Plenary Session Meeting Highlights Science of Science Management National Institutes of Health Bethesda, Maryland October 2-3, 2008

About the Conference

To support building capacity and infrastructure in the Science of Science Management, the National Institutes of Health (NIH) brought together a multi-disciplinary group of experts for a two-day meeting to create a forum to initiate the systematic research of science management issues, with a focus on providing evidence-based information for executives, scientists, practitioners, individuals, and policy decision-makers.

The evaluation of science has been problematic, due to the complexities of the research and development (R&D) process with its unknown timeframes, costs, and products. Shifting the focus to science management may foster more appropriate R&D performance assessments, develop schemas and models for benchmarking, and build the capacity to systematically research science management topics. These results can be used to foster evidence-based decisionmaking. The goal of this collaborative effort is to produce assessment models that can be researched and tested post-meeting.

Plenary Session Highlights October 2, 2008

NIH Director's Charge Elias Zerhouni, M.D.

Trying to define "the science of science management" is difficult, but from the perspective of the NIH Director, Dr. Zerhouni understands it to mean finding ways to better use the resources given to NIH by the American public, based on a set of principles. Dr. Zerhouni noted the irony that scientists believe that they are not really scientists, but rather artists using a method called the scientific method. And, "the first thing that we absolutely, positively hate is to have the scientific method applied to us."

The challenge is in trying to manage the unknown, since one cannot know when breakthroughs will occur. Several approaches can be taken along a spectrum. The most "libertarian" approach is to allow science to operate independently and with little direction. At the other end of the spectrum are constituencies that believe that NIH is failing its duty if it does not try to understand where the gaps are and try to fill them (e.g., the Human Genome Project, the Internet). A middle ground approach is to aim for explicit understanding, that is, information should flow within the scientific community in a way that allows every scientist to make their own decisions and come together as freely as they can on the basis of good information and as free as possible from biases, conflicts of interest, and tradition-bound concepts.

Although eliminating bias and conflict is difficult, the notion of transparent access to a large body of scientific information is not. This access is critically important because breakthroughs increasingly are interdisciplinary, occurring at the interface between disciplines. Thus, science must be organized to allow and promote such interchanges.

How to build feedback loops, or evaluate science, is especially baffling, and the subject of many conversations that Dr. Zerhouni has had when discussing NIH's mission and strategies in the international

arena. Are presentations, publications, citation indices, impact factors, or generated patterns useful evaluation criteria? Or is simply reviewing the scientific landscape and centers of excellence sufficient? The current focus for NIH is on creating a feedback loop based on better information and intelligent analysis of the totality of potential activities that occur in science. How does one separate the noise from the signal? How does one systematically conduct scientific portfolio analysis without lowering the potential for creativity around the margins?

It is useful to step back and look at the 150-year cycle of science. The first 50 years tend to be a reductionist period, focused on understanding the components of the system: DNA, RNA, proteins, and all the fundamental mechanisms and principles on which the system works by its elements. But at some point, the complexity of the system needs to be integrated—an integrationist phase. Will where the scientific community is in the cycle provide clues as to how to manage the science? Should methods of evaluation be based on currently accepted criteria? And, how can one make sure that the best information is available to the best scientists so that they can take on opportunities at their own pace within their own environment? At the end of the day, science is not a top-down activity. NIH can stimulate the process, but cannot do the science.

Opening Remarks

Science of Science Management: Bricklayers, Architects, and City Planners Alan Krensky, M.D., Director, Office of Portfolio Analysis and Strategic Initiatives (OPASI)

NIH's science of science management effort is part of the Roadmap for Medical Research. This conference is a first effort to determine what that term means. Dr. Krensky's title for the session reflects the many actors needed to conduct science, from those who do incremental, standard research (the bricklayers) to those conducting more innovative, high-risk work (the architects), to those who think broadly and in truly transformative ways, generating new paradigms (the city planners).

The fundamental questions are should science be managed, can science be managed, and how can or should NIH manage it? In addition, what factors should be considered, such as:

- Top-down versus bottom-up
- Group versus individual decisionmaking
- Investigator-driven versus directed-research
- Basic versus clinical
- Centers versus individual grants
- Innovation versus incrementalism
- Traditional evaluation versus new assessment models

OPASI and its three divisions are trying to change the culture of science management through strategic initiatives, evaluation, and portfolio analysis. The office has developed a definition of the science of science management for use at the meeting:

A process to understand stewardship and to foster innovative use of resources for planning, conducting, and disseminating scientific research to inform decisionmaking that enhances science productivity and improves public health.

