-0001-5109-3700.

Assessing value

(1) Define what is "success"

(2) Establish measures of success

(3) Create systems and supports to measure

(4) Collect data

(5) Analyze progress toward success

(6) Make adjustments, repeat

What is Failure?

Millennium Bridge was dubbed 'Wobbly Bridge' after a swaying motion led to its closure two days after opening

On 7 November 1940, the Tacoma Narrows Bridge collapsed under the force of wild oscillations caused by 40mph winds

http://eandt.theiet.org/magazine/2012/03/a-bridge-too-far.cfm

What is Success?

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- to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

http://www.nih.gov

What do we measure?

(1) Creative discoveries

(2) Innovative research strategies

(3) Application of discoveries and strategies

(4) Human and physical resources

(5) Knowledge base in medical sciences

(6) Integrity, accountability, and social responsibility

Logic Model

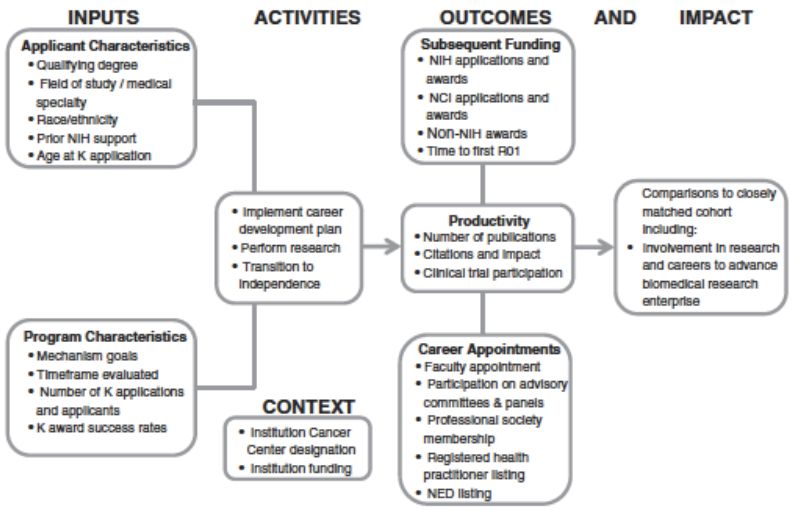


Fig. 1 Logic model of NCI K awards outcome evaluation. The logic model highlights K program inputs, activities, outcomes, and impact, as well as contextual factors. The inputs include the features (demographics) that define applicants to the NCI K program, as well as features of the K mechanisms. Activities include the actions that a funded researcher would take to further their research training and career plans, and context refers to specific features of the past and present environment in which program participants are functioning. Outcomes include measures that might be attributed to participation in the NCI K program and are divided into three broad categories of subsequent funding, productivity, and career appointments. Impact is assessed by comparing outcomes of closely matched cohorts of K awardees and non-awardees and examining proxies of scientific research and engagement

Mason, et al. (2013) Journal of Cancer Education 28:9-17 DOI: 10.1007/s13187-012-0444-yl

Outcomes: What discoveries has NIH funded?

NIH Public Access Policy Details

The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008). The law states:

The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, *That the NIH shall implement the public access policy in a manner consistent with copyright law.*

http://

fundref

An **industry-wide methodology** for connecting scholarly publications to research funders

HOW FUNDREF WORKS

1. FundRef Registry provides a taxonomy of 4000 standardized funder names.
2. Manuscript tracking system vendors incorporate FundRef Registry into the publication submission processes. Publishers ask authors to select correct funders and provide grant numbers upon manuscript submission.
3. Funder information transferred to publisher production systems.
4. Publishers send funder information to CrossRef
5. Funders and others query CrossRef and receive DOIs and metadata for articles resulting from their funding.
6. Publishers may display FundRef data in CrossMark Record tab.

FundRef Workflow

http://www.crossref.org/fundref/index.html

Recommend: NIH should participate in FundRef and encourage participation by other funders.

Outcomes: What "applications of discoveries" has NIH supported?

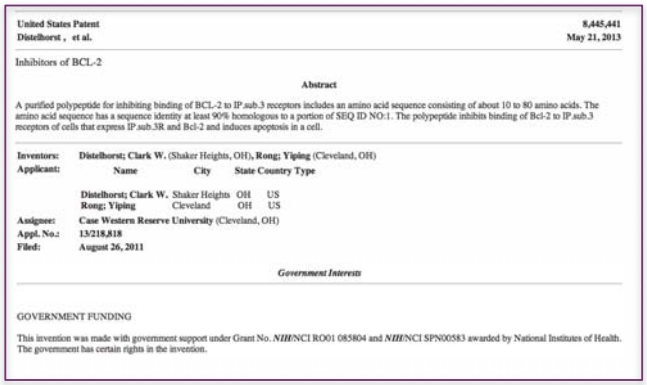
Bayh–Dole Act

From Wikipedia, the free encyclopedia

The **Bayh–Dole Act** or **Patent and Trademark Law Amendments Act** (Pub. L. 96-517, December 12, 1980) is United States legislation dealing with intellectual property arising from federal government-funded research. Sponsored by two senators, Birch Bayh of Indiana and Bob Dole of Kansas, the Act was adopted in 1980, is codified at 94 Stat. 3015, and in 35 U.S.C. § 200-212,[1] and is implemented by 37 C.F.R. 401.[2]

The key change made by Bayh-Dole was in ownership of inventions made with federal funding. Before the Bayh–Dole Act, federal research funding contracts and grants obligated inventors (where ever they worked) to assign inventions they made using federal funding to the federal government.[3] Bayh-Dole permits a university, small business, or non-profit institution to elect to pursue ownership of an invention in preference to the government.[4]

http://en.wikipedia.org/wiki/Bayh–Dole_Act



United States Patent
Distelhorst , et al.

8,445,441
May 21, 2013

Inhibitors of BCL-2

Abstract

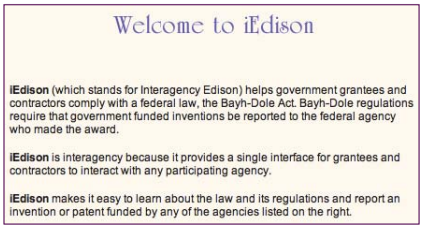
A purified polypeptide for inhibiting binding of BCL-2 to IP.sub.3 receptors includes an amino acid sequence consisting of about 10 to 80 amino acids. The amino acid sequence has a sequence identity at least 90% homologous to a portion of SEQ ID NO:1. The polypeptide inhibits binding of Bcl-2 to IP.sub.3 receptors of cells that express IP.sub.3R and Bcl-2 and induces apoptosis in a cell.

Inventors:	**Distelhorst; Clark W.** (Shaker Heights, OH), **Rong; Yiping** (Cleveland, OH)			
Applicant:	**Name**	**City**	**State**	**Country Type**
	Distelhorst; Clark W.	Shaker Heights	OH	US
	Rong; Yiping	Cleveland	OH	US
Assignee:	**Case Western Reserve University** (Cleveland, OH)			
Appl. No.:	**13/218,818**			
Filed:	**August 26, 2011**			

Government Interests

GOVERNMENT FUNDING

This invention was made with government support under Grant No. *NIH*NCI RO01 085804 and *NIH*NCI SPN00583 awarded by National Institutes of Health. The government has certain rights in the invention.



Welcome to iEdison

iEdison (which stands for Interagency Edison) helps government grantees and contractors comply with a federal law, the Bayh-Dole Act. Bayh-Dole regulations require that government funded inventions be reported to the federal agency who made the award.

iEdison is interagency because it provides a single interface for grantees and contractors to interact with any participating agency.

iEdison makes it easy to learn about the law and its regulations and report an invention or patent funded by any of the agencies listed on the right.

https://s-edison.info.nih.gov/iEdison/

Recommend: Work with USPTO to implement standards for collection of name and grant information

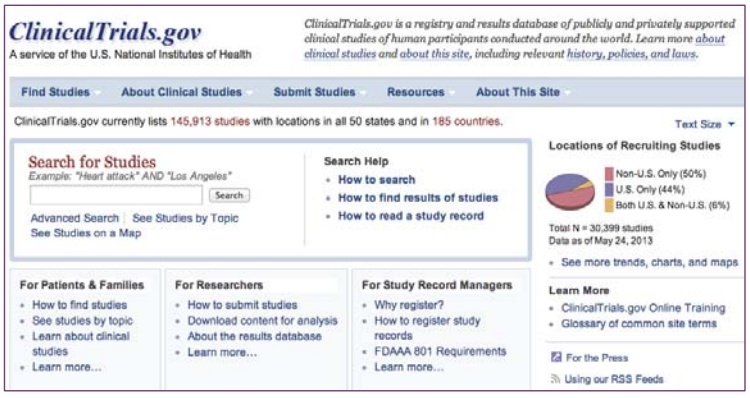
http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-adv.htm&r=17&f=G&l=50&d=PTXT&S1=NIH.GOTX.&OS=govt/NIH&RS=GOVT/NIH

Outcomes: Clinical trials

What is FDAAA (U.S. Public Law 110-85 or the Food and Drug Administration Amendments Act of 2007)?

On September 27, 2007, the President signed U.S. Public Law 110-85. The law includes a section on clinical trial databases (Title VIII) that expands the types of clinical trials that must be registered in ClinicalTrials.gov, increases the number of data elements that must be submitted, and also requires submission of certain results data.

http://grants.nih.gov/clinicaltrials_fdaaa/faq.htm



ClinicalTrials.gov
A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

ClinicalTrials.gov currently lists 145,913 studies with locations in all 50 states and in 185 countries.

Text Size

Search for Studies
Example: "Heart attack" AND "Los Angeles"
Search
Advanced Search | See Studies by Topic
See Studies on a Map

Search Help
- How to search
- How to find results of studies
- How to read a study record

Locations of Recruiting Studies
Non-U.S. Only (50%)
U.S. Only (44%)
Both U.S. & Non-U.S. (6%)
Total N = 30,399 studies
Data as of May 24, 2013
- See more trends, charts, and maps

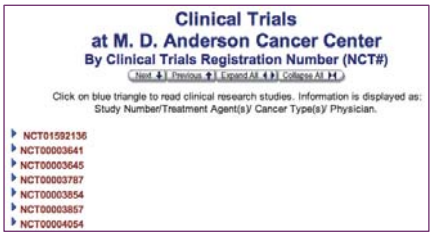
For Patients & Families
- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more…

For Researchers
- How to submit studies
- Download content for analysis
- About the results database
- Learn more…

For Study Record Managers
- Why register?
- How to register study records
- FDAAA 801 Requirements
- Learn more…

Learn More
- ClinicalTrials.gov Online Training
- Glossary of common site terms

For the Press
Using our RSS Feeds



Clinical Trials at M. D. Anderson Cancer Center
By Clinical Trials Registration Number (NCT#)

Next | Previous | Expand All | Collapse All

Click on blue triangle to read clinical research studies. Information is displayed as: Study Number/Treatment Agent(s)/ Cancer Type(s)/ Physician.

