Enhancing Public Input and Transparency in the National Institutes of Health Research Priority-Setting Process

A Report by
the NIH Director's
Council of Public Representatives (COPR)

Acknowledgements

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CONTENTS

Appendix

Executive Summary

Engaging the public is a major priority, it is a national priority, it is not an option.
—Elias Zerhouni, M.D.

The National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) was established by the NIH Director in 1998 in response to a need identified in the Institute of Medicine (IoM) report, *Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at the National Institutes of Health.* The COPR was established in recognition of the need for a forum through which the NIH leadership could interact with representatives of the public. To review the state of public input and participation at the NIH, COPR designated a Public Input and Participation Work Group (PIPWG) to gather information. In April 2003, PIPWG identified the two areas that would be the primary focus of this report: public input and transparency. PIPWG also found it necessary to define the term public. At its most encompassing, the public is everyone outside the NIH. COPR believes that the NIH, in its worthy goal of improving quality of life for all Americans, should facilitate the flow of information to and from *all* members of the public who are interested in a particular subject area. The NIH should also understand that the composition of the public varies, and strive to use the broadest practical definition.

Public Input

Because its $27 billion budget is derived from taxes, the NIH has a duty to educate members of the public about its mission and operations and solicit their input and participation in the research priority-setting agenda. The COPR believes members of the public should be recognized as equal participants in open discussions and should be one essential component in the research priority-setting process. In their examination of the state of public input and participation in the NIH research priority-setting process, COPR identified seven principles as important in reaching the public and facilitating its input.

1. Go Beyond the NIH Campus

The town hall meeting is a proactive outreach method that takes NIH officials off campus to cities and towns nationwide and gives average citizens access to top scientists and decision makers. Several Institutes and Centers use the town meeting strategy to disseminate their message, solicit input, and enhance access to NIH decision makers.

Recommendation 1: Go beyond the NIH campus to engage the American public where they live.

2. Partner with Communities

Forming continuing partnerships with local communities, grassroots organizations, and leaders creates an important conduit for ideas and input that builds lasting relationships. It is no small task to effectively engage local communities, their leaders, and grassroots groups in providing input on the complex issues involved in medical research. Institutes and Centers should seriously consider using best practices for actively seeking input from local community leaders and grassroots organizations, where appropriate.

Recommendation 2: Partner with local communities, grassroots organizations, and community leaders.

3. Use Proactive Outreach, Including High- and Low-Technology Approaches

Proactive outreach involves actively soliciting public input, such as sending e-mails and other information out for comment and distribution. The NIH should consider this approach to enhancing the transparency of its operations and increase public participation. Two NIH entities use media technologies to increase awareness and solicit feedback, and the NIH Director's Office of Communications and Public Liaison has a multimedia kit called the *NIH Talking Points Toolkit*. It is also important to continue to use and not abandon low-tech approaches for communication and comment, like printed material and annual reports.

Recommendation 3: Use proactive outreach, and provide access for non-Web users.

4. Increase Cross-Institute Communication

The Institutes and Centers use Working Groups and Progress Review Groups to focus resources, technology, and scientific opportunity on a specific disease or disorder. The National Heart Lung and Blood Institute, the National Institute of Neurological Disorders and Stroke (NINDS), and the National Cancer Institute (NCI) have all participated in such efforts. NIH staff members have also developed novel resources and methods for public outreach.

Recommendation 4: Develop more partnerships among Institutes and Centers and foster cross-Institute communication on crosscutting diseases or issues. COPR strongly encourages all Institutes and Centers to work together to share information throughout the NIH.

5. Promote Bidirectional Communication

Setting NIH research priorities should be a collaborative process in which the public is involved from the outset. For example, the National Institute of Arthritis and Musculoskeletal and Skin Diseases Community Health Care Center provides health care services related to arthritis, lupus, and other rheumatic diseases. The National Institute of Mental Health Regional Outreach Dialogue meetings are town hall meetings held in locations across the country. The National Institute of Diabetes and Digestive and Kidney Diseases is developing an education program to reduce morbidity and mortality caused by kidney disease.

Recommendation 5: Foster two-way communication and dialogue on an individual level and with communities where research is performed.

6. Make Sure Public Input Reaches Decision Makers

It is important that senior decision makers actively demonstrate a commitment to public input. One way to make this happen is to hold listening circles where directors and senior decision makers are present and can hear public input. Listening circles are forums in which people come together to share information and knowledge about a topic. As one example, National Library of Medicine (NLM) listening circles seek to share information about NLM.

Recommendation 6: Ensure that senior decision makers receive and fully consider public input.

7. Fully Utilize Advisory Councils and Their Public Members

Each Institute and Center charter mandates that persons who represent the general public fill a certain number of advisory council seats. Beyond the selection of advisory council public members is the issue of identifying those members as such. The National Institute on Deafness and other Communication Disorders, NCCAM, and NINDS routinely consult their advisory councils in the priority-setting and planning processes. The COPR urges Institutes and Centers to enhance the role of public members on Institute and Center advisory councils and consider creating new mechanisms to empower them.

Recommendation 7: Ensure that advisory council public members represent a broad range of public constituencies and that the councils are fully used as an important avenue for public input.

Transparency

In considering public input into the research priority-setting process at NIH, one issue warrants special focus—transparency. To study the transparency of the NIH research priority-setting process, COPR examined the activities and practices of various Institutes and Centers. In general, the results of these interviews were consistent with and significantly confirmed major conclusions and observations reached as a result of COPR's other investigations. In considering the goal of enhancing transparency, three types of activities were identified as fundamentally important: education, access, and active listening. It is not enough that transparency exists in the system in the form of opportunities for education and points of access.

