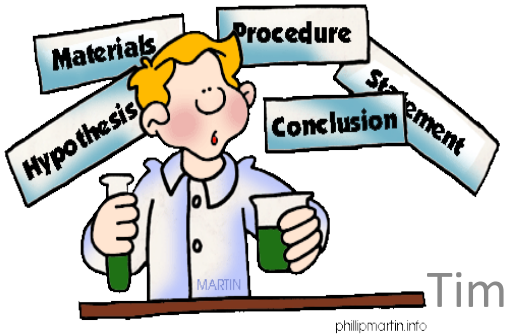
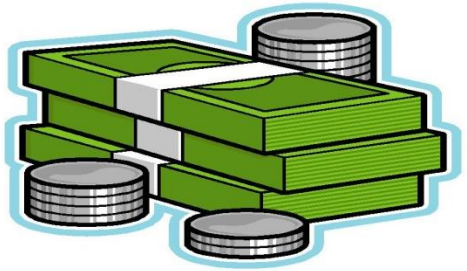
Benefit Cost-Analysis in the Outcome Evaluation of Small Biomedical Research Portfolios





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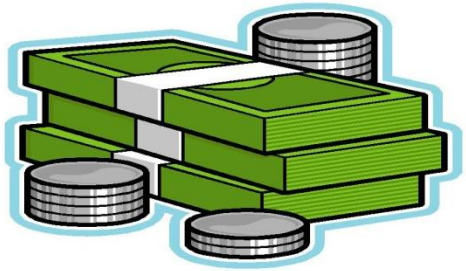
Introduction

Public funding of research includes many discrete components

- Setting research priorities
- Securing funds
- Funding research infrastructure
- Selecting and funding meritorious projects
- Conducting research
- Monitoring research progress
- Communicating research findings
- Training researchers



Evaluation of research, particularly biomedical research, **has entered a period of intense demand for rigorous methods and actionable results**. Challenges and opportunities exist in meeting this demand.

Goals of the National Institutes of Health

- Foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health

- Develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease

- 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

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

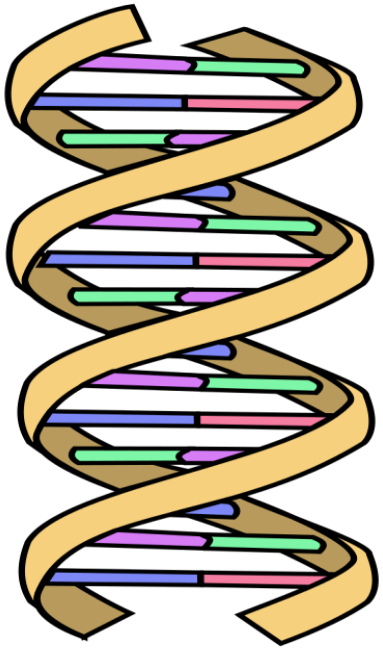
NIH Studies of Economic Return on Investment

Battelle (May 2011). "**Economic Impact of the Human Genome Project (HGP)**." http://battelle.org/docs/

$3.8 billion in extramural funding (nominal dollars)

Major findings

- The HGP and "associated research and industry activity directly and indirectly generated $796 billion in U.S. economic output" (p.ES-2)
- Return on $1 investment: $141
- Updated in 2013, greater ROI
- Restated some analyses, smaller ROI



NIH Studies of Economic ROI

Economic Return from the Women's Health Initiative (WHI) Estrogen Plus Progestin Clinical Trial, Roth et al., 2014

Major Findings

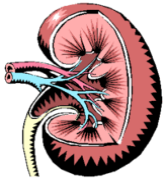
- $260 mil in extramural funding ($ 2012)
- Estimated savings from treatment & illnesses averted
- $35.2 billion saved in direct medical costs
- Net economic return: $37 billion
- Return on $1 investment: $140

University of Michigan
School of Public Health

"What does it take to change the world?"