- NCT01592136
- NCT00003641
- NCT00003645
- NCT00003787
- NCT00003854
- NCT00003857
- NCT00004054

http://utmx-ext01a.mdacc.tmc.edu/dept/prot/clinicaltrialswp.nsf/NCT?openview

Recommend: implement standards for collection of name and grant information

http://clinicaltrials.gov

Outcomes: Who did NIH train?

Posted on April 11, 2013 by Sally Rockey

Taking On the Challenge of Better Biomedical Workforce Data http://nexus.od.nih.gov/all/2013/04/11/taking-on-the-challenge-of-better-biomedical-workforce-data/

The primary goal of the NIH Advisory Committee to the Director (ACD) biomedical research workforce working group was the creation of pathways through undergraduate, graduate and postdoctoral training that provide excellent preparation for biomedical research careers in a timely fashion, and that ensure future US competitiveness and innovation in biomedical research. In their report, the working group members described how they were "frustrated and sometimes stymied" by the quality of the data available on the biomedical research workforce, e.g., major gaps in information on the total number of individuals working as postdocs, inadequate information on postdocs who obtained degrees in other countries, and lack of systematic data on graduate students trained in labs supported by NIH research grants.

So to this end, we've been working on a number of plans to try and fill these gaps in biomedical workforce information. Here's a quick overview of the directions we are headed.

Big Hopes, Small Changes for Biomedical Training http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2012_12_14/caredit.a1200136

By Michael Price
December 14, 2012

Tilghman, Rockey, and the others in the working group laid out several recommendations aimed at shortening and diversifying doctoral programs and postdoc positions, increasing the proportion of trainees supported by training grants and fellowships instead of research grants, collecting more data on career outcomes, improving postdoc salaries, and promoting the staff scientist career path. After the June meeting, ACD formed an implementation team, headed by Rockey, to decide which recommendations to implement, and how to do it.

- **Identification of all NIH-supported students and postdocs**
- **Automated NRSA training tables**
- **Develop a Fed-wide researcher profile system**
- **Encourage adoption of unique persistent researcher IDs**

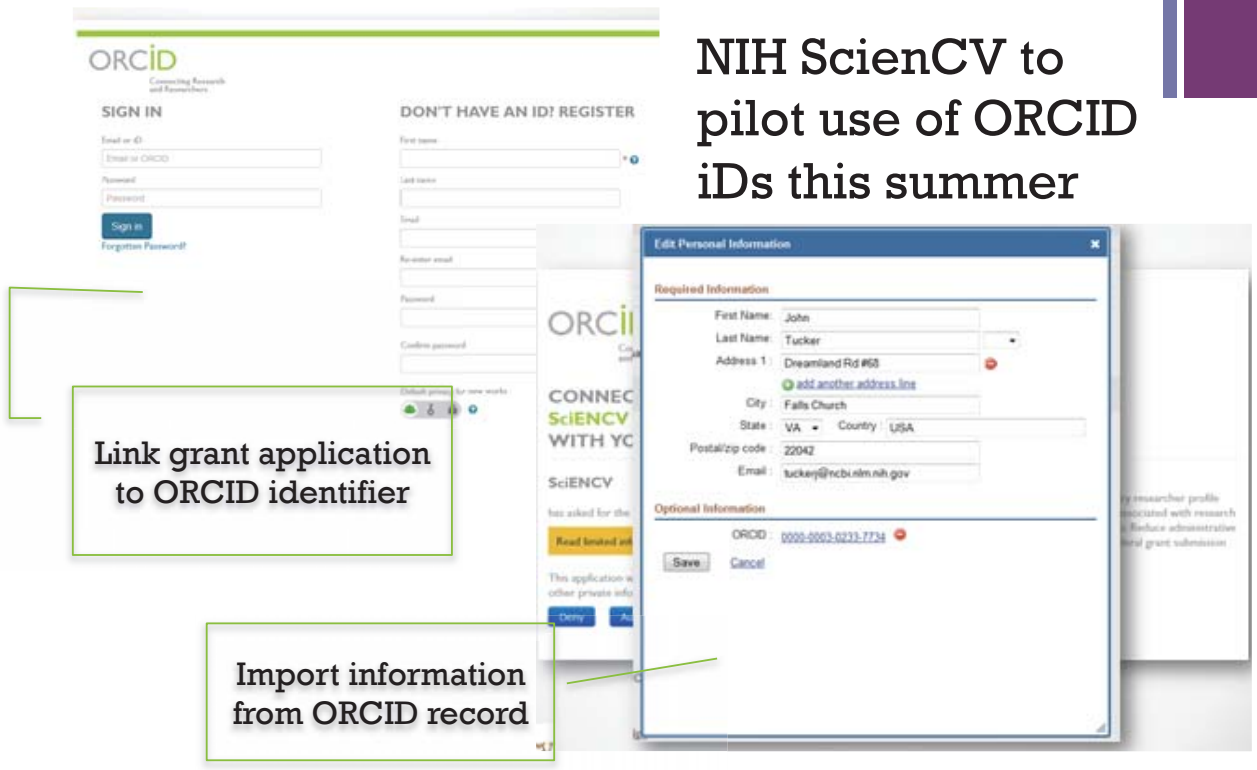
Tracking NIH-funded researchers

Encourage adoption of unique persistent researcher IDs: Identifying the output of individuals with commonly occurring names is difficult. Reducing name ambiguity within and across data systems is always expensive and time consuming. It appears that an international, non-profit organization called the Open Researcher and Contributor ID (ORCID) is gaining traction. ORCID is a persistent digital identifier that can be associated with author names in publications. The ORCID system also will allow individuals to identify their research output and create a registry of IDs. SciENcv will include a utility that make it easy for users to obtain an ORCID and to link it to their publications and grants. A broadly used researcher ID also will facilitate the identification of scientific output from those who work outside federally funded research programs. http://nexus.od.nih.gov/all/2013/04/11/taking-on-the-challenge-of-better-biomedical-workforce-data/

After Rockey's presentation, Tilghman remarked that although she was pleased that ACD seriously considered her report's recommendations, she "can't help but go back to [her] cynicism" about some of the language used in the implementation plans—specifically, the occurrence of words like "encourage" and "recommend." For example, she pointed to the implementation team's plan to encourage institutions to track and report the career outcomes for their students and postdocs. "This is a recommendation that's been made by every single committee, and always using the word 'encourage,'" she said. "It has been made for about 20 years and we know what the consequences of that [are]. ... Unless you have a stick, this won't happen."

Encourage? Require?

NIH ScienCV to pilot use of ORCID iDs this summer



Recommend: Implement ORCID

ORCID
Connecting Research and Researchers

ORCID provides a free registry of unique and persistent researcher identifiers. ORCID serves as a switchboard to link researcher identifiers, affiliations, and research works.

(1) Require use of ORCID IDs during the application process, link this to post-award outcomes reporting

(2) Require use of ORCID iDs for all persons supported on a grant

(3) Implement a workflow to post awarded grant information to a grantee's ORCID record

(4) Implement a workflow to allow researchers to search and link ORCID iDs to NIH grants in RePorter, and

(5) Link and store ORCID iDs in IMPAC II PI profile records.

(6) Encourage use of ORCID iDs by the USPTO and CT.org

Linking the who to the what: *Attributing Value*

Science. 2011 Aug 19;333(6045):1015-9. doi: 10.1126/science.1196783.

Race, ethnicity, and NIH research awards.

Ginther DK, Schaffer WT, Schnell J, Masimore B, Liu F, Haak LL, Kington R.

Department of Economics and Center for Science, Technology & Economic Policy, Institute for Policy & Social Research, University of Kansas, Lawrence, KS 66045, USA. dginther@ku.edu

Abstract

We investigated the association between a U.S. National Institutes of Health (NIH) R01 applicant's self-identified race or ethnicity and the probability of receiving an award by using data from the NIH IMPAC II grant database, the Thomson Reuters Web of Science, and other sources. Although proposals with strong priority scores were equally likely to be funded regardless of race, we find that Asians are 4 percentage points and black or African-American applicants are 13 percentage points less likely to receive NIH investigator-initiated research funding compared with whites. After controlling for the applicant's educational background, country of origin, training, previous research awards, publication record, and employer characteristics, we find that black applicants remain 10 percentage points less likely than whites to be awarded NIH research funding. Our results suggest some leverage points for policy intervention.

ADVISORY COMMITTEE TO THE DIRECTOR

Advisory Committee to the Director

Charter
Members
Meetings
Working Group Activities
Contact the ACD

Working Group on Diversity in the Biomedical Research Workforce

Working Group Reports

- Diversity in the Biomedical Research Workforce Working Group Report (PDF – 3,468KB)
- Executive Summary of the Working Group on Diversity in the Biomedical Research Workforce (PDF – 136KB)

NIH's Plan for Action:

- Evaluate current training programs
- Phase out unsuccessful programs, expand successful ones
- Increase number of early career reviewers, including those from underrepresented populations
- Examine grant review process for bias and develop interventions
- Improve support for grant applicants
- Gather expert advice on additional action steps

Summary

- Enhance existing datasets to support their use in evaluation (e.g., ensure that name and evidence information is collected in a fielded manner and exposed through public APIs)
- Work with other agencies to enhance existing datasets
- Map out program goals and clearly articulate measures
- Collect data (qual and quant) and test measures
- Use data to adjust programs

Assessing the Value of Biomedical Research: Developing Chains of Evidence

June 4, 2013

Della Hann, Ph.D.
Deputy Director
Office of Extramural Research
NIH

Setting the Stage

In FY 2009, NIH supported an estimated:

- Over 53,000 research projects/year;
- Over 313,000 research positions
- Research training on NRSA: ~16,400 positions
- Training on research grants: ~28,200 positions
- Over 6,000 research scientists in intramural program

Research Products: Reported to NIH

- Publications – most robust; coin of the realm
  - Citations in Clinical Guidelines
- Inventions, Patents and/or Licenses
- Technologies/Techniques
- Other Products, e.g., databases, animal models, instruments

NIH National Institutes of Health
Office of Extramural Research

Office of Extramural Research

- Designs new and more efficient methods of data collection to improve the breadth and quality of information on research products and the investigators we support
  - Electronic Application Forms
  - Research Performance Progress Reports (RPPR)
  - All Personnel Reports
- Creates the tools needed to query, navigate, and synthesize these diverse data sources, facilitating analysis of NIH-funded research and its outcomes.
  - RePORTER & ExPORTER
  - RCDC
  - SciENCV
  - Commons

NIH National Institutes of Health
Office of Extramural Research

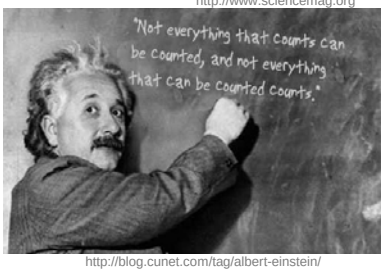
NIH OFFICE OF EXTRAMURAL RESEARCH

But is it Knowledge?

