

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL LIBRARY OF MEDICINE
MINUTES OF THE BOARD OF REGENTS
September 13-14, 2016**

The 173rd meeting of the Board of Regents was convened on September 13, 2016, at 9:00 a.m. in the Donald A.B. Lindberg Room, Building 38, National Library of Medicine (NLM), National Institutes of Health (NIH), in Bethesda, Maryland. The meeting was open to the public from 9:00 a.m. to 3:30 p.m., followed by a closed session for consideration of grant applications until 4:00 p.m. On September 14th, the meeting reopened from 9:00 a.m. until adjourning at 11:45 a.m.

MEMBERS PRESENT [Appendix A]:

Dr. Robert Greenes [Chair], Arizona State University
Ms. Sandra Martin, Wayne State University
Dr. Daniel Masys, University of Washington
Dr. Esther Sternberg, University of Arizona
Dr. Jill Taylor, Wadsworth Center, New York State Department of Health

MEMBERS NOT PRESENT

Dr. Alessandro Acquisti, Heinz College, Carnegie Mellon University

EX OFFICIO AND ALTERNATE MEMBERS PRESENT:

Col. Thomas Cantilina, United States Air Force
Dr. Wayman Cheatham, United States Navy Bureau of Medicine and Surgery
Mr. Christopher Cole, National Agricultural Library
Dr. Joseph Francis, Veterans Health Administration
Col. Michael Nelson, United States Army
Dr. James Olds, National Science Foundation
Dr. Dale Smith, Uniformed University Services of the Health Sciences
Dr. Richard Thomas, Uniformed Services University of the Health Sciences
RADM Sylvia Trent-Adams, Office of the Surgeon General, PHS
Ms. Meg Tulloch, Library of Congress

CONSULTANTS TO NLM PRESENT:

Ms. Jane Blumenthal, University of Michigan
Dr. Eric Horvitz (via teleconference), Microsoft Research
Dr. Gary Puckrein, National Minority Quality Forum
Dr. H. Kenneth Walker, Emory University School of Medicine

SPEAKERS AND INVITED GUESTS PRESENT:

Dr. Kathleen Brelsford, Duke University
Mr. Eric Dishman, National Institutes of Health, Office of the Director
Dr. Sandra Soo-Jin Lee, Stanford University

MEMBERS OF THE PUBLIC PRESENT:

Mr. Glen Campbell, Friends of the National Library of Medicine
Ms. Carla Funk, Friends of the National Library of Medicine
Dr. Lynne Holden, Friends of the National Library of Medicine
Ms. Lesley Macherelli, Healthbox
Dr. Barbara Redman, Friends of the National Library of Medicine
Dr. Elliot Siegel, Consultant
Mr. Thomas West, Krasnow Institute

FEDERAL EMPLOYEES PRESENT:

Dr. Patricia Flatley Brennan, Director, NLM
Ms. Betsy Humphreys, Deputy Director, NLM
Dr. Milton Corn, Deputy Director for Research and Education, NLM
Ms. Anne Altemus, Lister Hill Center, NLM
Ms. Dianne Babski, Division of Library Operations, NLM
Ms. Joyce Backus, Division of Library Operations, NLM
Dr. Olivier Bodenreider, Lister Hill Center, NLM
Ms. Sherri Calvo, Lister Hill Center, NLM
Dr. Dana Casciotti, Contractor, Office of Health Information Programs Development, NLM
Ms. Heather Collins, Contractor, Lister Hill Center, NLM
Ms. Kathy Cravedi, Office of Communications and Public Liaison, NLM
Mr. Ivor D'Souza, Office of Computer and Communications Systems, NLM
Mr. Todd Danielson, Office of the Director, NLM
Ms. Darlene Dodson, Office of the Director, NLM
Ms. Victoria Douglas, Division of Extramural Programs, NLM
Dr. Kathel Dunn, Division of Library Operations, NLM
Ms. Gale Dutcher, Division of Specialized Information Services, NLM
Dr. Valerie Florance, Division of Extramural Programs, NLM
Mr. David Gillikin, Division of Library Operations, NLM
Ms. Kendra Godwin, Associate Fellow, NLM
Dr. Kate Greenberg, Contractor, Lister Hill Center, NLM
Mr. John Harrington, Contractor, Lister Hill Center, NLM
Dr. Michael Huerta, Office of Health Information Program Development, NLM
Ms. Christine Ireland, Division of Extramural Programs, NLM
Ms. Megan Kellner, Associate Fellow, NLM
Ms. Janice Kelly, Division of Specialized Information Services, NLM
Dr. Alla Keselman, Division of Specialized Information Services, NLM
Dr. David Landsman, National Center for Biotechnology Information, NLM
Ms. Lisa Lang, Division of Library Operations, NLM
Dr. Clement McDonald, Lister Hill Center, NLM
Ms. Stephanie Morrison, Lister Hill Center, NLM
Ms. Tyler Moses, Associate Fellow, NLM
Mr. Dwight Mowery, Division of Extramural Programs, NLM
Ms. Tara Mowery, Office of Communications and Public Liaison, NLM
Mr. David Nash, Office of the Director, NLM
Ms. Candace Norton, Associate Fellow, NLM