Example 1

- **$5** – Average cost of one malaria bed net
- **$12 billion** – Estimated direct global costs of malaria (illness, treatment, premature death)



Example 2

- **$3.3 million** – Cost of 5 year federally funded study on Medicare payments for dialysis, medications, tests
- **$225 million** – Annual savings to Medicare from implementation of new dialysis payment system based on study

Information Needed to Determine Economic Outcomes of Biomedical Research on Observed Changes in Medical Treatment

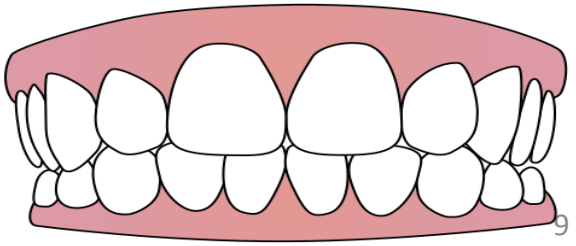
- Research associated with the observed change in medical treatment
- Observed change in medical treatment
- Attribution (descriptive or quantified) of the causal effect of observed biomedical research findings on the observed change in treatment

Information Needed to Determine Economic Outcomes

- Research associated with the observed change in medical treatment
  - Purpose and methods, showing at least a clear theoretical or hypothetical link to the treatment of interest
  - Outcomes, showing a clear potential link to the observed change in treatment
  - Costs
- Observed change in medical treatment
  - Description of the initial treatment and the change in treatment
  - Utilization data in population(s) of interest (frequency and intensity) for initial treatment
  - Costs of initial treatment
  - Economic and non-economic outcomes observed or predicted by the change in treatment
  - Identification of target populations most likely to be affected by the change in treatment
- Attribution (descriptive or quantified) of the causal effect of observed biomedical research findings on the observed change in treatment
  - Dissemination of the research findings must be established before a claim of attribution may be made
  - Attribution may be assessed by face validity, temporal validity, formal causal analysis, or other empirical method

Research Methods

- Five research programs identified: **dental sealants**, early childhood caries, oral cavity & pharyngeal cancers in the elderly, validated cell lines in head and neck cancers, and oral HPV infection
  - Evidence of benefit available in peer-reviewed science literature
- Data collected, consistent with model
- Evaluability assessment conducted: feasibility of economic outcome evaluation, given data collected
  - Recommendations if not feasible



Research Data Collected

Needed element	Available element(s)	Source
Purpose	Proposal, annual reports (narrative)	Internal documents
Method	Proposal, annual reports (narrative)	Internal documents
Outcomes	Annual reports, publications, patents, policies, treatment guidelines (narrative, quantitative)	Internal documents, public databases
Costs	Extramural program budgets (annual $)	Internal documents, public databases

Treatment Change Data Collected

Needed element	Available element(s)	Source
Description, initial	Utilization statistics for dental sealants with sub group analyses	MEPS, NHANES, internal document
Description, change	Increases in sealant use, especially in Medicaid populations, 1990-2010	MEPS, NHANES, internal document
Treatment cost	$ 11.60	Peer reviewed publication
Economic outcomes claimed (observed or hypothesized)	Benefit > $11.60 for high risk children 7-12 years old, peaking at $15.21 for 9 year olds	Peer reviewed publication
Target population(s) identified	High risk for dental caries	Peer reviewed publication

Attribution Data Collected

Needed element	Available element(s)	Source
Dissemination mechanism identified	Yes, Publication and citation counts	Bibliometric analysis
Face validity	Yes	Expert opinion
Temporal validity	Yes	Internal portfolio analysis
Causal analysis	Not done	

Results of the Evaluability Assessment

- Was the economic claim of treatment benefit credible?
  - Yes, but comprehensive lit review recommended
- Did utilization data support a treatment change in a targeted population?
  - Yes
- Was the research relevant to observed treatment change?
  - Yes
- Were the research findings disseminated prior to the observed treatment change?
  - Yes
- Was attribution (causal link between research & treatment change) established?
  - No, formal causal analysis (expert panel review) recommended

Conclusion

- Data were available to conduct an economic outcome study on the returns to investment of a federally funded dental sealant research program
- Evaluability assessment supported the need for additional data to:
  - Establish the causal link between the research and the observed change in treatment
  - Estimate the economic benefit of the observed change in oral health treatment
- Based on currently available data, **the research program is not ready for the evaluation of economic returns on investment**

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- The views expressed in this paper are those of the authors and not necessarily those of the National Institutes of Health or George Washington University.

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