- These products can be used as “metrics of Knowledge”
- But…. How to assess the “value” of this knowledge?
- Does anyone use the Knowledge to inform/improve health?

www.8020comms.com

http://www.sciencemag.org



http://blog.cunet.com/tag/albert-einstein/

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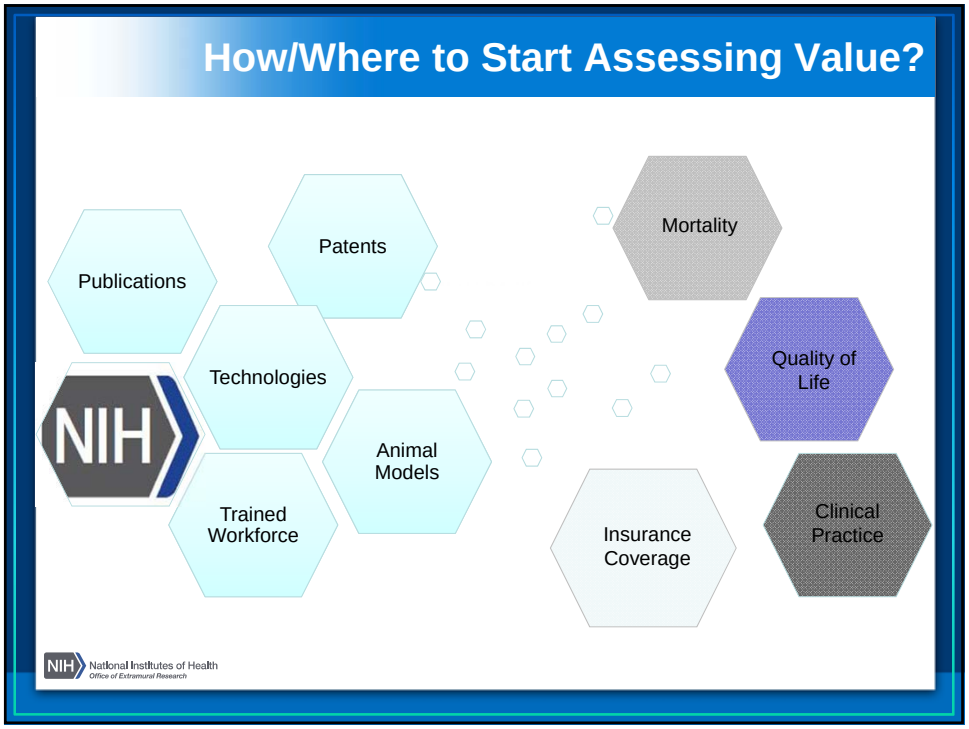
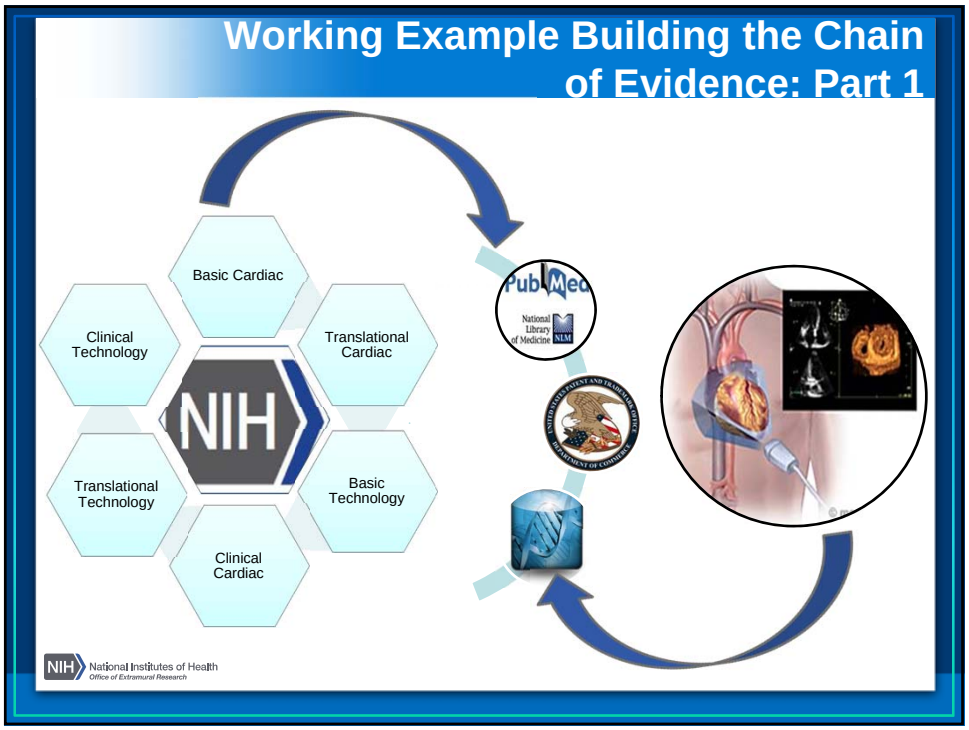
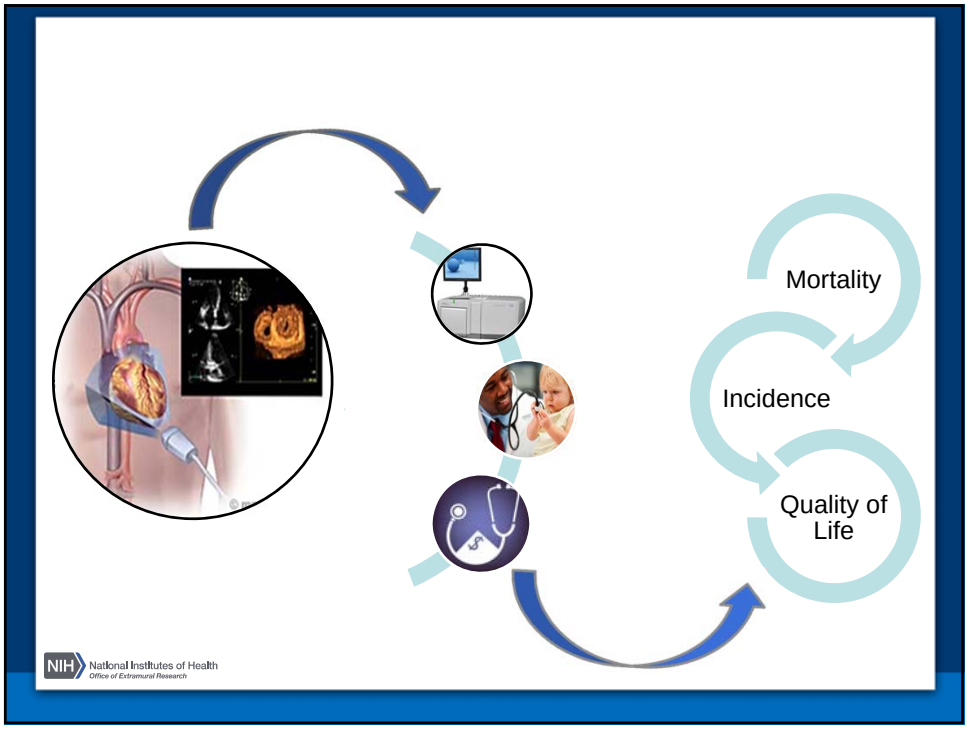
Diversity of Science Challenges Assessment of Value

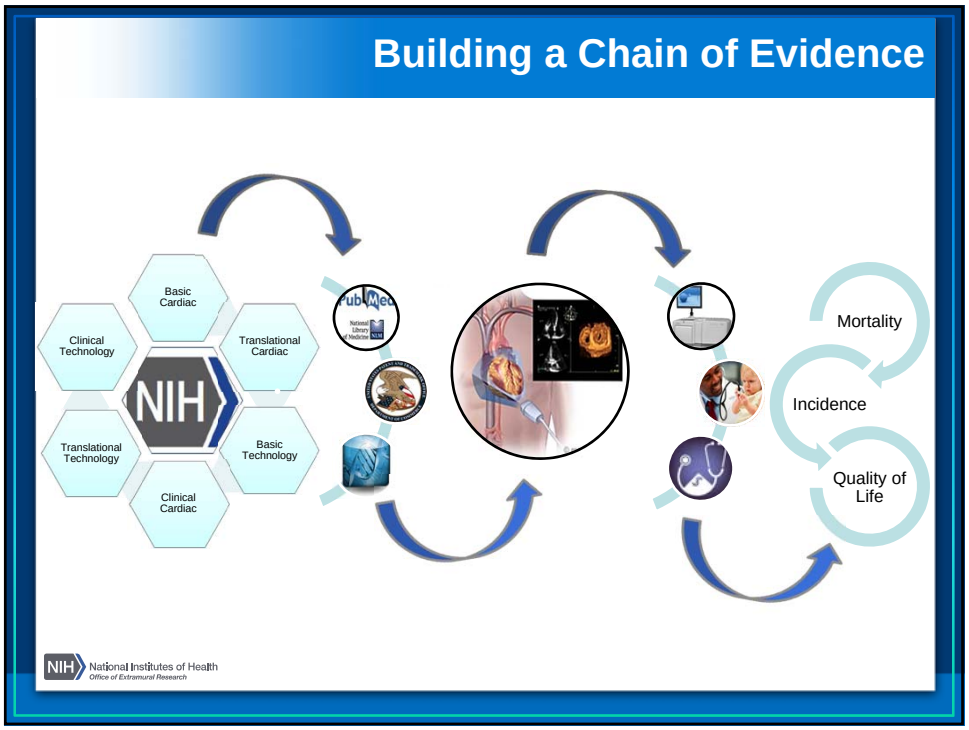
NIEHS
NIDCD
CIT
NATIONAL CANCER INSTITUTE
NURSING RESEARCH
National Human Genome Research Institute
National Institute on Aging
NICHD
National Institute of Child Health & Human Development
NIAID
FOGARTY
NIMH
National Institute of Mental Health
NIGMS
NLM
center for scientific review
Clinical Center
NCAM
NATIONAL CENTER FOR COMPLEMENTARY MEDICINE
NCMHD
National Eye Institute
NIDA
NATIONAL INSTITUTE ON DRUG ABUSE
NIBIB
NIAMS
NCATS
National Heart Lung and Blood Institute
National Institute of Dental and Craniofacial Research
NIDDK
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

NIH National Institutes of Health
Office of Extramural Research


How/Where to Start Assessing Value?
Publications
Patents
Technologies
NIH
Animal Models
Trained Workforce
Mortality
Quality of Life
Clinical Practice
Insurance Coverage
National Institutes of Health
Office of Extramural Research


Working Example Building the Chain of Evidence: Part 1
Basic Cardiac
Clinical Technology
Translational Cardiac
NIH
Translational Technology
Basic Technology
Clinical Cardiac
PubMed
National Library of Medicine
NLM
National Institutes of Health
Office of Extramural Research


Mortality
Incidence
Quality of Life
NIH National Institutes of Health
Office of Extramural Research


Building a Chain of Evidence
Basic Cardiac
Translational Cardiac
Basic Technology
Clinical Cardiac
Translational Technology
Clinical Technology
NIH
PubMed
Mortality
Incidence
Quality of Life
NIH National Institutes of Health
Office of Extramural Research

Building Chains of Evidence

Vision and Brainstorming

- Evidence will differ depending on the 'product'
- For any new initiative, could develop models of probable proximal and distal evidence
- Then consider, what databases could be tapped for assessing each part of the model
- If no databases available, are there ways to create the databases?

