

Toward a Scientific Basis for Managing NIH Research

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Celebrating our 30th anniversary !

Thank you.

- 1978 Launched efforts with Dr. Robert Levy, then director of NHLBI, to create a “science of science management” .
- 1980 Conference on the Development and Dissemination of Biomedical Innovation
- 1981 “ *Biomedical Innovation*” (MIT Press), edited by Roberts, Levy, Stan Finkelstein, Jay Moskowitz and Ed Sondik

Great team. But unfortunately no substantive follow-on !

Overview: *"Biomedical Innovation"*, 1981

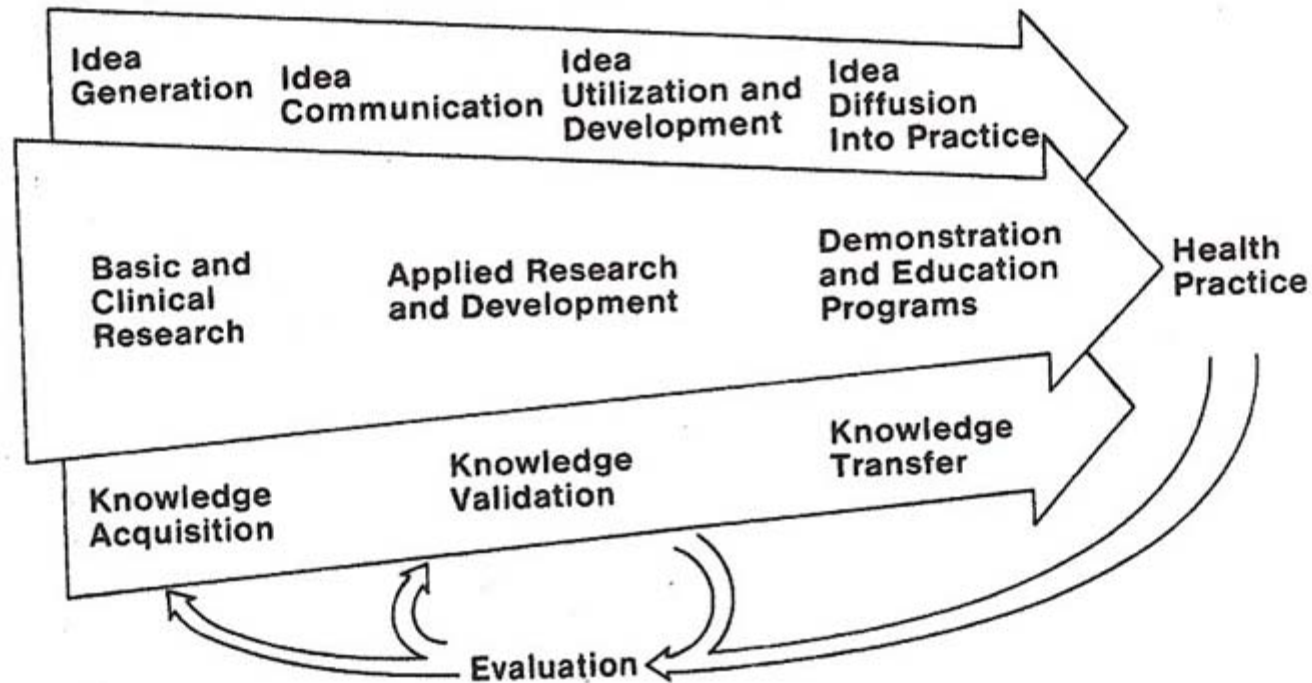


Figure 1.1 The biomedical research spectrum.

Top arrow: First four stages of discovery-innovation process
Middle arrow: Categories of research then being funded
Bottom arrow: Primary objectives of each phase of the research continuum
Evaluation as a potential feedback loop affecting all activities