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Dr. Barbara Rapp, Office of Health Information Program Development, NLM
Mr. Jerry Sheehan, Office of the Director, NLM
Dr. Hua-Chuan Sim, Division of Extramural Programs, NLM
Dr. George Thoma, Lister Hill Center, NLM
Dr. Rebecca Williams, National Center for Biotechnology Information, NLM
Mr. Phill Wolf, Contractor, Lister Hill Center, NLM
Dr. Fred Wood, Office of Health Information Program Development, NLM
Dr. Deborah Zarin, National Center for Biotechnology Information, NLM

I. OPENING REMARKS

Dr. Robert Greenes, NLM Board of Regents Chair, welcomed new NLM Director Dr. Patricia Flatley Brennan, the Regents, including incoming members Ms. Jane Blumenthal, Dr. Gary Puckrein, Dr. Nancy Cox (not present) and Dr. Eric Horvitz, and new ex-officio members and alternates to the 173rd meeting of the Board. He then introduced RADM Sylvia Trent-Adams, RN, PhD, Deputy Surgeon General of the Office of the Surgeon General (OSG).

II. REPORT FROM THE OFFICE OF THE SURGEON GENERAL, PHS

RADM Trent-Adams brought greetings from Surgeon General Dr. Vivek Murthy, who is on parental leave with a new baby. In recent months, the OSG been focused on the Ebola and Zika viruses. The staff has also been busy with the Surgeon General's agenda, like the 2015 launch of the "Step It Up!" campaign, a call to action to promote walking and walkable communities meant to expand participation in the First Lady's "Let's Move!" campaign. Bolstered by coordination with Centers for Disease Control and Prevention (CDC), OSG continues to work with communities across the United States, encouraging students in middle and high school to be more active as public schools have decreased exercise and fitness in their curricula.

Our opioid addiction campaign, Turn the Tide, offers a unique public health perspective focused on prevention, treatment and recovery. A partnership with Medicaid, Medicare, the Drug Enforcement Administration and the CDC, Turn the Tide encourages health care providers to improve their opioid prescribing practices. In August, the Office of the Surgeon General mailed a letter to more than 2.3 million licensed prescribers, asking them to take an online pledge to "end the opioids crisis." OSG is also working to educate communities on the importance of appropriate use of opioids and how to get services for individuals who are addicted.

RADM Trent-Adams announced that a report, *Facing Addiction in America: The Surgeon General's Report on Substance Use, Addiction, and Health*, will be issued later this year. OSG has already received a lot of feedback on its addictions campaign, and the report will address questions asked, suggestions made, and concerns raised. The report will focus on preventive measures within communities, the neurology of opioid addiction, and other topics, educating individuals who are addicted to substances and guiding them to services.

There is a serious shortage of treatment options in the US for those who are dealing with addiction. Surgeon General Murthy has been working with state and local jurisdictions to find

opportunities for us to engage in looking at alternative forms of pain management, including acupuncture, meditation, and exercise. The Surgeon General has been very active on social and national broadcast media talking about the opioid abuse problem to a wide audience.

RADM Trent-Adams said that the OSG has another special campaign underway this year on mental and emotional well-being. Emotional health is just as important to our overall well-being as our physical health. The OSG seeks to address not only the mental health needs of communities served across the US, but also how to assess current individual mental health status.