The goal of developing the science of science management is to provide evidence for decision-makers, additional information to aid judgments, historical illustration for predictive planning and management, and methodologies more appropriate for science assessment. Behind this goal is the mission of NIH, which is to generate knowledge in order to improve public health.

It is easiest to organize conceptual thinking about the science of science management around a continuum of vision into action:

- current state of knowledge assessment
- knowledge generation/advancement
- knowledge utilization/dissemination/diffusion
- public health impact

Keynote Remarks

Assessing Science: Toward a Scientific Basis for Managing NIH Research Edward Roberts, Ph.D., Professor of Management of Technology, Founder and Chair of MIT Entrepreneurship Center, Massachusetts Institute of Technology

Thirty years ago, Dr. Roberts suggested that allocating one percent of the NHLBI budget to focused research on managerial and organizational issues for scientific research would dramatically alter the institute's productivity and performance. While this did not happen, he continued to study this concept, and co-authored a book on the topic of biomedical innovation in 1981. The biomedical research spectrum, a model from the book, reflects thoughts about managing NIH research. The first stage in the spectrum relates to the discovery-innovation process: idea generation, idea communication, idea utilization and development, and idea diffusion into practice. Organizing a research program fundamentally structured around those stages would accomplish a level of know-how, skills, and capabilities that would dramatically alter how scientific institutions allocate funds and manage micro-allocation of funds to individuals, projects, teams, and laboratories. It is important to consider the following characteristics that may differentiate NIH research from other aspects of research:

- The close relationships formed between medical practitioners, students, and researchers
- The majority of biomedical research occurs in universities
- The lag between discoveries and their eventual validation and application
- The quick adoption of innovations prior to adequate validation
- High government regulation of product acceptability and diffusion
- The principle sponsor of biomedical research (the government) is not the customer (the public); medical practitioners constitute the intermediate market, not the final market

Two empirical research studies that attempted to influence selection criteria in scientific research and development were discussed. Project Hindsight concluded that sources of contributions tended to be proportional to the amount of money allocated to a sector. Universities were not more–or less–productive than industry. Time lags from basic research to application were very long. The Comroe-Dripps study concluded that clinical advances require input from all kinds of R&D. Mission-oriented research does not dominate. Lags between discovery and effective clinical application exist, comparable to those found by Project Hindsight.

Dr. Roberts outlined goals for an NIH research program to manage its own research, including:

- Stop using anecdotal evidence as the primary basis for policymaking.
- Achieve deeper understanding of how to organize and manage biomedical research aimed at detection, diagnosis, therapy, rehabilitation, and prevention of disease; examine how university and institutional policies affect the pace of scientific and clinical advance.

- Evolve a coherent strategy for understanding and evaluating the origins, development processes, transfer mechanisms, and early dissemination of new medical practice for assessing the effectiveness of alternative approaches.
- Translate research results into adopted and implemented NIH research policies and practices.

In conclusion, he suggested that as NIH considers new directions in management research it should launch more experiment-like studies, such as funding parallel research efforts with multiple groups and collaborating with pharmaceutical firms to gain access to similar experiments. Also, NIH should take a leadership role in examining in-depth the relationships between universities and entrepreneurial start-ups and the relationships between emerging technology firms and large pharmaceutical firms. Finally, NIH should provide meaningful samples of how medical innovations actually occur; the overall NIH polices that include funding allocations should reflect the possible kinds of research findings.

Discussion Points

- Levels of collaboration have been correlated to levels of productivity. Measuring scientific output and performance is difficult because there can be multiple measures of quality. Often "scientific stars" have high energy and high success in other areas. Although measuring scientific productivity is difficult, identifying people who make great discoveries can be done.
- NIH collects enormous amounts of data that are not being used explicitly, but rather are used implicitly. Defining independent and dependent variables that are built into hypotheses and then building them into NIH's routine data collection processes would be useful.
- Defining hypotheses at the outset will allow for building a program based on hindsight and successes and for examining failures. Without a balanced study of success and failure, there will be no data record of what went wrong.
- Research on research science of science management needs to be happening. Often there is not an explicit structure within a system to do a feedback loop to give back what is being observed. The Roadmap was created as an incubator space for new things NIH needs to do. The Pioneer Award addresses the question of why the same people do the same things over and over.
- It is important to study what is successful in science and how the success was achieved, but there also needs to be analysis of how research dollars are spent and whether they produce something useful. In the case of NIH, useful research should create a tangible improvement on the nation's health.
- Industry, government, and academics need to work together with philanthropy. Conflict of interest rules create barriers that are counter to the public good. The commingling of marketing and promotion under the guise of science can be toxic. It is essential that public trust in agencies that support the entrepreneurial spirit is not lost.
- Risk is a key term. When scientists start on new paths, it is risky. The same is true for starting the path of science of science management. Providing information that better enables scientists to self-manage as part of the project might be a better way to both affect their risk in innovating and decrease the risk of a different type of evaluation program.