8. Educate the Public about the NIH

The National Institute of Child Health and Human Development (NICHD) NIH 101 program helps educate the public about the NIH. NIH 101 includes a brief history of NIH and NICHD, information about how budgets and research priorities are set, a breakdown of the grant review process, information about how NICHD communicates research findings, and instructions for finding other NIH information. NICHD should be applauded for its innovation and initiative in engaging groups and responding to requests for information.

Recommendation 8: Actively develop tools and materials that help educate the public about the research priority-setting process and opportunities for public input.

9. Enhance Access

One transparency-enhancing activity that improves public access is the NCCAM Stakeholder Forums. During the forums, participants testified about their experiences and opinions related to developing the NCCAM Strategic Plan. Another example of improved access is the www.getinvolved.nih.gov Web site. NIH Institutes and Centers contribute information about public outreach events, public resources, and special public announcements. Such continual improvement of access for members of the public to learn about input opportunities and provide input should be maintained and supported.

Recommendation 9: **Continue to search for mechanisms that encourage public input into the research priority-setting process and that are easily accessible and provide information-sharing opportunities.**

10. Practice Active Listening

A transparency-enhancing activity related to active listening is the 2003 Survey of Cancer Advocacy Organizations conducted on behalf of the NCI and the NCI Director's Consumer Liaison Group (DCLG). The survey solicited information about each organization and its familiarity with NCI, thoughts about future DCLG direction, and preferred communication methods. NCI transparency was not the survey's main purpose, but some information was directly relevant. The survey was laudable in its use of an approach that actively solicited information from this sector of the public.

Recommendation 10: Actively solicit information from constituents and the general public about the public's experiences and perceptions of transparency at the NIH.

Support and Funding

11. Provide Adequate Resources

Implementing some of the above recommendations will require a significant investment of funding, staffing, and support.

Recommendation 11. Provide adequate resources in terms of funding, support, and staffing to allow for the successful accomplishment of these recommendations.

Conclusions

The guarantee of public input and participation in the NIH research priority-setting process and the transparency of that process are essential to promoting public trust in the research enterprise. The COPR recognizes that significant opportunities exist for public input and transparency that are not identified in this report. Support for and belief in the importance of public input into the NIH research priority-setting process must be embraced from the top down. It is clear that many Institutes and Centers at the NIH take the issue of public input and transparency seriously, but more could be done.

Introduction

> *Never doubt that a small group of thoughtful committed citizens can change the world. Indeed, it is the only thing that ever has.*
>
> *—Margaret Meade*

The National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) was established by the NIH Director in 1998 in response to a need identified in the Institute of Medicine (IoM) report, *Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at the National Institutes of Health.*[1]

The COPR was established in recognition of the need for a forum through which the NIH leadership could interact with representatives of the public. COPR is the primary mechanism by which public representatives can provide their perspective on matters of public interest and work with NIH leadership to increase public awareness of NIH and how it functions. The COPR is the primary mechanism for providing public input to NIH decision makers at the highest level. In recent efforts, COPR identified several areas in which the Council might be uniquely effective in helping the NIH Director understand the public perspective.

The IoM report examined four issues related to setting research priorities at NIH: allocation criteria, the decision-making process, the impact of congressional directives, and mechanisms for public input into the research priority-setting process. In the four years since the release of the IoM report, NIH has enhanced many activities related to public input and participation. In this 2004 report, COPR examines the results of those changes and makes recommendations for improvement.

To review the state of public input and participation at the NIH, COPR designated a public input and participation work group (PIPWG) to gather information. The work group began by educating itself about the flow of information between NIH and the publics it serves.

Between October 2002 and April 2003, through the work of PIPWG and with much collaboration with the Institute and Center Officers of Public Liaison (OPLs) and Communication Directors, COPR determined that many opportunities exist at the Institutes and Centers for transmitting information to the public. COPR also determined that there is substantial disparity between public participation at NIH in general, and public participation in the research priority-setting process identified in the IoM report. Further, the public tends to perceive the NIH research decision-making process as "secretive," difficult to understand, and ambiguous, resulting in a serious lack of transparency at the NIH from the public's perspective.

In April 2003, PIPWG identified the two areas that would be the primary focus of this report:

- ***Public input.*** Identify best practices for obtaining and using public input and participation in the research process.
- ***Transparency.*** Consider practices that enhance public examination and awareness of the *process* of making research choices and that enhance the access of senior NIH decision makers to public input into this process.

During this time, PIPWG also frequently found it necessary to define the term public. In reality, there are many types of publics. At its most encompassing, the public is everyone outside the NIH. More specific publics may include groupings of the following:

- Patients
- Patient advocates
- Constituency groups and organizations
- Nonprofits
- Health care providers
- Health care practitioners
- Investigators
- Research organizations
- Educators
- Media
- Congress

COPR believes that NIH, in its worthy goal of improving quality of life for all Americans, should facilitate the flow of information to and from *all* members of the public who are interested in a particular subject area. In facilitating this information flow, NIH should take special care to accommodate those who do not have ready access to computers.

NIH should also understand that the composition of the public varies, and strive to use the broadest practical definition. COPR urges that NIH carefully and regularly monitor which public is being served with regard to a particular subject and determine whether patients, patient advocates, constituency groups, and related organizations have appropriate roles. COPR believes these publics can and should play a broader role and that NIH should tailor its activities appropriately.