Children need to know the signs and symptoms of depression and how to engage with their parents and school officials to get help when they need it. OSG has been working with the CDC and the National Institute of Mental Health (NIMH) to look at the effect of mental illness on a chronic disease model. We've identified several studies that indicate that, if we are able to identify these conditions early, we are able to intervene at the earliest point in the disease and decrease the exacerbation of these conditions in adulthood.

RADM Trent-Adams next turned her attention to the Zika virus. OSG has been closely involved in the Zika response, working with entities across HHS as well as across the government. The Surgeon General led a delegation to Puerto Rico and held a press conference to heighten the need for community awareness and to provide education about Zika. An initial survey done by Puerto Rican officials showed that providers lacked basic knowledge of transmission modes and the importance of prevention, and that there was limited access to testing and screening resources.

The spread of Zika has been a challenge. In addition to cases in Florida, there was one case in Utah which resulted in the death of an elderly gentleman. Now, a family member who was caring for him has contracted Zika, so we are looking into a possible new mode of transmission.

RADM Trent-Adams indicated that the OSG has a unified command center, which has been set up in Puerto Rico; HHS is leading this effort on the island. Unfortunately, Zika will be with us for years because the virus is spread through maternal-child transmission. We hope to get better ultrasound capabilities across Puerto Rico and in other places where Zika has been reported, and to identify staff capable of providing ongoing care and treatment for these children as they grow.

RADM Trent-Adams concluded by describing the OSG's response to the Ebola virus, in which the Public Health Service played an important role. The OSG is now reviewing lessons learned, such as how to harness all agencies in a coordinated response, and the importance of communication and infrastructure on the ground when working with international entities. The OSG did a great job on Ebola overall, but there is still a lot to do, to meet future threats.

Board member Ms. Jane Blumenthal asked for more details about the Utah man who died from Zika. He had other health concerns, RADM Trent-Adams responded, but did have a very high level of the Zika virus in his bloodstream. The case is still under review.

In Puerto Rico, our biggest concern is microcephaly. The Department of Health there has done a good job monitoring kids throughout the school age years for that condition. The hope is to be able to build a database that will track these individuals over time, not only clinically but from a

sociological standpoint to identify developmental gaps for those born to women who had the Zika virus, but without microcephaly. Of course, one of many challenges is that the island is essentially bankrupt. RADM Trent-Adams said that their health care infrastructure is in disarray.

Trent-Adams said that the OSG is also concerned about the resistance of some mosquitoes to anti-Zika spraying. We need to figure out how to best help communities that have standing water, which is a major challenge in the tropical regions of the US, including Puerto Rico and the Virgin Islands. We also need to be concerned about the southern US as a whole, not just Florida, because their tropical climates can create conditions where Zika can spread very efficiently.

III. PRECISION MEDICINE INITIATIVE UPDATE

Dr. Greenes introduced former NLM Board of Regents member Eric Dishman, who has now been tapped to serve as director of the Precision Medicine Initiative (PMI) Cohort Program. In his new role, he is leading NIH's effort to coordinate the PMI research study of 1 million or more US volunteers in an exciting new effort to improve health and treat disease.

Mr. Dishman expressed great satisfaction at being back in the NLM Board Room, and at seeing his dear friend, NLM Director Dr. Patti Brennan, running the NLM.

He recounted his dramatic personal story—how he had cancer and was given many different treatments, but essentially it was guesswork. He wound up visiting several early genomics analytics companies and one of them sequenced his genome. The next step was three months of processing on the highest level computers at his employer, Intel, to get a clearer sense of his genome and pull all of my electronic health data to try and figure out what was causing his cancer. His clinical team put him on a pancreatic cancer drug and the next thing he knew, he was cancer free. An Intel employee donated a kidney to him and, today, at age 48, he's healthier than he was in his teens and twenties.

So, Mr. Dishman continued, it is definitely true he was meant to be here working on this cause—how to bring these data types together to individualize care and understand populations much better. With that in mind, he joined the working group of the PMI Cohort Program, currently working to invite a million or more volunteers reflecting the broad diversity of the United States to join this effort.