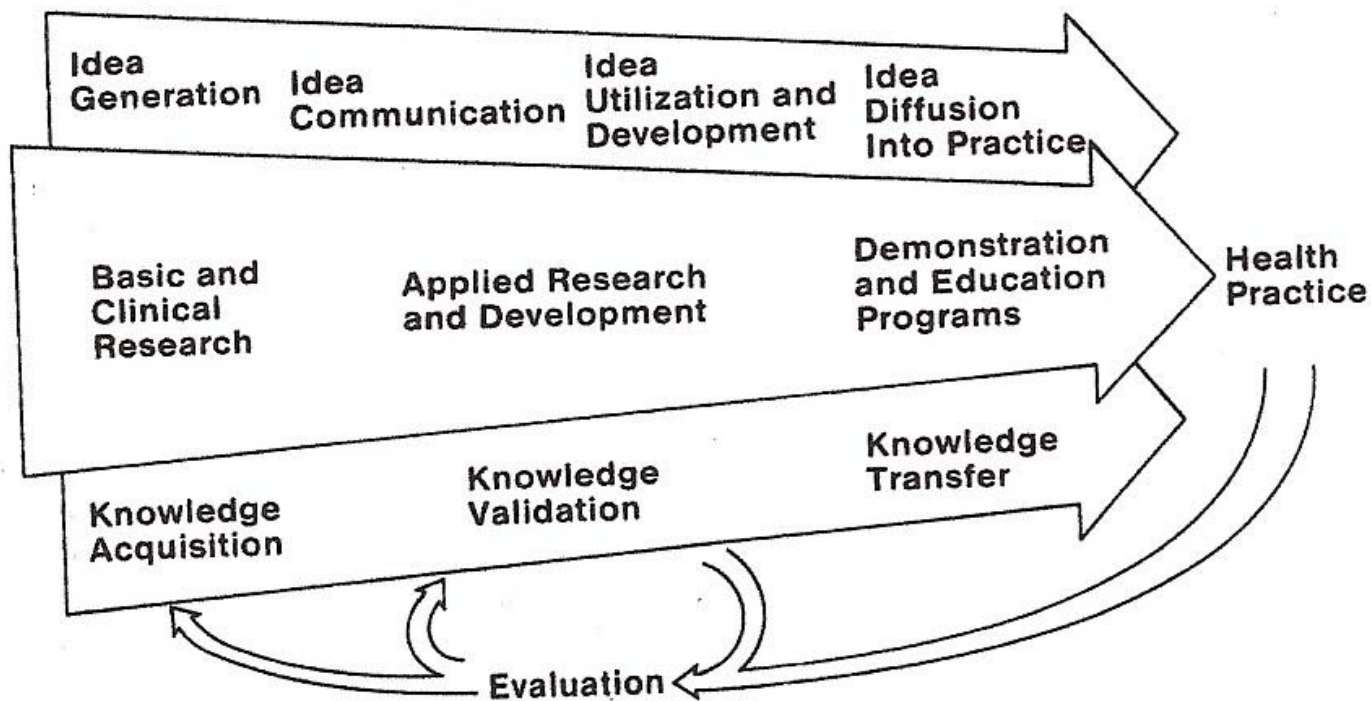


Figure 1.1 The biomedical research spectrum.

We must take into account some unique characteristics of the Health Sector which may make NIH research different

- Medical practitioners, and their students, sometimes enjoy close relationships with researchers.
- Majority of biomedical research takes place in universities.
- Considerable lag exists between discoveries and their eventual validation and application.
- Somewhat in contrast, adopting some innovations too quickly, prior to adequate validation, has had a negative effect on society.
- The Federal government sponsors much biomedical research, but unlike with Defense it is not the direct customer for the products of this research.
- Biomedical technology has the highest governmental regulation of product acceptability and diffusion.
- Medical practitioners are the intermediary market, and only after that comes the public as the ultimate consumers with health care needs.

What do we know about: Generation of ideas ?

- Group diversity in professional backgrounds and activities, age of group togetherness, supervisory skills, linkages to outside idea sources all affect R&D idea-generating performance. More collaboration leads to more productivity.
- Some ideas come from users, not researchers or producers. Most ideas that eventually get adopted originate outside the organizational unit that develops and uses them.

We know little about how the productivity of novel and eventually useful ideas is influenced by technological risk, by interactions among multiple technologies, by characteristics and organization of the individuals (including their gender), the groups, the project teams, the laboratories (including their size and leadership). Adam Jaffe showed (NSF 2006) that we still know little about measuring “scientific performance” itself.

- What affects the entry/exit of people into new fields? Yet isn't most of the money going to the “same” people to do the “same” kind of research?

What do we know about:

Communication of ideas, technical knowledge and materials ?

- Occurs through a myriad of formal and informal channels. Formal, such as papers, are not important to engineers, in sharp contrast to research scientists. Science may well be universal whereas technology is more local. This may be a prime differentiator between advances in medical tools, devices and practice in contrast with advances in basic knowledge. Biomedical materials transfers are also critical, e.g. reagents, tissues, cell lines and engineered mice. More open access enhances basic research. (Murray et al.)
- Some idea generators (i.e. those who are more “entrepreneurial”) are far more likely to “push” their ideas toward application and/or commercial development. We don’t know how much this affects overall lags or outcome quality.
- Bayh-Dole Act has influenced openness of scientific communication, patenting behavior, and university entrepreneurship. But we don’t know the net effects on medical innovation.

What do we know about: Clinical applications and development ?