Meeting Overview: If You Don't Discern, You Cannot Learn Deborah Duran, Ph.D., Chief of Systemic Assessment Branch (SAB), Division of Evaluation and Systematic Assessments (DESA), OPASI

Dr. Duran described the process leading up to the meeting. The mission of DESA is to inform strategic planning and coordinate assessments and evaluations of the NIH research agenda to provide essential information for decision making and reporting performance. SAB is responsible for organizational level required performance reporting and the Evaluation Branch is responsible for distributing a one-percent

set-aside to conduct specific evaluations. Thus, one of the impetuses of this conference is that NIH needs to be able to discern valid from anecdotal data, fact from fiction, and evidence from practice. The goal is to know when to intervene and when to get out of the way.

The continuum of science from discovery to practice has many unknowns, including time, cost, and outcomes (including unplanned products). Measures of progress along the continuum can be retrospective or prospective. Traditional evaluation approaches are insufficient for assessing innovation or large systems and initiatives or for conducting impact assessment. Often traditional approaches require force fitting the science into the evaluation model. To better discern, NIH needs better methodologies, different approaches, better metrics, tools that integrate, synthesize, and speak with each other, and best practices. This is particularly crucial as calls for accountability and demands increase. Using the wrong evaluation methods can create an erroneous view of performance. There are assessment efforts underway in other countries and other Federal agencies that should be studied for their utility to NIH.

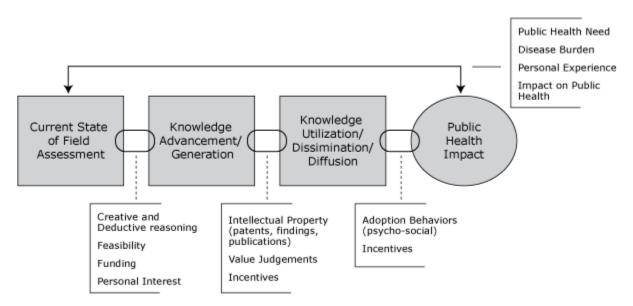
It is critical that NIH develop methods to critically assess science to guide decisionmaking without inhibiting innovation or imputing individuals or projects. Assessment tools should be flexible and adaptable and their development should benefit from the involvement of those being assessed—the scientific community.

Priority Questions for Breakout Discussion Groups

A core element of the meeting was four simultaneous, closed session breakout discussions, which align with the conceptual model of the meeting. The four constructs are:

- Current State of Knowledge Assessment
- Knowledge Generation/Advancement
- Knowledge Utilization/Dissemination/Diffusion
- Public Health Impact

Figure 1. Conceptual Model



Each breakout discussion focused on a single priority question in order to create a feasible crossdisciplinary assessment model. The discussions were led by NIH Institute Directors with the participation of invited experts and a cross-section of key NIH staff. This collaborative effort was aimed to result in a proposed assessment model that can be tested. The results can provide evidence-based information for decisionmakers to plan or to create policy. Introductions to the four concept areas were provided, as follows.

Current State of Knowledge Assessment David Wilson, Ph.D., George Mason University

If NIH is going to manage science it needs to have a good sense of what is known and what is unknown. How can NIH systematically establish current knowledge and identify gaps and opportunities? This information could then provide a more rational basis for setting funding levels, setting priorities, and processing input from stakeholders. Four key questions pertain:

- 1. What is needed to create a standard framework which comprehensively assesses the current state of knowledge in a field and determines the next generation of science needed?
- 2. Once a particular field is assessed, how can science needs be prioritized and funds best allocated to fill the gaps, to generate innovation, and to focus research in a particular area in order to create an impact?
- 3. What analytic tools or methods exist—either currently available or in principle—for identifying research knowledge gaps and opportunities?
- 4. How can NIH portfolio analysis be combined with other relevant approaches to best plan for the next generation of science; what would other information include to provide the best assessment of the current state of knowledge?