Volunteers in this program will have the opportunity to provide data on an ongoing basis in a variety of ways. This will be a very open project, with data shared freely in order to rapidly inform a wide range of research. Obviously, we'll de-identify personal health information and take appropriate risk-based controls around information that could be re-identified later in the process. We're not doing the research; we're building a national platform for the public, the Institutes and others to use, so they can conduct many significant studies based on it.

How is this different from other cohort programs? In its focus on diversity, for one thing. In our national melting pot, individual data will help us understand aspects of health, disease and genetics from all over the world. Diversity of health status is another key element. This is not a

disease-specific study but will have people in all stages of health. Diversity of data types is also essential; over time, we will collect a range of biological samples, electronic health data, etc. We are making sure this isn't a program solely with Tier 1 clinical research centers that already have Big Data infrastructures and data scientists, but that we also allow community colleges to participate and engage.

There are two primary methods we will use to bring people on board. One is the “direct volunteer” path—here's a number you can call, a website you can go to, an app that you can download, or my church or other institution reached out and they're going to onboard me in a traditional way. The other path is through health provider organizations (HPOs), which range from the Veterans Administration to regional medical centers to integrated delivery networks—all the different kinds of providers in the community whom local people feel they can trust.

What we're doing is revolutionary. At one of the working groups on this issue that I joined two years ago, I was sitting next to Dr. Francis Collins, and I whispered to him: “You do realize what you're trying to do is take NIH and NIH processes and people to make something that is more like what Google or a platform company would do, right?” Maybe that's why I ended up here.

Mr. Dishman next explained the organization of the Cohort Program, with its 33 awardees, 11 working groups or departments and 17 different federal agencies and departments. We have been able to work on legislative changes to facilitate this project for the long run, into the next Administration and beyond.

We are building a robust communities network. We are almost through reaching out to our top 50 community partners across the country who can help educate and inspire people locally to join the cohort program. We also have a 5,000-person community of beta testers, who are helping us evaluate the early capabilities of systems. We are testing the consent language, and getting feedback on content and design. Obviously, if we lose the trust of the participants because of security or if people aren't pleased with the privacy policy, we're off to a bad start. We do have the best experts working on these issues, however.

In closing, just a couple of thoughts on where we are in terms of the platform approach. This is the innovation funnel that every innovation company uses. What this describes is moving from conceptualization and ideation—the creative process—to implementation. What we are going to be doing over time is having multiple teams moving through this pipeline through launching a particular platform. Every time we do a release, we'll do an additional round of surveys, and each may have new updates and features for participants and researchers. People ask me when we are going to launch. Once we are through this pipeline and all terms and conditions are right for participants and researchers, we'll launch, but not before that. You can expect pilot launches of all of these capabilities this fall and winter.

Board member Dr. Jill Taylor asked whether part of the value of this is a long-term financial commitment by the government. Yes, Mr. Dishman replied. He wouldn't have taken the job unless there was strong bipartisan support, and there is. The PMI is one of the few things that Congress really sees and supports from an American health and competitiveness perspective.

Board consultant Dr. Gary Puckrein asked whether the project was bringing in small, minority technologists, because there is going to be a large amount of information transfer, and you don't want to have the large population be the end consumers, but not be involved in the build-out. This sounds like a great opportunity to have some knowledge transfer and development.

Mr. Dishman agreed. The program, inspired by President Obama himself, is to be part of the portfolio of the precision medicine efforts that include payment reform and care delivery. We want to use the investment to disrupt things in a positive way and so we're looking at ways that will work with federally qualified health centers, so they're able to do research on their own. We are also looking at STEM education programs, again, to teach communities so they can do this research on their own. In about four weeks, we'll launch a marketplace infrastructure. Certainly, one of its aims is to recruit people and companies from around the country to talk about and share their capabilities that we can add to the platform.

Board member Dr. Esther Sternberg mentioned work that she is doing with the US General Services Administration (GSA). What is the process for looping in other government agencies who have already established platforms, who may have lessons to share? So far, Mr. Dishman responded, the work groups are made up primarily of awardees, but the Cohort Program is reaching out to other government agencies and we will at some point have a formal liaison program to the many agencies that can share experiences and shed light.