Public Input

Because its $27 billion budget is derived from taxes, the NIH has a duty to educate members of the public about its mission and operations and solicit their input and participation in the research priority-setting agenda. Methods for accomplishing this goal differ based on the needs of diverse constituency groups that work with the 27 Institutes and Centers. Some Institutes and Centers are more proactive and targeted than others, depending on several factors, including the nature of their mission, the constituencies they serve, and the amount of their appropriation.

A proactive approach gives the public a greater awareness of NIH's desire for and openness to public input, and ultimately works to enhance transparency by promoting greater public awareness of and involvement in the research enterprise.

The vision of the IoM report[1 (p. 61)] was that the COPR recognize and identify "*channels through which the public can provide broad input into the NIH priority-setting processor or through which NIH can respond clearly and authoritatively to the public on issues of mutual concern*."

The COPR does not envision nor does it intend that members of the public are the sole determinants of the research priorities that are chosen at each Institute and Center. Rather, the COPR believes members of the public should be recognized as equal participants in open discussions, and one essential component in the research priority-setting process.

Improving Input at NIH

In their examination of the state of public input and participation in the NIH research priority-setting process, COPR identified the following seven principles as important in reaching the public and facilitating its input. Cited are some examples of best practices that represent these principles as carried out by selected individual Institutes and Centers. It should be noted, however, that this is in no way an exhaustive attempt to identify all effective practices conducted at all Institutes and Centers.

1. Go Beyond the NIH Campus

The town hall meeting is a proactive outreach method that takes NIH officials off campus to cities and towns nationwide and gives average citizens access to top scientists and decision makers. The public hears firsthand about NIH initiatives, and decision makers receive direct feedback about NIH work.

Several Institutes and Centers use the town meeting strategy to disseminate their message, solicit input, and enhance access to NIH decision makers. This strategy has been so successful for the National Institute of Environmental Health Sciences (NIEHS) that it recently published its experience with town meetings in the journal *Environmental Health Perspectives.*[2] The NIEHS found town meetings to be "a successful model for bringing academic researchers together with community residents, state and local departments of health, and community-based organizations to foster greater awareness of community needs, public health needs, and environmental health science research." Since 1998, the NIEHS has sponsored 16 town meetings nationwide and strongly supports this avenue for public input.

Another Center that has used the town meeting approach is the National Center for Complementary and Alternative Medicine (NCCAM). NCCAM has held three town meetings nationwide in collaboration with existing NCCAM research centers. The purpose of these town meetings was to give the public an opportunity to learn about the latest research being conducted and ask questions, and for the Institute to answer questions and obtain input from the public. The meetings were attended by the Institute Director and included an address by him. There were 700 to 800 attendees at the most recent meeting.

The benefits of going beyond the NIH campus include:

- Receiving ideas from a new perspective.
- Creating new methods of working with the community.
- Strengthening public good will and support.
- Enhancing public access to NIH decision makers.

> **Recommendation 1: Go beyond the NIH campus to engage the American public where they live.**
>
> **NIH Institutes and Centers should take their message to and solicit ideas from the American public through the use of regional forums and town meetings. The NIH Office of the Director and Institutes and Centers should collaborate to reduce costs.**

2. Partner with Communities

Forming continuing partnerships with local communities, grassroots organizations, and leaders creates an important conduit for ideas and input that builds lasting relationships.

Much is said in the NIH Roadmap for Medical Research about the need for collaboration between important entities to advance the research enterprise. An element of such collaboration that requires involvement but is sometimes overlooked is partnering with local communities and grassroots organizations. A grassroots organization is a group that is in touch with members of the local community. Especially important are groups from rural or non-urban areas that often represent particular interests of local community members.

It is no small task to effectively engage local communities, their leaders, and grassroots groups to provide input on complex issues like medical research. A commitment is needed and resources must be expended to ensure that grassroots organizations, their leaders, and their communities are consulted. They must be assured that their input will be thoroughly considered and incorporated.

Several Institutes and Centers underscore the value of such involvement in their research-setting process. One example involves the work of the National Eye Institute and the National Library of Medicine. Both held listening circles in areas where the predominant population was Native American and Native Hawaiian. The goal of these meetings was to seek input from constituencies that are traditionally underserved but represent an important viewpoint.

Another NIH effort to partner with population groups at a local level involves the National Cancer Institute (NCI). The NCI, through grant funding, sponsored the development of a video program to help physicians learn culturally sensitive communication techniques for talking about cancer and the importance of clinical trials with low-income African Americans. The project centered on direct focus group input from public housing residents in Cleveland, Ohio.

The benefits of partnering with local communities and grassroots organizations include:

- Receiving immediate feedback on important issues.
- Creating a sense of connection with policy and decision makers.
- Forming an open conduit for continuing dialogues.
- Accessing viewpoints from those outside the mainstream.

Institutes and Centers should seriously consider using the best practice of actively seeking input from local community leaders and grassroots organizations, where appropriate. Significant and important ideas exist beyond the NIH campus that decision makers should hear. Cost considerations may present a challenge but, by working together wherever possible, Institutes and Centers may be able to manage the associated costs.

> **Recommendation 2: Partner with local communities, grassroots organizations, and community leaders.**
>
> **NIH should consider forming or enhancing partnerships with local groups and leaders to help foster an atmosphere in which ideas and input can be shared.**

3. Use Proactive Outreach, Including High- and Low-Technology Approaches

Proactive outreach involves actively soliciting public input, such as sending out e-mails and other information out for comment and distribution. Proactive outreach increases opportunities to build closer working relationships by taking NIH access to the public, not waiting for the public to come to the NIH. New technologies create new opportunities for soliciting public input; COPR encourages aggressive use of these pathways.