This leads to an overarching question:

What components should be included in a comprehensive framework of processes, analytic tools, and methods that can be used to assess and prioritize the state of knowledge in a basic clinical or population-based research field to encourage innovation and advancement?

And a priority question:

How do we assess the current state of knowledge to identify science opportunity for innovative research?

Meaningful differences exist between basic, clinical, and population-based approaches, thus, tools need to be sensitive to those differences and responsive to the important characteristics of research in different areas. Portfolio analysis is an important but insufficient tool, as are bibliometrics.

Knowledge Generation and Advancement Susan Cozzens, Ph.D., Georgia Institute of Technology

Knowledge generation is part of the mission of NIH, but different types of knowledge require different assessment frameworks. Basic research and clinical research cannot be assessed in exactly the same way. Key questions include:

- 1. How can we comprehensively assess science management processes, political and social influences, collaborations, and knowledge generation in order to determine research outcomes that can best inform decision-making?
- 2. What standardized models and measures can be developed and potentially used as benchmarks for assessing the likelihood of knowledge generation from the different kinds of NIH programs with various funding mechanism approaches?
- 3. What are indicators/metrics across research and development fields that can best depict the generation of new knowledge and assess the value added of a large initiative, system assessment and/or science organization?
- 4. How can the knowledge generated from "failed" or "negative" research be assessed to facilitate the development of high risk/high reward, innovative research? What is the best method for assessing high risk science, as well as impactful science?
- 5. How do we assess "successful" research programs beyond the use of bibliometrics? How can these non-bibliometric measures be positioned in the management of science to be a useful component for assessing knowledge generation and informing decision-making during science planning and selection? How can bibliometrics be used more effectively in concert with non-bibliometric methodologies?

These leads to an overarching question:

What is needed for a comprehensive assessment of NIH knowledge generation and advancement?

And a priority question:

What is needed for the assessment of NIH knowledge generation?

Knowledge Utilization, Dissemination, and Diffusion Lynne Zucker, Ph.D. University of California-Los Angeles

The key variables in use, dissemination, and diffusion of knowledge are incentives, adoption of information, and the perceived importance or public health benefit. Key questions include:

- 1. How can NIH assess the effectiveness of various communication methods utilized in order to determine how to maximize our role in disseminating results of research information in a manner that diffuses the results into medical practice, industry adoption, public health practice, and policy development?
- 2. How does NIH ensure that the "right" people are being trained for the "right" scientific fields in order to maintain a continuum of scientist for generations that can sustain a viable scientific workforce?
- 3. When and how can social networks and collaborations facilitate the communication, dissemination, and utilization of research knowledge? Who are the key players and how can these systems be utilized to better foster their role in ensuring the application of the information?
- 4. When and how are stakeholders critical in the planning, implementation and reporting of scientific advancements? How can research results be appropriately provided to them at key

points in order to foster their input into the management of science?

5. How can a systematic approach for reporting science advances and science management best practices be developed to better inform decision-makers during scientific planning, prioritizing and budgeting time periods? What tools could be used to best disseminate the information in real time and with realistic feasibility?

These leads to an overarching question:

How can social networks and collaborations among constituents/ stakeholders facilitate the exchange and use of relevant knowledge to enhance learning and innovation and to facilitate the utilization of the information in practical applications and at key decision points?

And a priority question:

How can we best leverage social networks to facilitate information utilization?

Public Health Impact Doris Rubio, Ph.D., University of Pittsburgh

Measuring public health impact is particularly challenging because there are so many variables beyond research influencing health and disease and there is no linear progression from research to improved health. In addition, it can be difficult to discern mediators from moderators. Key questions include:

- 1. How can NIH capture the contribution of basic, clinical, and translation research to changes in public health? What are the potential constructs, concepts, or data that should be included?
- 2. What are the pathways of public health impact offered by various research projects that were considered high risk/high reward and innovative?
- 3. How can NIH appropriately assess the impact of research activities? What indicators would be most relevant and feasible given quality of life, temporal, and economic factors?
- 4. How can a systematic model be developed that effectively incorporates public health needs into the NIH decision making process, assesses outcomes of the endeavors, and facilitates associated feedback loops?
- 5. When and how can research findings be translated into public health science policies and/or standards of care to improve public health benefits? How can the impact be assessed?