Ex-officio representative Dr. Wayman Cheatham from the Office of the Navy Surgeon General commended Mr. Dishman for his presentation and asked about his strategy to get past the policy and oversight individuals who staff the 17 federal agencies involved, and actually get his message to the operational or mission-oriented counterparts. Mr. Dishman said that we are working on the drafts of the transition plan for the HHS Secretary and the White House. We sometime use the acronym RP, meaning the "real people" at the agencies who are going to get the work done. We're trying to reach the high-level officials, but also quickly trying to identify the RPs on the ground that will endure the Administration change and will help out.

NLM Deputy Director Ms. Betsy Humphreys suggested that, when the Cohort Program is ready to ask people to join in large numbers that they reach out to the National Network of Libraries of Medicine. Mr. Dishman said I'd love for these people to get the word out. He noted that there are multiple threads of connection between this project and NLM, including standards and electronic health records. He and the PMI senior staff will continue to be in close contact with the Library throughout.

IV. MAY MINUTES AND FUTURE MEETINGS

The Regents approved without change the minutes from May 3-4, 2016 meeting. The February 2017 meeting will take place on February 7-8, 2017, the 2017 Spring meeting will take place May 9-10, 2017, and the Board approved holding the Fall meeting September 12-13, 2017.

V. PRESENTATION OF REGENTS AWARD

Dr. Greenes next presented the NLM Regents Award, established in 1970 to recognize scholarship or technical achievement. It is the highest honor the Board can give to a member of the staff. This year, it goes to Dr. Alla Keselman, a senior social science analyst in the Specialized Information Services division. She was recognized “for sustained excellence in research, scholarship, and mentoring in the field of health information for the public, and in particular for co-editing the book, *Meeting Health Information Needs Outside of Healthcare: Opportunities and Challenges*. The Board gave her an enthusiastic round of applause.

VI. NEXT NLM STRATEGIC PLAN

NLM Director Dr. Patti Brennan opened what turned out to be a lively and wide-ranging discussion of strategic planning activities.

NLM has a long history of developing visionary long range plans that have led to amazing information resources now in use around the world. Now, on the brink of our third century, we are ready to undertake this process again. Dr. Brennan shared several video clips prepared by the Audiovisual Program Development Branch, tracing the arc of the Library’s history starting in 1956, when the legislation creating the NLM identified its two main roles: to assist in the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and public health.

The wise visionaries who penned that legislation meant “medicine” in the broadest sense, and actually enumerated in the law such aspects as public health, nursing and dentistry which has allowed NLM to have a mandate to serve many people in many disciplines.

We find ourselves in an environment that is full of excitement, challenge and risk, and the Board of Regents is responsible for guiding our strategic plan and bringing it into fruition in about a year. Dr. Brennan then gave her vision about what NLM might be encountering and what our strategic plan might be identifying as critical. She played another video, to highlight several themes.

Certainly part of our mission is to deliver the right information at the right time to those in need, whether it’s a researcher trying to evaluate the genetic structure or a mom trying to figure out whether a kid needs to go to school or she should probably consult with a doctor first. First and foremost, the charge she gave to the Board is to create a dynamic and vibrant strategic plan for the NLM. The report that the Working Group of the Advisory Committee to the Director (ACD) of NIH wrote a year ago constitutes a good framework. She asked the Board to draw on the talents of the 1,700 people who work at NLM and the broader talent pool of our advisors and stakeholders to formulate that strategic plan.

Second, NLM was called upon to do a functional audit, to understand what we are doing and what we are spending. She has already charged NLM Budget Officer Darlene Dodson to begin that internal evaluation. Third, and something that is very important, we need to remember that we serve everyone from infants to elders to scientists to school kids. We have a huge

constituency with whom to engage. Finally, she welcomed the Board's support as she worked with NLM Executive Officer Todd Danielson to evaluate the physical plant because, while this is a beautiful and glorious building, it needs a little work. Dr. Brennan next recognized Board chair Dr. Greenes.