In 1979, telephone company ads encouraged the use of long-distance telephone service to “reach out and touch someone.” NIH should consider the same approach in its effort to enhance the transparency of its operations and increase public participation. By using accepted, proactive public outreach tactics such as push e-mails, direct mail, response cards, and videotapes, the NIH can solicit input related to the research priority-setting process.

A growing number of Americans rely on the Internet to acquire information, do business, or stay in touch. According to a February 2004 survey by the nonprofit Pew Internet and American Life Project, 63% of American adults have access to the Internet. A July 2003 survey by the same group indicated that 80% of American Internet users have searched online for information on at least one of 16 major health topics. Based on these statistics, a successful organization would try to engage this growing, technologically astute population segment to solicit feedback and ideas or build organizational awareness. The NIH should use these tools to strive for continuity with the public, and develop standard practices to make public interaction user friendly and build closer working relationships with constituency groups and the public.

Two NIH entities already take advantage of media technologies to increase awareness and solicit feedback. The NIH Director’s Office of Public Liaison is developing a constituency outreach database to build organizational awareness on activities and topics related to central NIH issues. This database will provide information to targeted and broad-based constituencies and NIH stakeholders through push e-mail. The content will include information on the NIH Roadmap for Medical Research, the evolving NIH Public Trust Initiative, and special staffing alerts from the NIH Director.

In addition, the NIH Director's Office of Public Liaison has a multimedia kit called the *NIH Talking Points Toolkit*. The kit was originally designed as a guide for COPR members who spoke to groups about the NIH. COPR believes its use might be broadened and expanded as a resource for the public that could be adapted by each Institute. The boxed kit's centerpiece is a professionally produced videotape that chronicles the NIH history and mission and helps convey the importance of NIH's work to outside groups. The video is accompanied by paper copies and disk copies of NIH 101 and COPR 101 PowerPoint presentations, a disk copy of the NIH Almanac (a multimedia resource), and resource lists of NIH Web links that include information such as toll-free numbers for questions about specific diseases; Web site locations for learning more about NIH-funded institutions, research centers, hospitals, and universities by state; and highlights of recent NIH research advances.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is using the Internet to solicit feedback on its annual report. This effort uses push e-mails, which are distributed to people on a specific mailing list to invite them to read the annual report online and comment on it. The e-mail describes the project's background, states the intent to solicit an opinion, and includes the annual report's Web address. This has been a successful tactic for NIAAA.

Additionally, it is important to continue to use and not abandon low-tech approaches for communication and comment, like printed material and annual reports. While the Internet provides an instant means for bidirectional communication with a large portion of the public, traditional modes of communication remain an effective method for engaging important segments of the public that may be less involved with newer technologies. Maintaining a low-tech approach while exploring newer communications strategies and technologies will ensure broad public involvement.

The benefits of using proactive outreach include:

- Building trust through transparent efforts to seek and consider the public perspective.
- Gaining immediate feedback from targeted groups.
- Increasing public input with maximum cost efficiency.
- Enhancing and developing new relationships with constituency groups and the public.

The best practice of increasing the use of innovative public outreach techniques and using them proactively will strengthen NIH transparency and benefit the institution and the public.

Recommendation 3: Use proactive outreach, and provide access for non-Web users.

New technologies provide more opportunities for soliciting public input. NIH is encouraged to continue and enhance aggressive proactive outreach to the public, such as sending out e-mails and other solicitations for comment. At the same time, NIH should create alternative outreach methods to Web-based systems, such as printing and mailing annual reports to constituency groups for comment.

4. Increase Cross-Institute Communication

The Institutes and Centers use Working Groups and Progress Review Groups to focus resources, technology, and scientific opportunity on a specific disease or disorder. The Neuro-Oncology Program by the NCI and the National Institute on Neurological Disorders and Stroke (NINDS) is an example of cross-Institute collaboration at NIH.

Research into many diseases is carried out simultaneously at several Institutes and Centers. Collaboration is generally desirable but does not always occur in individual laboratories. Working Groups and Progress Review Groups bring together scientists and clinicians from many disciplines and intra- and extramural institutions. NIH emphasizes investigator-initiated proposals and research, but collaborative work on specific diseases has had significant results. Including public members in these bodies offers a critical perspective and demonstrates the strong interest and shared commitment that patients, their families, and other members of the public have in addressing issues and solving problems.

In 2002, the National Heart Lung and Blood Institute organized a workshop on sarcoidosis, a disease that causes inflammation of the body’s tissues. Investigators and clinicians from other Institutes and Centers and from universities and research centers nationwide were invited. A sarcoidosis Patient Interest Organization (PIO) was also invited to participate. These representatives attended an evening presentation before the workshop to learn about the most recent treatment advances. During the workshop the next day, the representatives shared patient perspectives and added to the information available to scientific members.

From 2000 through 2003, NINDS supported a Public-Private Working Group devoted to Parkinson’s disease. This group meets annually in person and telephones biweekly to discuss research advances and priority-setting processes. This group includes NIH scientific staff, industry representatives, patients, and caregivers.

In 2000, the NCI and NINDS jointly held a broadly focused Brain Tumor Progress Review Group. Attendees included NCI and NINDS senior staff and researchers, and clinicians from both Institutes and from U.S. and Canadian universities and medical centers. Patients, patient advocates, and industry representatives were also invited. A priority of the Progress Review Group was to improve communication among the represented communities and examine the state of the research.