These leads to an overarching question:

What systemic models for improved public health, including pathways and contexts, could be useful for informing multiple NIH decision-making processes?

And a priority question:

How do we measure the impact of NIH research on public health?

Plenary Session Highlights October 3, 2008

Evaluation/Assessment Topics

OPASI invited four speakers to present their experiences and thoughts on Evaluation and Assessment topics. The presentations were followed by a discussion period that allowed other meeting attendees to comment. The following summaries highlight key points from each presentation and the discussion period.

Dr. William Trochim, Science of Science Management: Systems Evaluation and Assessment. Science is a complex system. To understand it we will need to use systems thinking and systems approaches. We should examine how one of the most important systems theories in the history of the life sciences – evolutionary theory – might us develop a Science of Science Management. For example, we are trying to *evolve* better science management by encouraging management variations and selectively retaining those that appear to be most effective; an evolutionary trial-and-error approach. An evolutionary, ecological systems approach could examine, among other things: the phylogeny (family tree or historical evolution) of science management ideas; their ontogeny (how a management idea evolves in the course of its implementation); symbiosis and co-evolution (how we can get different people incentivized to provide information/data as part of an exchange that gives them what they each want locally); and, the dangers of monoculture (lock-in to management approaches before assessing them well). Science is a social system, conducted by human beings with varying incentives and different points of view. Evaluation plays a key role both prospectively in identifying needs and potential management interventions and retrospectively by assessing what works and providing feedback. Scientists often resist the management and evaluation of science, and it is important to demonstrate how such management could improve their work from their perspective. Scientists may not be well-suited or well-trained for managing science. A central challenge for science management is how to integrate the system of science with the system of practice to improve the public's health. This challenge requires an investment from NIH to develop new types of evaluation and systemic assessment that will be needed to provide input and feedback for science management efforts in the 21st century

Dr. Scott Stern, *The Citation Revolution Meets the Identification Revolution: Opportunities for Science Policy Evaluation and Assessment.*

In science of science management, shifts have occurred in identifying the roles of institutions and the roles of policies. Methodology changes and the increased availability of data have allowed social scientists, economists, sociologists, public policy researchers, and management researchers to address policy evaluation questions. The identification revolution involves looking at how policy and procedures matter vs. selection and focus, and demonstrates the importance of policy, a strong management structure, and institutional forms. The citation revolution examines how comparable pieces of knowledge diffuse within different institutional environments over time, space, and context. Transferring materials from the university setting to an institution that allows open or certified access to data makes available the underlying citations from the original scientific research article to follow-on researchers. There is a high rate of return calculation associated with making knowledge from previously funded research projects and making those data available to the next generation.

Dr. David Wilson, Musings on Meta-analysis and Scientific Progress

Focusing on the knowledge generated in studies, including the processes by which we accumulate knowledge, should be a part of the science of science management. It is important to synthesize results across studies, and not only understand the citations, but also understand how the data in individual studies are connected and build on each other. This is similar to a meta-analysis, which uses a systematic

approach to accumulate results across studies, to establish gaps in knowledge and research opportunities, and to inform policy and decision-making about future research and funding directions. Challenges that exist to effectively manage science and accumulate knowledge include:

- A lack of sufficient replications.
- Whether to invest in large clinical trials or multiple smaller trials.
- Ensuring sufficient core elements across sites and across studies, as well as variation to allow for meaningful aggregation.
- Developing registries of clinical trials, which can provide an unbiased approach to accessing and keeping track of knowledge that is gained.

Dr. Doris Rubio, Evaluation in the Context of Science Management

Evaluation requires data to answer questions. One method to collect data is an online, web-based repository that investigators or institutions could update annually about study benchmarks, desired outcomes, and research paybacks. This database would facilitate open data exchange among researchers and allow for real-time program evaluation. Experts from knowledge assessment, knowledge generation, knowledge utilization, and public health should participate in developing the system to help delineate important areas for inclusion. The system criteria should not become burdensome, but should be flexible, adaptable, and straightforward to avoid ambiguity with outcomes and interpretation of findings. Such a data-capturing system should consider: evidence and how it impacts clinical practice and care; the time lag between findings generated in experience and when science catches up; and factors that affect the U.S. health care system.