Dr. Greenes noted that there have already been discussions involving himself, Dr. Brennan, Deputy Director Betsy Humphreys and Dr. Mike Huerta, Associate Director for Health Information Programs Development. This group helped to provide staffing for the planning process, and appointed a special Planning Subcommittee. Board members Dr. Dan Masys and Dr. Jill Taylor have agreed to co-chair it, and Dr. Greenes and Ms. Sandra Martin will also be members, although that doesn't mean that anyone on the Board is excluded. [NOTE: Dr. James Olds and Dr. Eric Horvitz were added to the Planning Subcommittee shortly after the meeting.] The Subcommittee will engage every member of the Board and solicit input throughout the process. Dr. Greenes then asked Dr. Masys to describe past NLM long-range planning efforts.

Dr. Masys reviewed NLM long-range plans back to 1985, noting that we stand on the shoulders of very capable groups. A 2005 planning panel issued its report covering 2006-2016. Yet, they also took a bold approach, examining the time range of 2005-2025. Dr. Masys just read the resulting vision again this morning and said it seems like it could have been written yesterday.

It suggests a methodology for how we might proceed—with a clean sheet of paper. If NLM didn't exist, what should it look like? Dr. Masys noted that in reading the ACD working group report, he expected to find a nuanced critical assessment, but instead discovered “a love letter to the NLM.”

Dr. Masys then opened the discussion, indicating that he would harvest everyone's initial response for how we might do the next round of planning. What are the most important issues we should address? When we look at the way the previous reports approached their topic segmentation, each one had subcommittees and focus groups that were centered on specific topics and goals. In 1985-86, there was a planning process that involved over 200 people and they were divided into five planning areas that were titled: 1) Building the Library's collection; 2) Locating and accessing the literature; 3) Obtaining factual information from databases; 4) Informatics; and 5) Information technology for health professionals.

Dr. Greenes observed that, when one does a strategic plan, one often starts with a vision which is a set of states that you see the world in, in the future. After that, your strategies and tactics are the verbs of what you might do. One of the questions that we want to address is who the intended audience is for the plan. Obviously, NIH is one, but there is a broader world of translation, delivery of care, etc. Obviously, we have a lot going on with the Precision Medicine Initiative, the digitization of health data, and health care payment reforms. We may need to reconfigure the systems that will deliver new knowledge and continually improve.

By phone, Board member Dr. Eric Horvitz mentioned that the 1985-86 planning group, while prescient, had no notion of what the web would become and how much the average consumer would be able to access health information. The reason I like the *vision* first is that we need to

think about how the rest of the world provides access to resources, and then what NLM does to complement or amplify the overall experience for people on the consumer side.

In 1985-86, Dr. Masys added, the highest priority was creating databases for molecular biology and genetics. The Human Genome Project was in its early stages and the proposal that the NLM could capture and help interpret the blueprint for a human being caught the imagination of Congress as a supplemental project to NLM's traditional mission related to the published literature. If the planning process would be were able to identify a similar novel opportunity now, like the PMI, which could hold out great potential.

What would be the mechanics of the planning process, Dr. Greenes asked. Do we have a way to take notes? Dr. Huerta said that the Office of Health Information Programs Development (OHIPD), which he heads, will organize the meetings and take notes, but there are other people at NLM whom they will engage to assist on a regular basis.

Board member Dr. Esther Sternberg, jumping off from the talk about the PMI and engaging Congress, noted the potential of wearable health and fitness devices. But the trick is merging multiple data streams and incorporating, in addition, the environment. When you think about point of health care delivery, patients are moving from hospital to clinic-based medicine to preventive health care, so the home and the person becomes the place and the focus of health and disease. To her, that's an over-arching theme and the place where medicine is moving.

As I listen to the discussion, Dr. Greenes said, we're dividing the themes into public health, personal care, and the person's underlying science and genomics. Do those categories cover everything? Put another way, said Dr. Sternberg, you're referring to a scale that runs from the molecular to the human to the population at large, but the same methodologies underline. Then the question is, how do you merge these massive data streams?

Dr. Cheatham mentioned the importance of leveraging Big Data, and using a process applying an algorithm or evolving algorithms that allow us to use all of the data that is available. Perhaps we can integrate that so the mathematical model will lead us to important outcomes. Conversely, if you look at population data or demographics and put those in boxes, you actually isolate yourself, as opposed to putting them into a structure that allows borrowing, synergies and discoveries to become apparent.