NIH National Institutes of Health
Office of Extramural Research

- Office of Extramural Research can help with:
  - Designing methods to acquire relevant data
  - Creating the tools needed to query, navigate, and synthesize data
  - Analyzing the models to assess value of research

NIH National Institutes of Health
Office of Extramural Research

“The crucial variable in the process of turning knowledge into value is creativity.”

- John Kao

NIH National Institutes of Health
Office of Extramural Research

Altmetrics and Revolutions:

New metrics for a new era of Web-native Scholarship.

bit.ly/nih-smrb-altmetrics
@jasonpriem

June 5, N H SMRB VOBR Mtg
Washington DC

What you do matters so much.

Communication is the soul of **science.**

Ye Olde Letter

	The Letter
tech	pen and paper
products	letter
filters	personal

In 1665 the first revolution:

Oldenburg publishes Phil. Trans; applies the best available technology printing press) to vastly improve dissemination.

A Step Forward : the Journal

	The Letter	The Journal
tech	pen and paper	printing press
products	letter	article
filters	personal	peer-review

A second revolution is coming

	The Letter	The Journal	The DcJ
tech	pen and paper	printing press	the web
products	letter	article	ecerything
filters	personal	peer-review	altmetrics

But journal are already online

Your revolution is over, sir!

"The Digital Publishing Revolution Is Over"

Online journals are paper journals delivered by faster horses.

The First Revolution promoted homogeneity of outputs.

The standardized article was born of the need for industrial-scale replication and interchangeability.

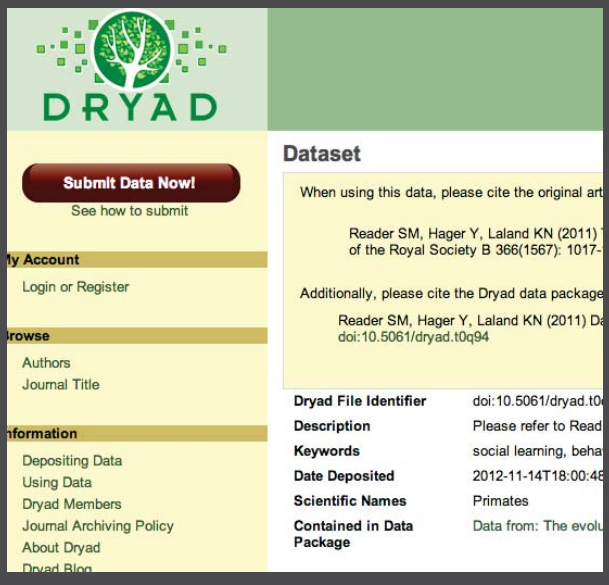
The Second Revolution will promote diversity of outputs

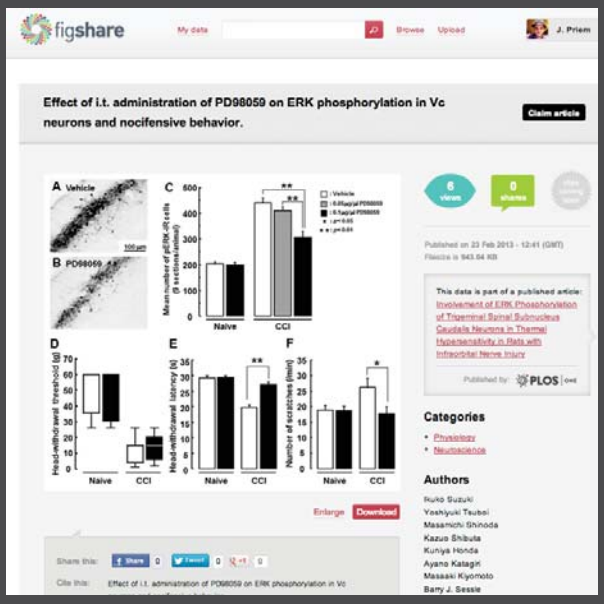
With publication nearly free, it becomes trivial to capture the missing pieces of the scholarly record.

Instead of moving paper products faster, we can create web-native science.

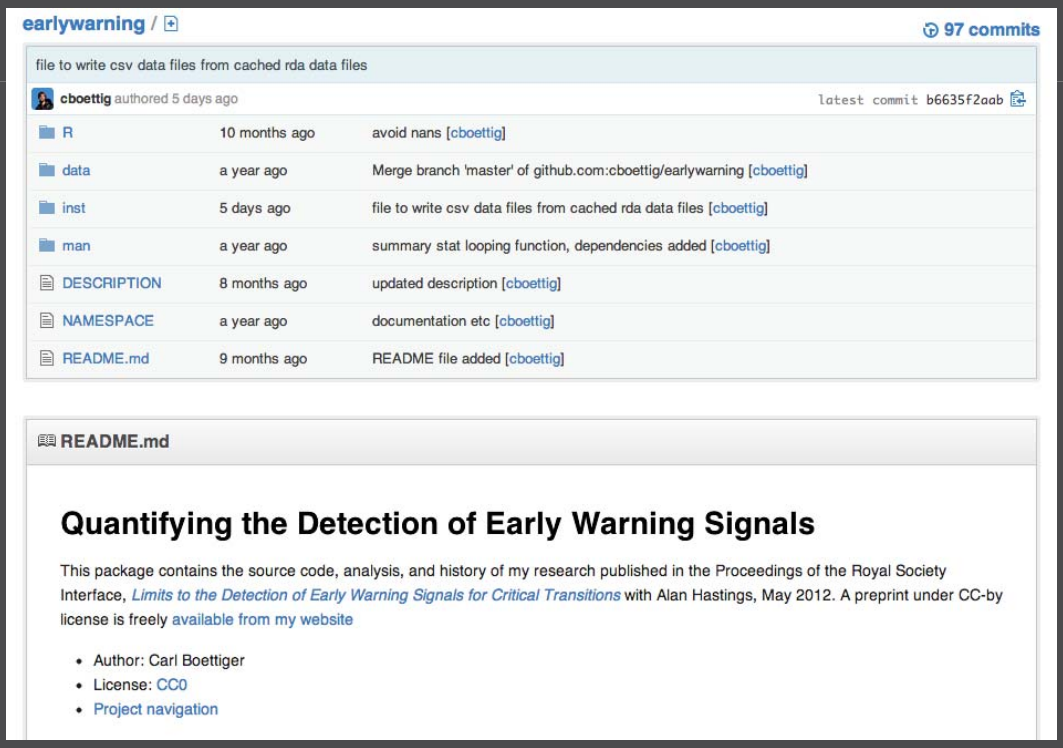
Conversation stories analysis data

data





analysis



earlywarning / 97 commits

file to write csv data files from cached rda data files

cboettig authored 5 days ago — latest commit b6635f2aab

R	10 months ago	avoid nans [cboettig]
data	a year ago	Merge branch 'master' of github.com:cboettig/earlywarning [cboettig]
inst	5 days ago	file to write csv data files from cached rda data files [cboettig]
man	a year ago	summary stat looping function, dependencies added [cboettig]
DESCRIPTION	8 months ago	updated description [cboettig]
NAMESPACE	a year ago	documentation etc [cboettig]
README.md	9 months ago	README file added [cboettig]

README.md

Quantifying the Detection of Early Warning Signals

This package contains the source code, analysis, and history of my research published in the Proceedings of the Royal Society Interface, *Limits to the Detection of Early Warning Signals for Critical Transitions* with Alan Hastings, May 2012. A preprint under CC-by license is freely available from my website

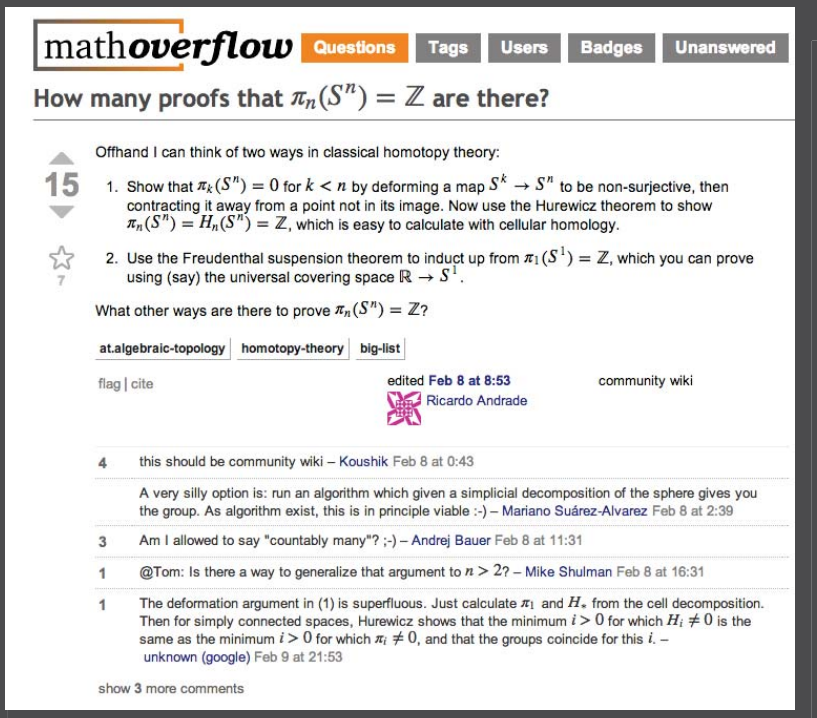
- Author: Carl Boettiger
- License: CC0
- Project navigation

stories

fiction:
short story, novella, novel, series, play,
film, comic book, etc, etc...