NIH staff members have developed novel resources and methods for outreach to the public. In 2002, the Offices of Public Liaison formed a Regional Outreach Work Group to identify ways to enable NIH outreach staff to share information on regional outreach efforts, best practices, and lessons learned.

The benefits of using Working Groups and Progress Review Groups include:

- Bringing the public perspective directly to scientists and decision makers.
- Enhancing trust among researchers, patients, families, and groups.
- Facilitating information sharing across NIH.
- Promoting the replication of best practices and successful activities across NIH.

Recommendation 4: Develop more partnerships among Institutes and Centers and foster cross-Institute communication on crosscutting diseases or issues. COPR strongly encourages all Institutes and Centers to work to share information throughout NIH.

> **NIH should consider developing a mechanism similar to Working Groups and Progress Review Groups that promote sharing resources, technology, and scientific opportunity on a specific disease or disorder. Tools and resources for sharing information such as those developed by the Regional Outreach Work Group are only as useful as the information that is provided by the individual Institutes and Centers. To foster cross-Institute communication, each Institute and Center must commit to active participation in all information-sharing efforts.**

5. Promote Bidirectional Communication

Setting research priorities at NIH should be a collaborative process in which the public is involved from the outset. For research priority setting to be truly collaborative, Institutes and Centers must create and maximize opportunities for two-way communication and dialogue with individuals and communities. Three examples of this are the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) Community Health Care Center, the NIMH Regional Outreach Dialogue meetings, and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Kidney Disease Education Program.

The NIAMS Community Health Care Center in Washington, DC, is a medical and health information center that provides health care services related to arthritis, lupus, and other rheumatic diseases. Patients who suspect they have such a disease or who have been diagnosed can receive medical attention by self referral or referral by a health care provider.

Depending on their medical condition, patients are eligible for primary treatment, more advanced treatment and testing, or clinical trials and experimental treatments. In addition to treating an essentially minority population (African-American and Hispanic), the Center raises awareness of health disparities in rheumatic diseases, increases minority participation in research studies, and boosts the number of underrepresented biomedical researchers in this field. Moreover, patients are empowered to become participants in their own research protocols.

The NIMH Regional Outreach Dialogue meetings are a series of town hall meetings held in various locations across the country. They have been held in Anchorage, San Antonio, Chicago, Pittsburgh, and Albuquerque, and have addressed topics relating to mental health issues important to traditionally underserved populations. A primary purpose of the meetings is to promote two-way communication: not just to disseminate information about NIMH research, but to hear public input.

Although the dialogue meetings are one-time events, what is notable is the extensive amount of preparation that goes into each one. Prior to planning a meeting or setting an agenda, several field visits to the area are conducted. During these visits, NIMH staff members engage in a dialogue with local people and representatives of communities of interest. This give-and-take of information is used to discover local concerns and set an agenda, and to identify appropriate individuals and groups to invite to participate. Approximately 300 people participated in the last meeting in Albuquerque. NIMH is represented by the Director and Deputy Director and staff and top researchers in areas of interest for that topic or population.

The NIDDK is developing an education program, the national Kidney Disease Education Program, to reduce morbidity and mortality caused by kidney disease and its complications. Prior to launching a nationwide program, a pilot program is currently being implemented. The pilot program is designed to reach out to African Americans, a group at very high risk for diabetes, hypertension, and kidney disease. In the process of developing the pilot program, a series of focus groups was convened to identify channels, intervention strategies, and messages that would be most effective in increasing awareness of kidney disease. Additionally, this information was used to develop culturally appropriate and meaningful materials.

The benefits of two-way communication and dialogue include:

- Developing ongoing relationships between the NIH and local communities that foster trust and increase engagement in the clinical research enterprise.
- Developing a truly community-based research agenda shaped by meaningful input and collaboration.
- Increasing the participant investment in the process and outcome.

> **Recommendation 5: Foster two-way communication and dialogue on an individual level and with communities where research is performed.**
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> **COPR encourages NIH to use a collaborative approach with the public whenever possible, in particular with research participants. This involves an ongoing process of two-way communication and dialogue as activities and research are undertaken and research priorities are set.**

6. Make Sure Public Input Reaches Decision Makers

It is important that senior decision makers actively demonstrate a commitment to public input. This would ensure that future decisions concerning NIH research and priority setting are transparent, and that public input and participation are solicited.

One way to make this happen would be to hold listening circles where directors and senior decision makers are present and can hear public input. The National Library of Medicine (NLM) holds listening circles with the Native American population and has arranged for these listening groups to be held in the Dakotas and other areas, during which senior NIH officials met with the leadership of the tribal or native nations.

Listening circles are forums in which people come together to share information and knowledge about a topic. The idea is for everyone to be respectful, foster dialogue, and listen to each other. The purpose or outcome is to find common ground from which collaboration may occur or a decision can be made. Traditionally, circles are planned in advance and the forum convenes over several days. Contemporary listening circles use invitations and an agenda and are somewhat more formal, but they have the same purpose. Every attempt is made to follow the culturally appropriate protocol of the native community or group.

NLM listening circles seek to share information about NLM. This is accomplished by informing native leaders about outreach projects with tribal communities and promoting library science as a career path for Native American students. NLM also solicits input and feedback about how they can best disseminate health information and use technology, educate tribes about NLM and NIH funding opportunities, and identify collaboration and partnership opportunities.