Dr. Puckrein discussed a couple of currents in the US that are profoundly important. First, the demographic shift, which offers great opportunities for NLM to play an important role, because some populations are not good health care consumers. There has not been a sustained and concentrated effort to date, so engaging and educating these populations will be really important. We also need a serious discussion on sustainability and issues related to climate change, but really what we're grappling with is how do we control health outcomes?

Ex-officio representative Ms. Meg Tulloch from the Library of Congress described a different perspective—creating the strategic plan for a national information infrastructure. She hoped that the heads of the national libraries, including the National Agricultural Library, would get together and start thinking about their very different disciplines but common interests.

Ms. Blumenthal said that libraries are no longer just about collections; they are services and infrastructures, moving from being a support service to being partners in research and education. We talk about translational medicine, and libraries have been translating complex scientific and health related concepts into terms that the lay person can understand for centuries. Dr. Taylor agreed, saying that building a national information infrastructure was also going to be important for the PMI and other Big Data endeavors.

Ms. Humphreys said that all members would receive an updated version of a summary of NLM activities, similar to that delivered to the ACD Working Group. That group made only six recommendations, Dr. Masys added, but we would ignore those at our peril.

Dr. Brennan observed that the NIH overall strategic plan has four statements, but the last one has to do with efficiency, with a clear message that we must be efficient in our stewardship of NLM resources.

The group talked more about the report of the ACD Working Group. Ms. Humphreys said that she and others at NLM were gratified that the first statement of its report dealt with the wide spectrum of user groups, and how those are key to the mission and purpose of NLM.

Dr. Cheatham suggested that strategic planning consider the mindset of Millennials, and focus on what's important to them and future generations and how they gather information.

Ex-officio representative Col. Thomas Cantilina said that one underlying theme is “What is health information?” Dr. Sternberg said she'd take it even further and ask, “What is health”? Does the definition take into account socioeconomic and community issues that are an essential part of public health? What can the NLM do best to help advance health?

Ex-officio member Dr. Dale Smith discussed historical views of medicine that were later proven erroneous. As we look at public-private partnerships, education, and the dissemination of information to the public, we need to make sure that trusted information is a definable product.

Dr. Masys noted that former NLM Director Dr. Donald Lindberg, in response to the 2006 plan, mentioned necessary building maintenance and lack of adequate space as threats to the future success of the library. A third NLM building was planned but never built, too.

Col. Cantilina asked, what is unique to NLM? Where can you go that they can't? There are things that NLM can do that nobody else can. What else can we do that nobody else can do because of the clout and reputation that you bring to the table which is extremely important and has been established over many years.

Dr. Brennan reminded the group that we are getting more access from computers than from humans right now, so we need to think in many cases that the recipient is not a person but a machine—the idea being that we need to think of methods of dissemination and reception not only through the human eyes.

RADM Sylvia Trent-Adams posed the question: If NLM did not exist, what would happen? Obviously, we are in a more diverse country than was the case under previous long-range plans, and we also have different mechanisms through which we receive our information.

Dr. Masys recounted a dramatic moment in the discussions around PMI at the White House. NCBI's Dr. Jim Ostell was asked by a former Silicon Valley executive, what is the volume of transactions at NLM? And he replied, "We handle 7,000 requests per second." The entire group of senior technology experts froze as they realized this was at a scale they had no idea about.

Dr. Greenes thanked the group for their input, and suggested they start thinking about the audience and the constituencies we're trying to reach out to, and the stakeholders. Think about our charge. There will be time for more discussion tomorrow.

VII. GENETICS HOME REFERENCE: OVERVIEW AND CURRENT STATUS

Ms. Stephanie Morrison of the Lister Hill Center gave an overview of Genetics Home Reference (GHR), an NLM resource on genetic conditions and related genes and chromosomes, which was launched in 2003 in response to public interest in accessible and trustworthy genetics information. The site offers information on more than 2,400 genetic summaries, including 1,100 health conditions and 1,300 genes, and a section called "Help Me Understand Genetics" that provides background information. GHR is written and updated by NLM staff with review from experts at NIH and around the world. Patients, students, teachers, health professionals, and geneticists use the site. About 72 percent of users are first-time visitors, more than half seek information on a specific disease or health condition, and 86 percent say they found the information they needed. The website gets a monthly average of about 3.5 million page views from 1.7 million visitors. Information from GHR is available from MedlinePlus Connect, a service that provides information related to patient conditions, tests, and medications recorded in electronic health records, personal health records, and more.