scholarship:
paper, monograph,
video, blog posts, notebooks, infographics,
slides, etc, etc

conversation



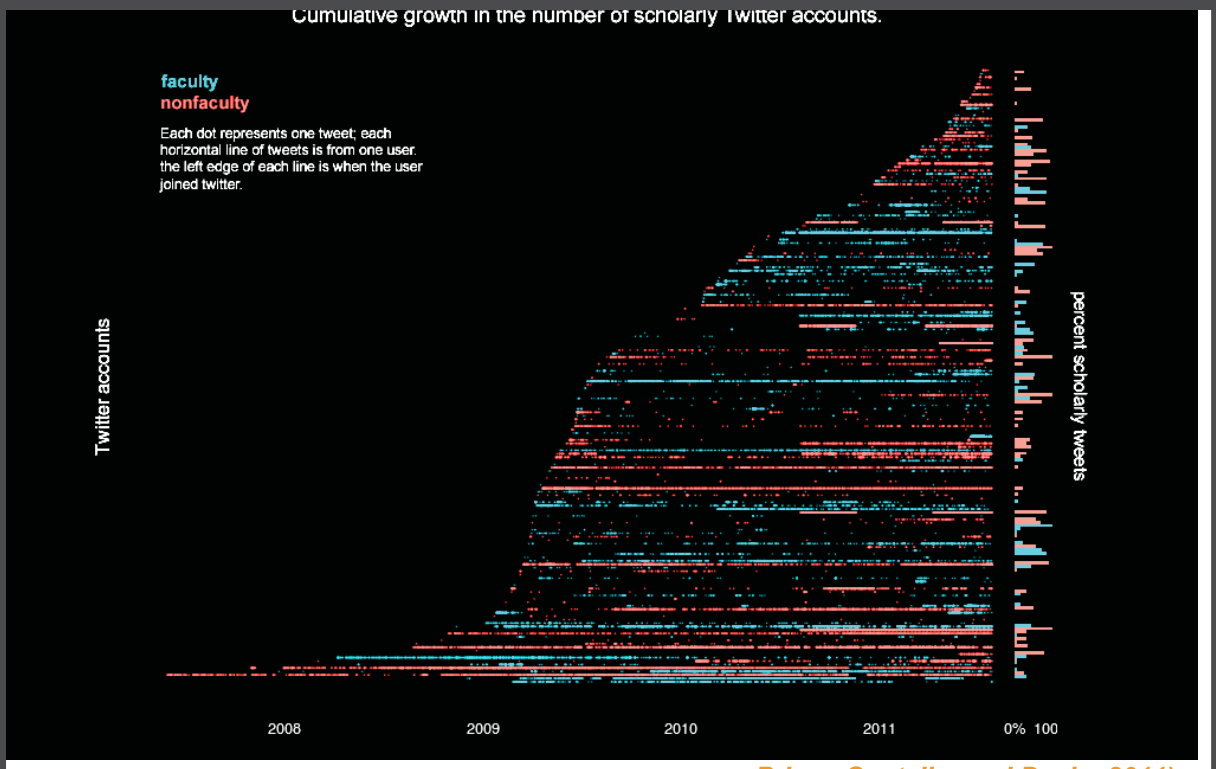
Example : Twitter

In one month, over 58k citations from Twitter to scholarly articles (citwaitions?)

> It is like having a jury preselect what will probably interest you.. Occasionally there will be something that people will link to, and it will change what I think, or what IIm doing, or what IIm interested in.
>
> -study participant

Priem and Costello, 2010)

Example : Twitter



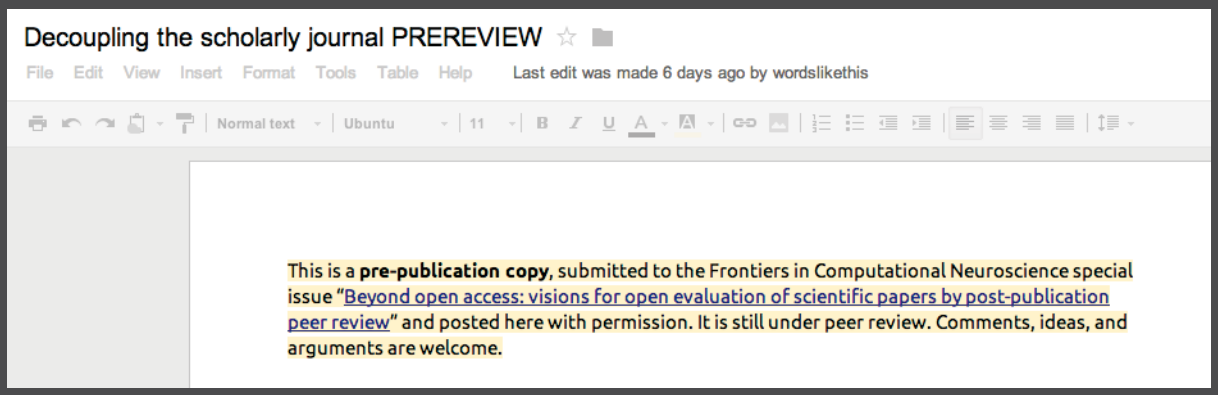
Priem, Costello, and Dzuba 2011)

Web-native science means we can start making public, not merely "Publishing "

Here's my journal:

Here's how I publish:

The Decoupled Journal article: a case study.



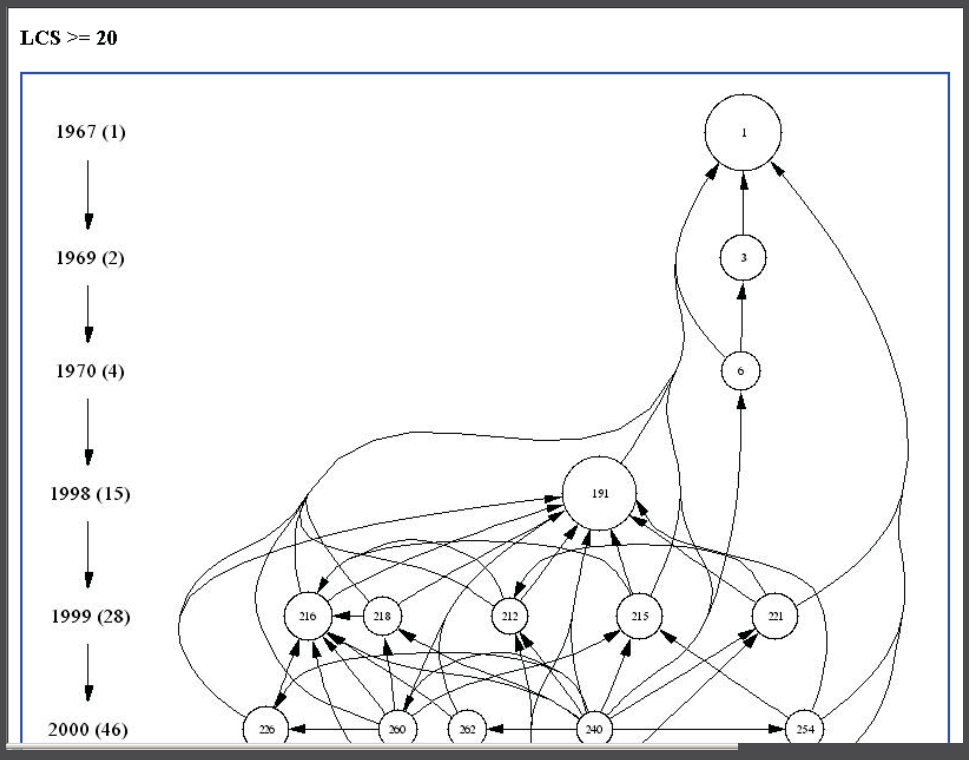
But how do we filter? How do we measure?

Don't turn off the taps,

Build boats.

The old way: countin' citations

And that's awesome!



histcite example

But citations only tell part of the story

Spotting emerging research fronts will require tracking "formal and informal communication" Kuhn, 1977)

Heart of scholarly communication is "visits, personal contacts, and letters." (Bernal, 1944)

"...there are undoubtedly highly useful journals that are not cited frequently." Garfield, 1972)

Impact has multiple dimensions:

Audience:	**Scholar, public**
Engagement type:	**Views, discussion,saves, citation,** recommendation

Impact has multiple dimensions:

	scholarly	**public**
recommended		
cited		
discussed		
saved		
scholarly		

Bibliometrics measures citation

	scholarly	public
recommended		
cited	traditional citation	
discussed		
saved		
scholarly		

Altmetrics measures impact:

	scholarly	public
recommended	faculty of 1000	popular press
cited	traditional citation	wikipedia
discussed	scholarly blogs	blogs, twitter
saved	mendeley citeulike	delicious
scholarly	pdf views	html views

Bibliometrics measures citation

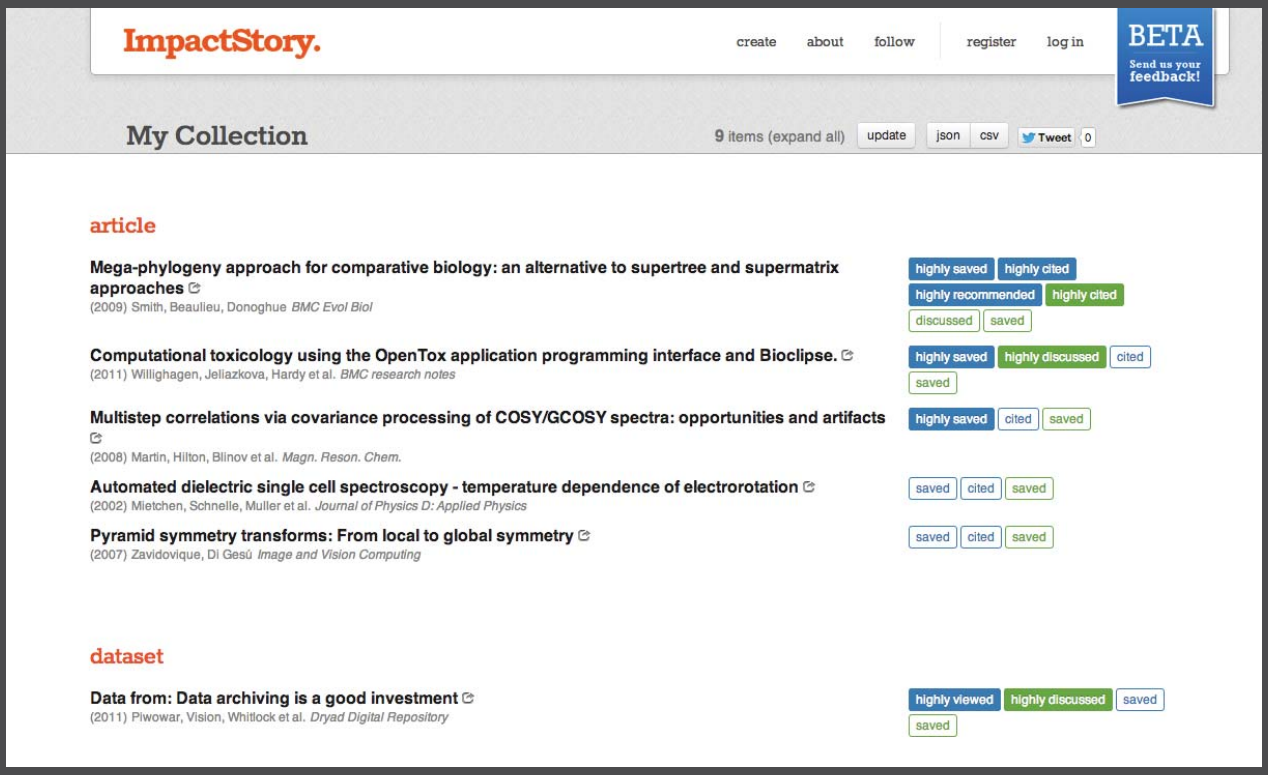
altmetrics mines **impact on the** next one.