The benefits of ensuring that senior decision makers receive and fully consider public input include:

- Making the NIH more transparent in its dissemination of information and education of the public.
- For the NIH leadership, increasing communication with the public by attending these forums, asking questions, listening, and stating what NIH can offer.
- For members of the public, learning how to access health information, leading to healthier communities and reduced health care costs to the nation.

Recommendation 6: Ensure that senior decision makers receive and fully consider public input.

COPR encourages NIH to develop a mechanism by which Institute and Center directors and senior NIH leadership can listen and receive public input in a way that is similar to the listening circle model used by the Native American population. If senior decision makers recognize and embrace the importance of public input, this will ensure that future NIH research and priority-setting decisions are transparent and public input is solicited.

7. Fully Utilize Advisory Councils and Their Public Members

Each Institute and Center charter mandates that persons who represent the general public fill a certain number of advisory council seats. The 1998 IoM report noted that slots reserved for public members on some advisory councils did not always represent the broad range of NIH public constituencies. According to the report, underrepresented groups included representatives of patients, their families, and persons with special health problems (e.g., particular ethnic groups, low-income populations, and women).

In contrast, the NCCAM charter requires that three of six advisory council slots reserved for public members be filled with persons who represent the interests of individual consumers of complementary and alternative medicine. While not necessarily endorsing a rigid mandate for all Institutes and Centers, COPR supports the inclusive intent that this requirement represents.

Beyond the selection of advisory council public members is the issue of identifying those members as such. There are a variety of cultures and practices among the Institutes and Centers in this regard. Some Institutes and Centers, perhaps to make sure that all advisory council members are seen and treated equally, do not identify individuals who fill their public slots. This interest in equality is legitimate, but care should be taken that this practice does not obscure the fact that some public slots may be filled by persons who do not represent what most would consider the general public. It is therefore essential that each Institute and Center examine its selection and identification of advisory council public members. Institutes and Centers should fill those slots with individuals who represent the sensibilities of a broad range of public constituencies, and consider identifying them so they might be fully utilized as valuable sources of public input.

Further, the National Research Council's 2003 report, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*,[3] noted that "Advisory councils should routinely and consistently be consulted in the priority-setting and planning process of an institute." COPR agrees that advisory councils and their public members should be recognized as an invaluable source of and conduit for public input into the Institute and Center priority-setting process.

Examples of this principle are found in the recent practices of the National Institute on Deafness and other Communication Disorders (NIDCD) and NINDS. Public members of the NIDCD advisory council served on the subcommittee charged with writing the NIDCD Strategic Plan. The day before the group began writing, public members from many organizations (from small self-help and advocacy groups to large medical, scientific, and allied health organizations that certify medical and allied professional programs) provided written or oral testimony about research needs. Their information and perspectives influenced the content of the strategic plan. NINDS also involves advisory council public members in several important subcommittees devoted to key planning and priority-setting issues, including the subcommittee charged with developing the NINDS Strategic Plan.

NCCAM also uses its advisory council as a conduit for public input. NCCAM advisory council meetings include open forums where members of the public offer input. This is an important, regular access point for the public to communicate with senior decision makers. COPR strongly urges that each Institute and Center consider implementing similar practices.

The COPR urges Institutes and Centers to enhance the role of public members on Institute and Center advisory councils and consider creating new mechanisms to empower them. One possibility would be to bring the public members together regularly to discuss their role as public members, further define their role and how they bring the public perspective to council efforts, and work to identify new ways they can work together to enhance their participation on NIH Institute and Center councils. Another possibility would be to examine the role of Institute and Center Offices of Public Liaison in orienting public members of NIH advisory councils.

The benefits of ensuring that advisory council public members represent the public and that advisory councils are used as a resource and conduit for public input include:

- Offering a permanent, easily identifiable, accessible avenue for public input at the highest levels of Institutes and Centers.
- Demonstrating to the public that their viewpoints and input are valued and taken seriously.
- Providing an opportunity for open communication and building public member partnerships across the NIH at the highest levels.

Recommendation 7: Ensure that advisory council public members represent a broad range of public constituencies and that the councils are fully used as an important avenue for public input.

NIH and the Institutes and Centers should ensure that public advisory council members represent a broad range of public constituencies. Consideration should be given to the advantages of enhancing transparency and effectiveness in identifying the public members as such. Steps should be taken to ensure that public advisory council members are fully used as an important source of public input into the research priority-setting process through involvement in activities such as strategic planning. Finally, public advisory council members should be thoroughly oriented and empowered in

their role as representatives of the public perspective through training and cross-Institute meetings.

Transparency

In considering public input into the research priority-setting process at NIH, one issue warrants special focus—transparency. Transparency refers to how clear, understandable, and accessible to the public is the process by which NIH sets research priorities, and how much of the process is open to public examination.

In an age of diminishing budgets, pressure for information about how research dollars are spent and how such decisions are made will only increase. One of three themes of the NIH Roadmap is Re-engineering the Clinical Research Enterprise. This involves, in part, engaging the public more fully in the clinical research enterprise, which requires the public's trust. Transparency is an essential ingredient in developing and maintaining public trust.

To study the transparency of the NIH research priority-setting process, COPR examined the activities and practices of various Institutes and Centers. For a perspective external to NIH, interviews were conducted with Voluntary Health Association (VHA) workers. COPR members asked questions about VHA experience in working with NIH, and solicited input on transparency and suggestions for improvement.