Discussion Points

- Science is a living, breathing superorganism that is constantly changing.
- A shared data repository would be useful for replication of studies, which is the core of science. This data repository would allow for examination of the data set from the perspective of various branches of science.
- Conversations between natural scientists and social scientists are important. Techniques are available that allow for the generation of quasi-experimental results. It is important to record how decisions are made, what was not done in particular studies, what options were considered and rejected, attributes grant applicants and were not funded, how decisions were made, and the rate of return for making materials public. This generates tools, which are important.
- While anonymized information should be publicly available, a database needs several levels with certain clearance levels required for access to non-anonymous information. To encourage better comparisons and conclusions, the database should not be limited to NIH funding, but should include other institutions as well as research published in scientific journals to allow a broader cross-section of studies funded from the private sector and foundations. To avoid imposing burden on researchers who won't necessarily understand the reason for the level of detail, the system should be immediately available to researchers and their institutions, and appropriate incentives should be determined. It will be important to consider the privacy of failures and the privacy of processes in science, as well as the tradeoffs for principal investigators if we want to access this information. When building the database, it would be advantageous to include machine-understandable interfaces, data analysis tools, collaborative tagging, and meta-data techniques. Additional information that could be included in the database:
 - The nature of the investigation process
 - The kinds of questions previously asked
 - Single or multiple investigators
 - The size, organizational structure, and laboratory structure, of the group doing the work

Knowledge Discovery/Management

OPASI invited four speakers to present their experiences and thoughts on Knowledge Discovery/Management. The presentations were followed by a discussion period that allowed other meeting attendees to comment. The following summaries highlight key points from each presentation and the discussion period.

Ms. Mary Kane, Science Management Using Organizational Knowledge

Knowledge management concepts and systems provide both an opportunity for science managers to improve planning, management, and research innovation and also a tool for science research. For science to advance, it is important to have prospective thinking from the organization on what is required as well as retrospective analysis research data. It is more efficient to use existing data and systems to assess current systems and improve upon them, supplementing existing data with new inquiries to answer an organization's planning needs. Using an approach that combines contributions from independent studies with knowledge obtained through organizational inquiry will yield higher quality management and operational decisions. Managing science initiatives, and the organize, and apply knowledge; identify knowledge gaps; and enable focused assessment of results. In designing a science management and evaluation approach that seeks the best science possible, it is critical to consider several points. Some that have been suggested by previous work within NIH include the relevance of the research to participants, community involvement in development and implementation, biomedical objectives, resource utilization, operations and management, communication, collaboration, and harmonization to actualize the science agenda.

Dr. Katy Börner, Computational Scientometrics Studying Science by Scientific Means

Scientometrics is the study of science by scientific means. Today, science is driven by effective collaborations rather than by prolific single experts. Despite widespread belief, the internet does not lead to more global citation patterns, perhaps because social research networks underlie scholarly activity. Researchers tend to consider who they will face at the next conference or meeting when completing references for papers. Communicating the results of science analysis requires tailoring specifically to individual user groups, such as economic decision makers, science policy makers, scholars, or other data providers. Challenges with science of science studies include: identification of needs and priorities of different user groups; improved definitions of terms such as impact and interdisciplinary; standard data sets that will allow science of science studies to be replicated; well-documented case studies and evaluation; and communication of good practices, major results, and new datasets/tools. Science of science studies can augment, but not replace human judgment.

Dr. Jason Owen-Smith, Networks and Institutions in the Utilization of Science

Networks are patterns of interaction – relationships, citations, individual interaction, or organizational collaboration – among participants in a particular field. Networks can help shape perceptions and capacities for action and their structure allow for information to be shared quickly. Network connections are important for utilizing knowledge, managing the flow of information from discovery to practice, and diffusing innovation. Institutions set rules and expectations that define goals, rewards, incentives, roles, standards of appropriate behavior, and work patterns. Institutions create expectations by imposing and regulating rules, identifying incentives, and setting up norms of behavior. While institutions determine why people want information and how they understand it, networks determine how people access and mobilize the information. It is important to learn about the channels through which various stakeholders – academic scientists, working scientists, physicians, patients, legislators, CEOs – access, use, and make sense of information. Involving diverse stakeholders in networks may increase utilization, but it also may

shift the dynamics of science. Separating stakeholders from the discovery process will maintain purity and autonomy of science but may widen the gap from bench to bedside. When seeking to understand how networks and institutions work together, it is important to consider the tradeoffs, channels, and rules.