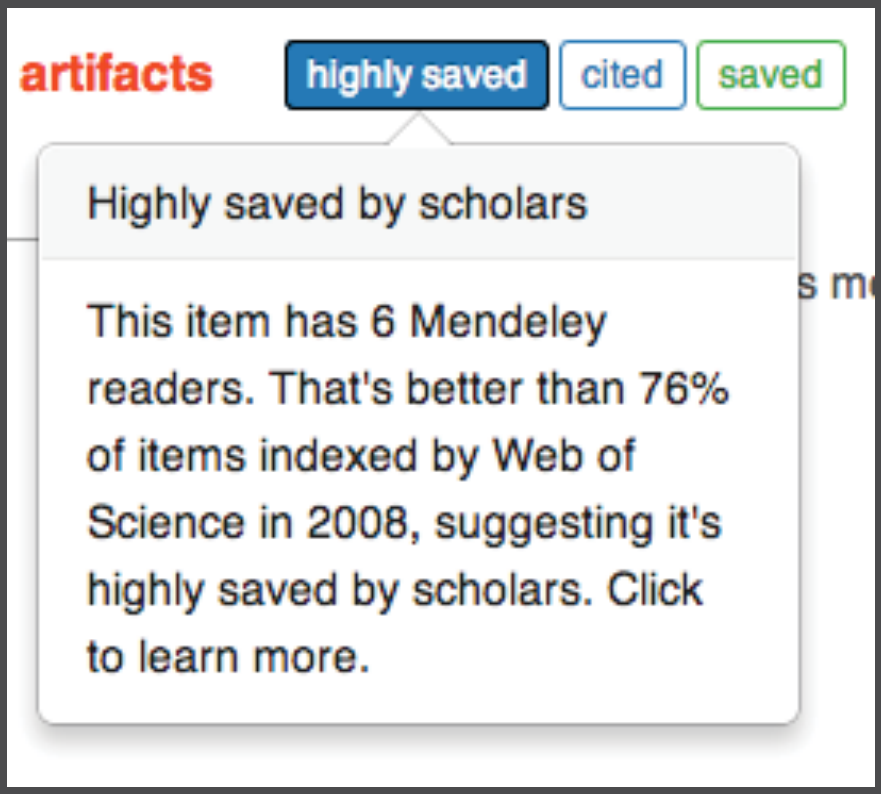
ImpactStory.

An open-source, nonprofit startup to gather and share altmetrics.

Heather Piwowar
Jason Priem

ALFRED P. SLOAN FOUNDATION

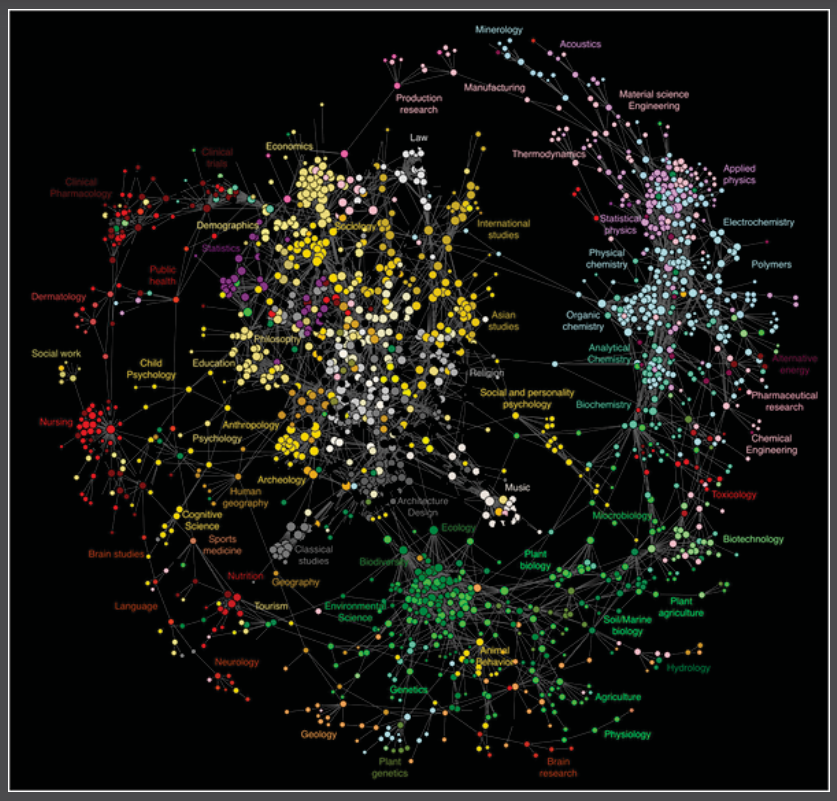




Why Altmetrics?

- Faster evaluation.
- Reward broader impacts.
- Reward web-native products.
- Build web-native filters

The network is the key



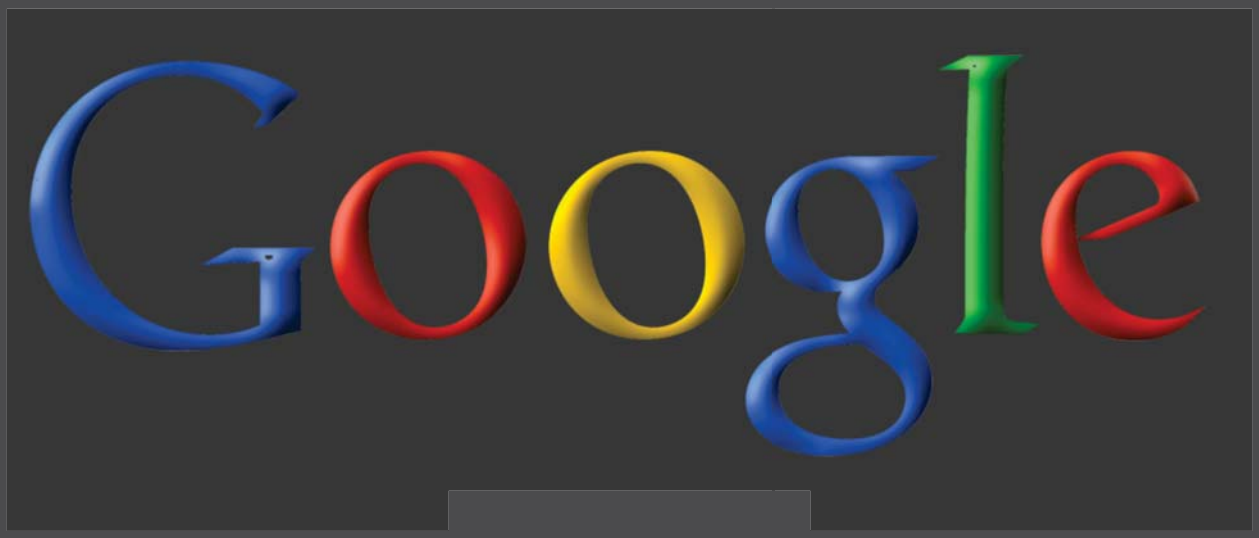
Bollen, J., Van de Sompel, H., Hagberg, A., Bettencourt, L., Chute, R., Rodriguez, M. A., & Balakireva, L. 2009). Clickstream Data Yields High-Resolution Maps of Science. PLoS ONE, 43), e4803. doi:10.1371/journal.pone.0004803

At web scale, the value isn't in manual curation...

YAHOO!®

ask these guys

It's in mining the network



The second revolution has started.

Once we have altmetric data, it's too useful to ignore; alternative filters and even certification paths based on this data will open.

As Peter Vinkler says, citation graph data is like Chekhov's gun: once on stage, it has to be fired.

A wise men, that Chekov

Thanks!

Advisors:

- Brad Hemminger,
- Todd Vision

Funders:

- Alfred P. Sloan Foundation
- DataONE
- Dryad
- National Science Foundation
- Open Society Foundations

Questions?

Jason Priem @jasonpriem, http://jasonpriem.org

This is a living document; if a particular version is important to you, make sure you link to that revision.

NIH National Institutes of Health
Turning Discovery Into Health
Scientific Management Review Board

SMRB Working Group on the Value of Biomedical Research

Gail Cassell, PhD
Chair, VOBR Working Group

Working Group Roster

NON-FEDERAL

- Gail Cassell, PhD *(Chair)*
- Norman Augustine
- Hon. Daniel Goldin
- Garry Neil, MD
- Gilbert Omenn, MD, PhD
- William Roper, MD, MPH
- Arthur Rubenstein, MBBCh

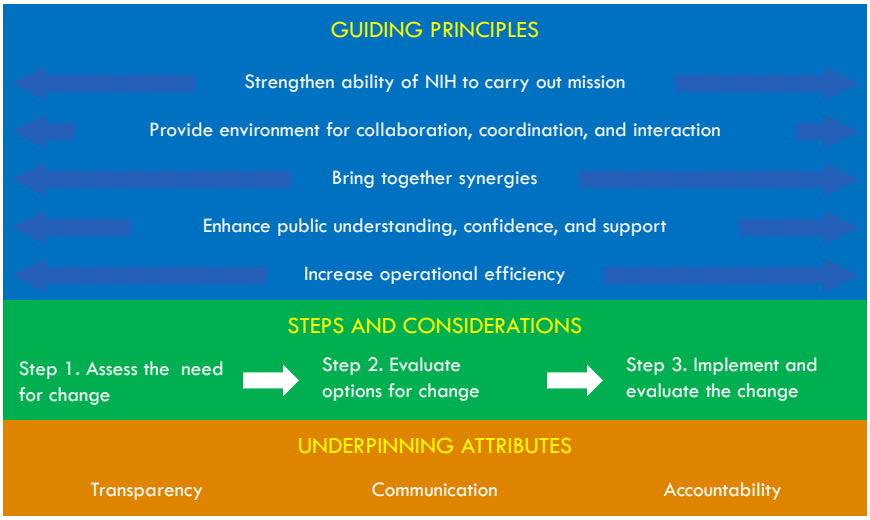
FEDERAL

- Alan Guttmacher, MD
- Richard Hodes, MD
- Stephen Katz, MD, PhD
- Griffin Rodgers, MD, MACP
- Martha Somerman, DDS, PhD