In general, the results of these interviews were consistent with and significantly confirmed major conclusions and observations reached as a result of COPR's other investigations. In particular, the suggestion that NIH leadership leave the campus to meet the public through town meetings and regional outreach activities received nearly universal support. Details of the interviews are not enumerated here, but the information obtained is incorporated throughout this report.

Enhancing Transparency at NIH

In considering the goal of enhancing transparency, three types of activities were identified as fundamentally important: education, access, and active listening. Education involves teaching the public about how the priority-setting process works and about what is being done to obtain and use public input. Access relates to the availability of ways public input can be given that will influence research priority setting. This includes the public's ability to observe the process and to see how decisions are made and what factors are considered.

It is not enough that transparency exists in the system in the form of opportunities for education and points of access. Active listening relates to the need to solicit and understand the public's view of the NIH research priority-setting process. This perspective is essential; the perception of a lack of transparency is just as damaging to public trust as an actual lack of transparency. Some representative examples of these three activities are discussed in the following paragraphs. There is some overlap in the activities discussed here and those mentioned in the previous section because best practices for public input also enhance transparency.

8. Educate the Public about the NIH

The National Institute of Child Health and Human Development (NICHD) NIH 101 program helps educate the public about the NIH. The program is a seminar conducted as requested by the NICHD Program and OPL staff. Subjects include presentations from the Institute and Center Office of Budget and Communications and an optional tour of one of the NICHD intramural labs on the NIH Bethesda campus.

The NIH 101 presentation includes a brief history of NIH and NICHD, information about how budgets and research priorities are set, a breakdown of the grant review process, information about how NICHD communicates research findings, and instructions for finding other useful NIH information.

The program is offered to non-NIH research advocacy or patient representative organizations. NICHD publicizes this offering through Friends of the NICHD and other contacts. Typically, new staff members of research or patient advocacy groups who need to understand NIH inner workings take advantage of the program, but other groups can request a presentation.

This NIH 101 was developed several years ago, after the IoM report’s release, as an effort to engage interested groups. The presentation is tailored to audience interests and generally is well received.

NICHD should be applauded for its innovation and initiative in engaging groups and responding to requests for information. The NIH 101 class has worked well for NICHD, but more could be done to promote the program’s availability. A Web-based version has yet to be developed and most seminars take place on the NIH campus rather than around the country. Still, this program is a solid example to be replicated by other Institutes and Centers in their efforts to engage the public and enhance the transparency of their work.

The benefits of developing educational tools and materials for the public include:

- Helping the public better understand the multiple factors and complexity involved in the research priority-setting process.
- Informing the public about efforts already being made by the Institutes and Centers to solicit and incorporate public input.
- Helping the public become more effective collaborators with the Institutes and Centers in the research priority-setting process.

Recommendation 8: Actively develop tools and materials that help educate the public about the research priority-setting process and opportunities for public input.

One tool might be a series of Web-based interactive training modules or tutorials. More specifically, it is recommended that two of these modules focus on 1) basic information on how the research priority-setting process works at NIH, and 2) basic information on accessing the NIH and providing input. While these topics are the focus of this report, it should be noted that the concept of using this medium need not be confined to these topics, and tutorials on a variety of subjects would be useful. These subjects could include basic information about the NIH, the grant process, the NIH Roadmap, and others. The advantages of this approach are many. The

tutorials are self-paced and individuals can review and refer to them as often as needed. It is possible to use a broad range of media, including other Web pages, video, text, and sound. New information and changing data, such as budget numbers, can easily be incorporated.

9. Enhance Access

One transparency-enhancing activity that improves public access is the NCCAM Stakeholder Forums. In developing their second 5-year strategic plan, NCCAM held two open forums, one on the NIH Bethesda campus and one in Seattle, Washington. People and organizations on NCCAM's mail and e-mail lists were invited to participate. The forums were publicized through the media and on the NCCAM Web site.

During the forums, participants testified about their experiences and opinions related to development of the NCCAM Strategic Plan. A listening panel of top NCCAM administrators, including the NCCAM Director, heard the testimony. During this process there was a brief opportunity for questions and answers and dialogue among participants and the listening panel. At the end of each forum, the Director summarized major themes and offered initial thoughts and responses. After the forums, information obtained was transcribed and incorporated into the strategic planning process. A draft plan will be posted on the NCCAM Web site and the public will have another opportunity to comment.

The NCCAM Stakeholder Forums are notable in several ways for their impact on enhancing transparency. They solicit public input from the beginning of the strategic planning process and address issues of education and access. By providing an opportunity for dialogue with and response by the listening panel, members of the public in attendance received immediate information and feedback on their input.

The forums also provided a venue for publicizing other opportunities for public input, such as the ongoing acceptance of written public comments and the opportunity for online public comment on the draft strategic plan. Holding one of the forums off campus to increase accessibility was commendable. COPR feels that such stakeholder forums are worthy of consideration by all Institutes and Centers in developing their strategic plans.

Another example of improved access and enhanced transparency is the www.getinvolved.nih.gov Web site. The Director's OPL, Institute and Center OPLs, and Communication Directors have undertaken an extensive effort to improve the Web interface and make information more accessible about resources and opportunities for public input and participation. *The NIH Public Bulletin* is a product of NIH-wide information sharing and coordination, and provides a public resource that no single Institute or Center could offer.

Every month, NIH Institutes and Centers contribute information about public outreach events, public resources, and special public announcements. The Office of the Director's OPL compiles the submissions and posts them in the *NIH Public Bulletin* on the www.getinvolved.nih.gov Web site. The Institutes and Centers can also post items for public input or comment in this central location.