Dr. Nate Osgood, *Knowledge Discovery and Management (Public Health)*

Several gaps exist related to knowledge discovery and management, particularly in the area of health impact. Public health information is currently fragmented and diffused. When trying to assess public health impact of interventions, scientists are restricted by dealing with fragmented information that is scattered among many stakeholders. Cross-linking diverse databases will provide a resource for answers to questions that previously have been difficult to evaluate. The data do not have to be housed under one functional roof, but they should be cross-linked, which would allow researchers review many data sets simultaneously. A public health repository can allow for reproducible models, provide a platform for checking hypotheses with longitudinal data, and for calibrating and parameterizing models. Another important issue is leveraging and incentivizing the shift to user-based content and user-contributed meta data in the public health arena. Many traditional websites are being complemented by user-generated content, collaborative tagging, social bookmarking, and other techniques that allow effective sharing of information. One point to consider is designing incentives that reward quantity of contributions vs. quality of contributions, the sharing of negative results, and reproduction of past results.

Discussion Points

- To scientists, science is about innovation, but the culture of scientific review stifles innovation.
- Direct person-to-person communications among members of network universities, institutions, companies will enrich the utilization of science. NIH staff should be part of the networks studying the flow of information and how people are influenced.
- Classifying relationships among the data will make them more useful for measuring quality.
- NIH should be the repository of verbal, oral, and written information. Although a large amount of money is invested in private sector research, accessing that data and integrating it in a useful way is a large undertaking. Rather than focus on the enormity of linking all data, perhaps a good starting point is to begin with in-house data and broaden to other government agencies.
- It is important to be thoughtful about the type and purpose of data being collected. Before launching a campaign to gather large amounts of data, it would be wise to develop pilot projects that allow determination of which data are useful and how they can be used. Sometimes it is not clear until all data are in hand whether the data will actually be meaningful.
- One high-priority area is building links across different kinds of databases, starting with population samples that are characterized with good data. Thus far, NIH has not utilized its database-linking efforts and IT capability. This work cannot be done on totally de-identified and anonymized datasets. So the planning needs to be strategic, perhaps starting with the non-genetic information that does not have the same privacy and confidentiality issues as genetic information. When too many firewalls exist, the data are protected, but they become unusable because researchers won't access them.
- Stricter human subjects protection rules prevent U.S. researchers from collecting population-level data that can be useful in judging the public health impact of scientific discovery.
- Systems modeling and other systems science methodologies can influence public health by informing policy.

Systems/Modeling/Policy Topics

OPASI invited four speakers to present their experiences and thoughts on Systems/Modeling/Policy. The presentations were followed by a discussion period that allowed other meeting attendees to comment. The following summaries highlight key points from each presentation and the discussion period.

Dr. Adam Jaffe, Thinking Systematically about the Impact of NIH on the Country

When thinking about NIH in terms of creating new knowledge or taking it all the way through the public health impact, NIH is part of a system. Decisions NIH makes about what and how it funds create incentives for scientists and other institutions, which then make decisions on how to allocate their time, money, and other resources. So decisions have a huge impact not only on the institutions involved, but also on the generation of new knowledge and public health. Since NIH is inducing and incentivizing people to do things, the direct and indirect impact created is much larger than one might think. When considering assessment, evaluation, and management decisions, it is important not only to focus on spending money efficiently, but also to focus on the fact that these decisions affect many other institutions and may lead to large direct and indirect consequences.

Dr. Susan Cozzens, Systems of Innovation in Biomedicine and Health

The concept of innovation systems focuses on the variation and the characteristics of a selection environment. The main concept of this system is learning – learning by doing, learning by using, and learning by interacting. This translates into the process of generating new approaches or various ideas that create the innovation area being discussed, testing the approaches in practice, and the adopting and diffusing those ideas. The learning concept needs to include other forms of accumulation of knowledge, such as education and training, learning on the job, and building competence. In a health systems of innovation concept, learning comes from interaction from the whole system, circular exchange of information between institutions (doctors, hospitals, public health systems), organizations that disseminate information (research organizations, information services), and organizations that create rules (regulatory agencies, insurance industry, NIH, funding organizations). The end goal is to address health challenges, improve public health and identify broader goals that influence the way organizations operate.