Working Group Activities to Date

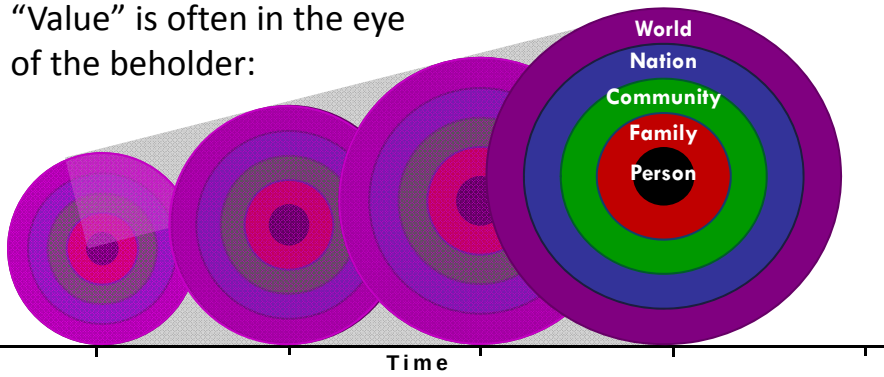
- **July 11, 2012 (SMRB):** NIH Director issues charge to SMRB regarding assessing the value of biomedical research
- **Sept–Dec 2012:** Compilation and analysis of relevant literature; discussion of basic evaluation framework
- **January 14, 2013 (SMRB):** SMRB meeting includes panel session focused on the economic value of biomedical research; VOBR Working Group members review relevant literature
- **March 2013:** Briefings by NIH staff on data collection and analysis tools and technology transfer; draft framework for tools and metrics for assessing value
- **April 2013:** Draft outline of report; discuss types of value and major elements of charge
- **May 2013:** Prepare questions for June 4 panel discussions

Deliberative Process



Definition of Value

"Value" is often in the eye of the beholder:

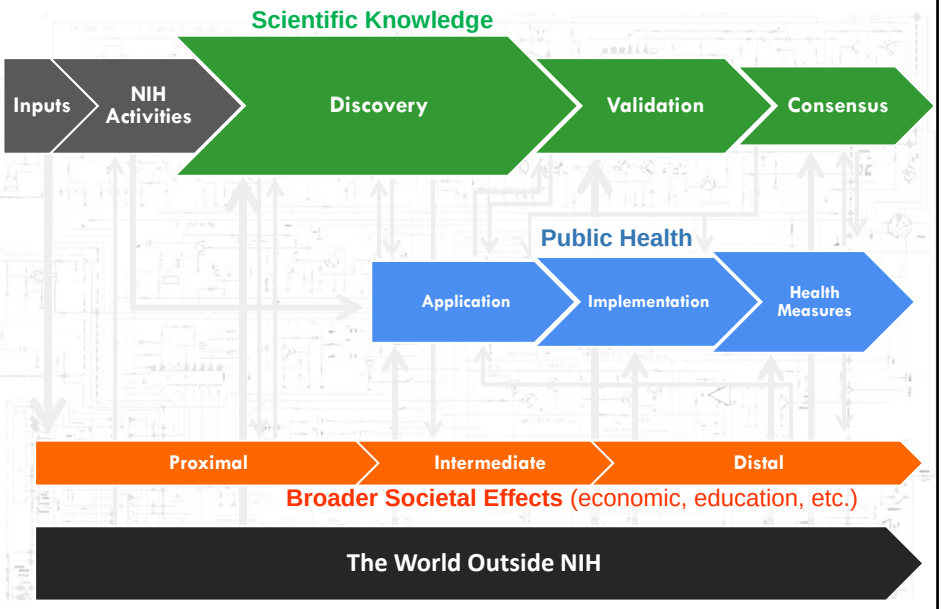


What constitutes value, who makes that determination, and how can it be observed across time?

Three Types of Value

- NIH's mission is to seek **fundamental knowledge** about the nature and behavior of living systems and the application of that knowledge to **enhance health, lengthen life, and reduce the burdens of illness and disability**.
- The Working Group has divided areas of biomedical research value into three streams:
  - Scientific knowledge
  - Public health
  - Broader societal impact

Basic Framework for NIH Value



Major Elements of the Charge

1. **Principles** that should underlie assessments of value
2. Advice regarding sound **methods and strategies** for assessing value
3. Advice regarding **study questions and selection of study topics** (e.g., case studies)

Charge Element 1: Principles

Guiding Principles, Limitations, & Caveats

Why does NIH need to better assess its value? What can we accomplish with this effort?

The SMRB is tasked with advising NIH on the objectives of value assessments and the realistic boundaries of assessing, attributing, and communicating value.

Charge Element 1: Principles

Principles Underlying Value Assessment

- Attribution
- Causality
- Precision
- Comprehensiveness
- Disclosure of assessment limitations
- Reflect values of society
- Other?

Charge Element 1: Principles

Challenges with Assessing Value

Assessing the value of biomedical research is difficult due to challenges with assigning attribution and causality.

- Multiple factors and sectors influence the **downstream effects** of NIH activities.
- It is difficult to estimate and account for the **lag time** between research and impact.
- There are myriad challenges in collecting and analyzing data that **accurately capture the outcomes** of NIH activities.

Is there anything unique for NIH, compared with other R&D agencies, in these challenges?

Charge Element 1: Principles

Common Elements of Value Assessments

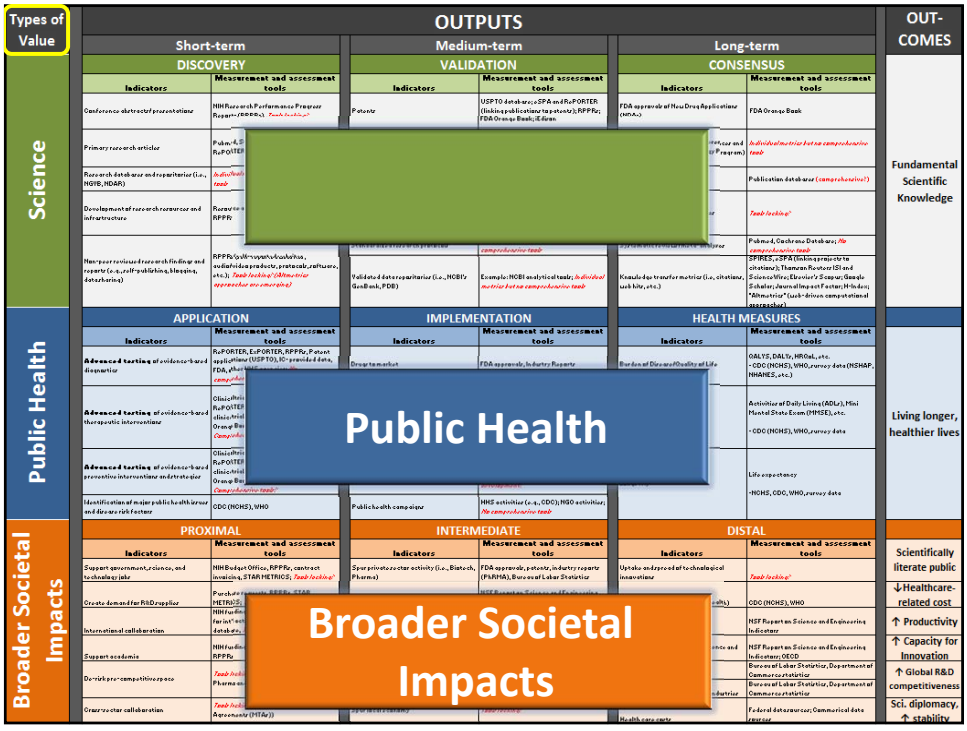
- Many models for assessing value have been developed for different contexts
- It would be useful to develop a generic model that can be customized and adapted to various study questions
- Identification of the critical components of such a model should be part of the Working Group's findings