This is an ongoing process, and the work of continually improving access for members of the public to learn about input opportunities and provide input should be maintained and supported.

The benefits of enhancing access to the research priority-setting process include:

- Allowing the Institutes and Centers to obtain input from a broader cross-section of the various NIH publics.
- Communicating to the public that its opinions are valued, sought after, and used as an integral part of the research priority-setting process.
- Building a sense of inclusion and providing opportunities for involvement among the various NIH publics.

> **Recommendation 9**: **Continue to search for mechanisms that encourage public input into the research priority-setting process and that are easily accessible and provide information-sharing opportunities.**
>
> **Seeking ways to promote and facilitate public input into the research priority-setting process should be an ongoing agenda item for all Institutes and Centers. In addition to constantly attempting to find new avenues for public access to the process, existing methods should also be examined, evaluated, and refined.**

10. Practice Active Listening

A transparency-enhancing activity related to the concept of active listening is the 2003 Survey of Cancer Advocacy Organizations conducted on behalf of NCI and the NCI Director's Consumer Liaison Group (DCLG). NCI contracted with an independent market research firm to conduct a survey of 152 cancer advocacy organizations.

The survey solicited information about each organization and its familiarity with NCI, thoughts about future DCLG direction and activities, and preferred communication methods. The survey yielded important information about respondents' perceptions of and experiences with NCI. Respondents discussed NCI efforts that were useful and effective and those that needed improvement.

Although NCI transparency and research priority setting were not the survey's main purpose, some information was directly relevant. An example is a recommendation that NCI find better ways to communicate to the cancer advocacy community its strategy and how it prioritizes research.

The survey was particularly laudable in its use of an approach that actively and thoroughly solicited information from this sector of the public. Such proactive measures for obtaining public input are worthy of serious consideration and replication across Institutes and Centers.

The benefits of actively soliciting information from constituents and the public include:

- Obtaining important information from constituent public members that otherwise would be missed.
- Using the information regarding experiences and perceptions to enhance and improve the transparency of the process.

- Improving the perception of NIH and the individual Institutes and Centers regarding their commitment to and interest in a transparent process.
- Creating trust by soliciting and valuing public comments.

Recommendation 10: Actively solicit information from constituents and the general public about the public's experiences and perceptions of transparency at NIH.

It is not enough to passively await comments from the public regarding their experiences and perceptions of transparency at NIH. The Institutes and Centers should actively seek this input on an ongoing basis. If the costs involved are prohibitive, this may be an opportunity for a number of Institutes and Centers to pool their resources.

Support and Funding

11. Provide Adequate Resources

Implementing some of the above recommendations will require a significant investment of funding, staffing, and support. In a period of declining budgets, this may involve difficult choices. Nevertheless, COPR believes that the goals of improving public input into the research priority-setting process and enhancing the transparency of that process are extremely important, particularly when these goals are considered in light of their impact on increasing public trust.

Recommendation 11. Provide adequate resources in terms of funding, support, and staffing to allow for the successful accomplishment of these recommendations.

Whether support is provided by increasing personnel and other resources within NIH, providing a budget to contract services from outside vendors or other agencies, or improving resource sharing among Institutes and Centers, the commitment to improving public input and enhancing transparency must be serious. Implementation of these recommendations will only be effective if the level of support is adequate to the tasks involved.

Conclusions

The guarantee of public input and participation in the NIH research priority-setting process and the transparency of that process are essential to promoting public trust in the research enterprise. This report identifies seven principles for improving public input into the research priority-setting process, and offers examples of best practices that effectively employ these principles and recommendations related to each. The report also cites three activities with specific examples that enhance transparency, and makes accompanying recommendations. Finally, the report addresses the need for adequate funding and support for implementing the recommendations.

The COPR recognizes that significant opportunities exist for public input and transparency that have not been identified in this report. We urge senior staff at each Institute and Center to consider not only the *process* for public input, but also the *intent* of each example cited. The spirit in which this report is received will determine the effectiveness of the efforts of each Institute and Center in this regard.

Support for and belief in the importance of public input into the research priority-setting process at NIH must be embraced from the top down. The degree to which this occurs will determine the success of attempts to incorporate public input, how transparent the process is, and ultimately how trustworthy the NIH, the Institutes and Centers, and the clinical research enterprise are in the public's mind.

It is clear from our efforts that many Institutes and Centers at the NIH take the issue of public input and transparency seriously, but more could be done. The NIH has shown genuine concern for issues of public input and transparency; however, more coordination of activities and cooperation between the Institutes and Centers would be beneficial. NIH efforts related to public input and transparency are improving substantially, but this is clearly an endeavor for which there is no end.

Appendix

Members of the Director's Council of Public Representatives
April 1, 2003 – March 31, 2004

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Acronyms

COPR	NIH Director's Council of Public Representatives
DCLG	NCI Director's Consumer Liaison Group
ICs	NIH Institutes and Centers
IoM	Institute of Medicine
NIH	National Institutes of Health
NCCAM	National Center for Complementary and Alternative Medicine
NCI	National Cancer Institute
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NICHD	National Institute of Child Health and Human Development
NIDCD	National Institute on Deafness and other Communication Disorders
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIMH	National Institute of Mental Health
NINDS	National Institute on Neurological Diseases and Stroke
NKDEP	National Kidney Disease Education Program
NLM	National Library of Medicine
OPL	Officer of Public Liaison
PIO	Patient Interest Organization
PIPWG	Public Input and Participation Work Group
VHA	Voluntary Health Association