Dr. Lynne Zucker, Science and Management of Radical Change

Technology transfer is the movement of ideas in people. Active transfer involves learning, and not a simple diffusion process. Working together at the lab bench, for example in nano-bio, is one of the main mechanisms; good indicators of this process are joint authorship on a scientific article and co-inventors on a patent. Conditions of radical change and breakthroughs that lead to dramatic change impact scientific productivity and how knowledge is transferred. A scientific breakthrough can actually change industry enough to lead to the birth of a new industry. At that point, firms that cannot compete either transform and incorporate the new knowledge, get acquired by another company, or go bankrupt. When a new industry is created, it is difficult to gather data because the traditional sources of archival data may no longer be available or function well. When breakthroughs occur, several complex processes underlie this transformation. Often, the firms are transformed in a way that promotes scientific productivity, encourages publication, decreases lags in allowing things to be published, and provides support for scientific research.

Dr. Daniel Sarewitz, Paths to Outcome-Based Innovation Policy: Theory, Methods, Tools

In the process of problem solving, there often is a strong signal of pre-existing technological capacity that allows rapid advance of know-how. This differs distinctively from the standard model where knowledge is the foundation for know-how, and focuses on the ability of practitioners to act effectively to achieve a desired outcome independent from the state of fundamental knowledge. Technological capabilities leverage the ability to rapidly advance science because they provide a performance baseline and tend to have a positive political effect that rallies constituencies. This has profound implications for the

connection between inputs into research and development and public health. NIH, as a recipient of those inputs, is one component of the system. Value assertions, such as the value of a particular R&D program to society, tend to justify public investments in science. It is important to understand how values relate to institutional capabilities and realties to see whether the promises made on behalf of R&D can be linked coherently to the outcomes they predict. Problems around which society organizes itself tend to be caused by multiple stressors, and potential solution paths may thus follow different trajectories. A decision tool that allows decision makers to view multiple trajectories toward a particular desired goal (e.g., perinatal health) would provide a lot of data on a variety of programs (e.g., developmental biology vs. nutrition), organizations (e.g., NIH vs. USDA), and activities (e.g., research vs. social policy), and would help make clear the variety of paths—and policy interventions—available in pursuing a particular desired outcome.

Discussion:

- An organization may invest in a process to achieve a desired outcome. The actual outcome may be completely different than what was originally anticipated, but may still have extraordinary value in another area. It is important to include the concept of uncertainty in a management of science model, because complex, unpredictable factors can change the anticipated outcome.
- When thinking about the impact of NIH on incentive structures, innovation systems, and how the two interact, it is helpful to focus on the how this relates to the science of science management.
- The role of incentives, and impact of changes in incentives to the participant on productivity and success of the networks and of the whole system, needs to be carefully considered and included in any models.
- NIH funds not only projects and people, but also the infrastructure that spreads across other areas.
- One purpose of this meeting is not just to come up with an agenda for science of science management, but also to define how one builds a field and to think about creating incentives and an infrastructure to support that.
- One objective is to consider educational challenges for universities to build a field of science management, including how to encourage development of Ph.D. and master's programs.
- The public should be thought not as a status, but as an integral force overall. There is a public component in most categories problem-solving organizations, research organizations and information services, and health and safety organizations. It might be helpful to study the public as an important part of the total effort.
- A tension exists between what is happening to the economy, industrial growth and employment growth, and the idea of contributing to health outcomes. As companies grow, jobs are created and health benefits may increase. When concentrating on the direct benefit of public health, the indirect benefits cannot be omitted because they are part of how the enterprise is funded and are part of the return to the enterprise.
- From the implementation perspective, data, tools, systems, and modeling can be combined with policy considerations in an effort to get answers to questions. Through the process, the focus will shift to data that do not exist, but that are needed. By incentivizing these data, it is possible to uncover the information and answers related to science management, portfolio analysis, and others. It is important to view database development from two directions: 1) build it and they will come and 2) what questions are needed to advance science more quickly, more targeted, and more appropriately.
- One thing to consider is determining how to disaggregate the concepts and components and stakeholders of process that generally are assumed to be together before building a set of models that will help provide understanding of tradeoffs in different pathways to similar outcomes.
- Reviewing feedback cycles, multi-level modeling, and the context in which they operate are important concepts.

- The synergy between health research, the pharmaceutical industry, and the devices industry is an important public benefit.
- A tension exists between the desire for imperial models that allow for tasks to be completed predictably, and a sense that intervening in the complex system to discover a desired outcome may be surprising.
- A good counterbalance to the focus on models, data collection, and understanding the system is a focus on pluralism and how one understands available options and institutional, political and cultural challenges to taking a pluralistic approach.