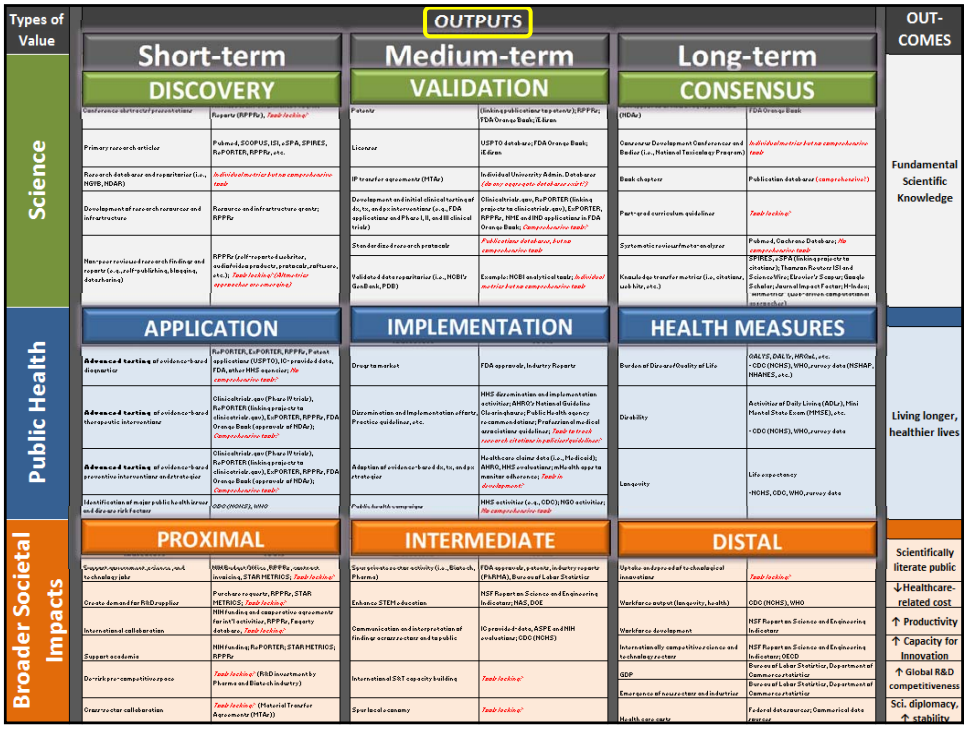
Charge Element 2: Methods & Strategies

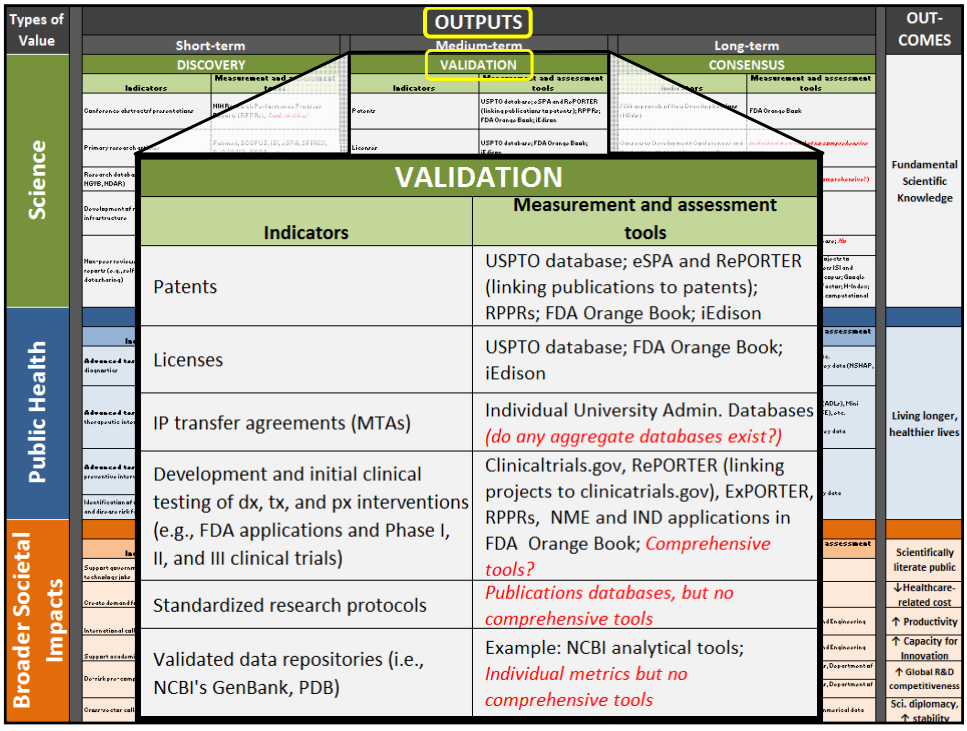
Methods & Strategies

How should we measure value?

The SMRB is tasked with identifying a set of metrics and strategies (established and emerging) that are most appropriate for this task.




Types of Value
OUTPUTS
Short-term
Medium-term
Long-term
OUT-COMES
Science
DISCOVERY
VALIDATION
CONSENSUS
Fundamental Scientific Knowledge
Public Health
APPLICATION
IMPLEMENTATION
HEALTH MEASURES
Living longer, healthier lives
Broader Societal Impacts
PROXIMAL
INTERMEDIATE
DISTAL
Scientifically literate public
↓Healthcare-related cost
↑ Productivity
↑ Capacity for Innovation
↑ Global R&D competitiveness
Sci. diplomacy, ↑ stability


Types of Value
OUTPUTS
Short-term
Medium-term
Long-term
OUT-COMES
Science
DISCOVERY
VALIDATION
CONSENSUS
Indicators
Measurement and assessment tools
Patents
USPTO database; eSPA and RePORTER (linking publications to patents); RPPRs; FDA Orange Book; iEdison
Licenses
USPTO database; FDA Orange Book; iEdison
IP transfer agreements (MTAs)
Individual University Admin. Databases
(do any aggregate databases exist?)
Development and initial clinical testing of dx, tx, and px interventions (e.g., FDA applications and Phase I, II, and III clinical trials)
Clinicaltrials.gov, RePORTER (linking projects to clinicatrials.gov), ExPORTER, RPPRs, NME and IND applications in FDA Orange Book; Comprehensive tools?
Standardized research protocols
Publications databases, but no comprehensive tools
Validated data repositories (i.e., NCBI's GenBank, PDB)
Example: NCBI analytical tools; Individual metrics but no comprehensive tools
Public Health
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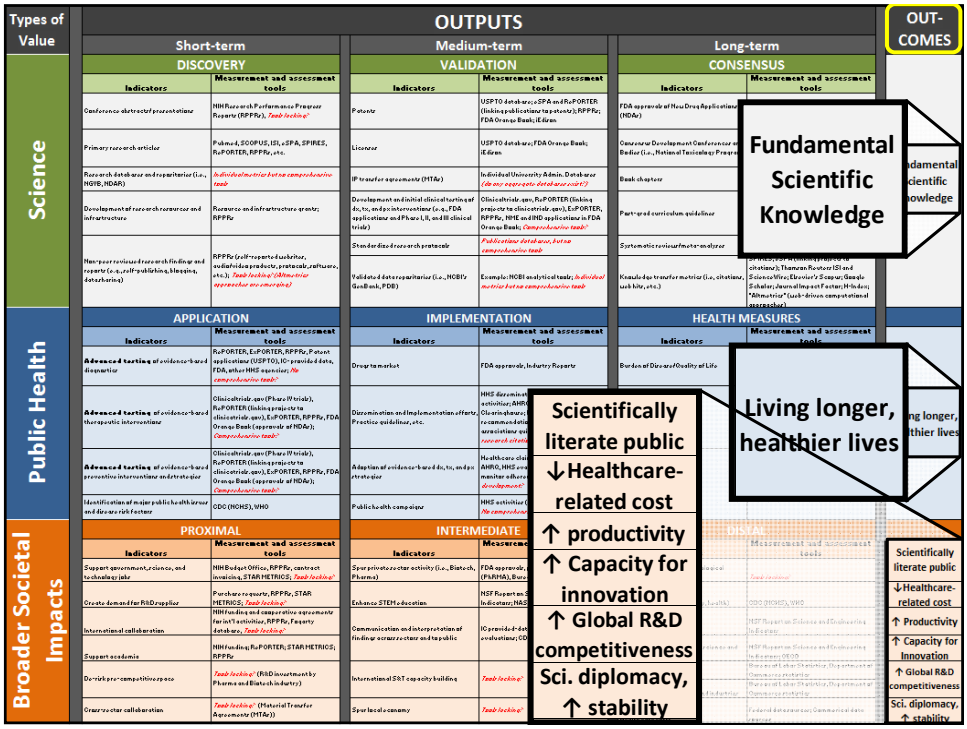
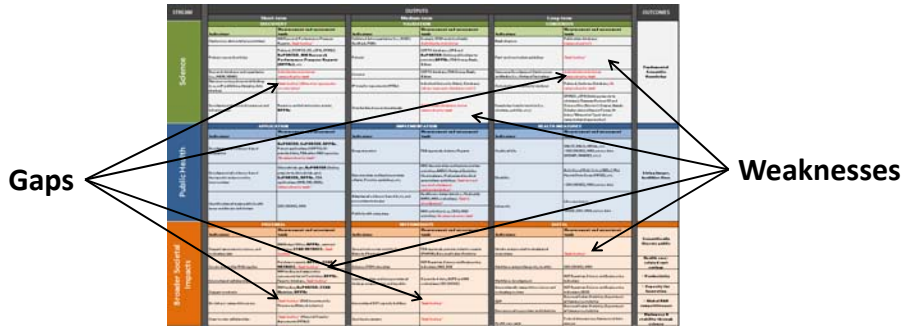


Charge Element 2: Methods & Strategies

Existing Metrics: Room to Improve



Charge Element 3: Study Selection

Study Question & Topic Selection

What topics best communicate and represent NIH's value?

The broad scope of NIH research and the multitude of potential outcomes to be measured pose challenges to assessment efforts. The SMRB is tasked with advising NIH regarding the selection of study topics that are feasible and representative.

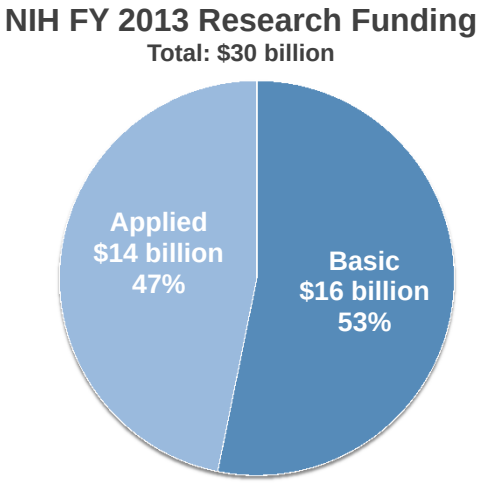
Charge Element 3: Study Selection

Goals of Case Study Selection

- **Illustrate the full spectrum of NIH research, including:**
  - Basic and clinical research
  - Slow and quick time to payoff
  - Successes and "failures"
- **Underscore the importance of investments in basic research**

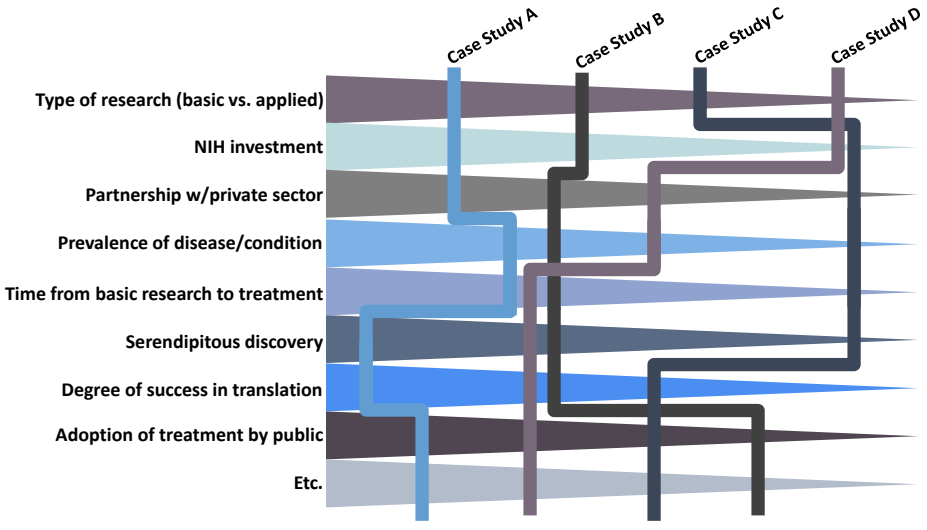
Charge Element 3: Study Selection

Goals of Case Study Selection *(cont.)*



Charge Element 3: Study Selection

Goals of Case Study Selection *(cont.)*



Goals for Today's Presentations

- Discuss principles and attributes of how to define and assess value
- Learn of opportunities to improve assessments
- Engage experts in ways to assess value of scientific knowledge, public health, and broader societal effects of biomedical research, including:
  - Strengths and gaps of prior studies
  - Landscape of current efforts
  - Outlook for future endeavors
- Discuss the relevance of these findings to NIH

Panel Sessions and Roundtable

- **Panel I:** *Assessing the Value of Biomedical Research: Principles, Metrics, Strategies, and Caveats*
- **Panel II:** *Public Health Outputs and Outcomes of Biomedical Research*
- **Panel III:** *Broader Societal Impacts of Biomedical Research*
- **Roundtable Discussion of Value of Biomedical Research Themes**

Panel Sessions and VOBR Working Group Deliverables