- Only a small fraction of knowledge generated from biomedical research is selected for the development of clinical applications. 30% of the human genome has not yet been thoroughly studied.
- Different factors must affect product innovation and innovation in clinical practices.
- Bayh-Dole Act has influenced investigator research selection toward more applications-orientation.
- Networked clusters of universities, biotech firms and pharmaceutical labs are altering the nature and pace of clinical developments. (Powell & Owen-Smith, Zucker & Darby)

Only two ambitious empirical research attempts to influence selection criteria in scientific research and development

1. Project Hindsight: Department of Defense, 1966-1969
20 major weapon systems
710 RXD (Research and Exploratory Development) Events that were the bases for the technological advances
2. Comroe-Dripps: NHLBI, 1971-1977
Top 10 clinical advances in cardiovascular-pulmonary medicine and surgery
663 (or 529?) key articles that were essential to the advances
3. Some methodology problems in both studies. But other studies (e.g. NSF's Project TRACES) were merely poor attempts to refute Hindsight conclusions and provided no useful insights.

Project Hindsight's key conclusions

- The sources of key contributions from Defense R&D spending tended to be proportional to the amount of funds allocated to each sector, with universities being no more productive than industry.
- Higher R&D effectiveness toward Defense goals accompanied mission-oriented research.
- The time lags from basic research to application were so long that merely a tiny fraction of funded basic research got into applications over a 30 year period, mostly those related to the transistor.

Comroe-Dripps results, as seen in Stokes' Matrix of how science is structured (Baldwin, NIH 2007)
Their strongest conclusions: Clinical advances require inputs from all kinds of R&D. But mission-oriented research does not dominate.

Comroe-Dripps study — results

Fundamental?	Yes	Pure Basic Research 37%	Use-inspired Basic Research 25%
	No	Natural History 15%	Pure Applied Research 21%
		Low	High
		Useful?	

Review and Synthesis 2%

It takes all kinds!

Lags between discovery and effective clinical application

(Comroe-Dripps data, p. 3)

% of cases (n = 111)	Years of lag
8	0.1-1
18	1 - 10
17	11 - 20
39	21 - 50
18	> 50
Weighted average	➤ 30 years

Outcomes of these two major studies

- Some insights provided relating to broad funding allocation categories in Defense and NIH research.
- Some interesting data generated on lags between discovery and application.
- No perspectives gained on the organization and management of people, teams, projects, programs, laboratories et al. for either Defense or Health.
- More thoughtfully designed studies could have provided better guidance for the “science of science management” .

What do we know about: Diffusion and adoption of technology ?

- Extensive research on the diffusion/adoption process. Less clear on hospital adoption of technology. Much less research on actual use.
- Decision by prospective users to adopt may relate to characteristics of the new technology and/or the user.
- Strong role of personal experience and informal communications networks among physicians, who are akin to engineers in reliance upon informal sources rather than peer-reviewed scientific publications.
- FDA impact has, relative to other countries, increased U.S. lags in drug and device approval and use, but we don't know whether the overall social outcome is better or worse.

Comroe-Dripps Recommendation

#1

- Though more difficult than laboratory or clinical research, research on research (the process and pace of discovery) can be done and deserves increasing attention from scientists and science administrators who need objective data to recommend or make biomedical science policy.

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Goals for the requisite NIH research program on managing its own research

- STOP using anecdotal evidence as primary basis for policy-making, even when coming from panels of “wise old men” !
- Achieve deeper understanding about how to organize and manage research aimed at: Detection, diagnosis, therapy, rehabilitation and prevention of disease -- “biomedical technology” in the broadest sense. Examine how university and other institutional policies affect pace of scientific and clinical advance (e.g., Stern on Biological Resource Centers).
- Evolve a coherent strategy for understanding and evaluating the: origins, development processes, transfer mechanisms, and early dissemination of new medical practice, and for assessing the effectiveness/productivity of alternate approaches to these issues.

Alternative way to formulate overall “research on research” program could be to focus on: Strategy, structure, staffing, and supporting systems for biomedical research and technology.

- Translate these research results into adopted and implemented NIH research policies and practices.

Some suggested new directions for NIH management research

- Launch more experiment-like studies, tied to live monitoring of organizational and managerial dimensions:
Fund parallel research efforts with multiple groups.
Use close ties to large pharma to permit researchers to gain access to “natural experiments” of competitive industrial labs working on similar programs.
- The world has changed: Now NIH needs to examine in depth the relationships between universities and biotech startups and between the new companies and their pharmaceutical partners in drug development.
- Produce studies that provide meaningful samples of how medical innovations actually develop. Overall policies including funding allocations must reflect the research findings.