Survey results guided the GHR's redesign. For example, one respondent wrote, "I was tempted to leave immediately after seeing your website because I thought 'Hmmm, this looks out of date' even though it wasn't! You had very important and relevant information that I nearly just discounted because of your website style, so please update it!" The site now has a modern look with more images and is more accessible and shareable via mobile devices. Content, including new health conditions, will continually be added.

After her presentation, there were comments and questions. Ms. Martin asked about the reading level. Ms. Morrison replied that measuring the reading level using available tools is difficult because the site uses big medical terms, but then defines them for the public. That said, material is written for readers without a medical background. Board consultant Dr. Kenneth Walker said the site helps answer two questions human beings obsess about: "How did I get here?" and "Who am I?" through trusted data, multiple sources of input, and a vast range of information for both the public and scientists. He said the site is a model for NLM because it addresses a need.

Dr. Masys raised the issue about what should be the litmus test for when NLM should create synthesized information, i.e., act as an author and publisher, as opposed to being an integrator

and access channel for information created elsewhere. An obvious criterion would be that NLM alone could do it or that NLM has a unique advantage for doing it. The latter was the case when GHR was initiated, but does NLM have a mechanism for sensing environmental changes that may mean that this or any other NLM resource may no longer be needed or may have been surpassed by resources available elsewhere?

Ms. Humphreys said that she had scheduled the presentation on GHR, an excellent, heavily used, and recently re-designed NLM resource, to promote discussion of just these general issues, which apply to other NLM resources as well, as preparation for strategic planning.

Dr. Masys expressed concern that the current approach to development of GHR cannot scale, as new knowledge relevant to its scope is being generated more rapidly. Dr. Taylor underscored this point, stating that this is an incredible resource for parents with children with inherited diseases, but there is going to be a lot more information very quickly. Lister Hill Center Director Dr. Clem McDonald commented that the Board was raising excellent points, but that GHR did cover the great majority of topics that current users were seeking.

Dr. Puckrein brought up the importance of making it possible to integrate the great information in GHR in other systems and resources. In the discussion of this point, Ms. Morrison indicated that GHR does not yet have applications programming interface (API) access to its underlying data, although it does provide API access to webpages, which is used in MedlinePlus Connect. This is due in part to concern about presenting the information in an appropriate context. Ex-officio representative Dr. Joseph Francis brought up some parallel issues at the Veterans Health Administration, Section 508, and how others can use public data released by the VA. Ms. Tulloch and Dr. Francis both addressed differences between public and private sites, but favored release of data for easy use by outside systems.

Dr. Brennan said the Strategic Planning Group and the strategic planning process should address these concerns. She said the GHR is an extremely well-known entry to NLM and NIH that leads to other types of information resources. Yet there are questions of scalability, prioritization, and balancing library collection management with science communication. She was impressed to see the partnerships involved in building GHR. She would like the Strategic Planning Group to think about how NLM builds products and how we might establish a general technical platform that would allow us to build products, of which GHR is an excellent example, and scale them up rapidly as new information needs arise.

VIII. ETHICAL APPROACHES TO RESEARCH USE OF CLINICAL RECORDS AND DATA

NLM grantee Dr. Kathleen Brelsford, senior social scientist at the Program for Empirical Bioethics at Duke University, spoke on behalf of the grant's principal investigator, Dr. Laura Beskow. Dr. Brelsford presented results on patient perspectives regarding the acceptability of three different approaches to notifying patients about research use of clinical records: general notification, broad permission, and categorical consent. She also described patient willingness to share non-identifiable and identifiable data in clinical records with different types of researchers.

Her presentation was based on findings from 120 in-depth interviews the Empirical Bioethics team conducted in four diverse counties in the southeastern United States: Durham, NC; Cabarrus, NC; Quitman, MS; and Mingo, WV. She described the diversity of the four sites and noted the challenges they had recruiting people, primarily because of distrust in research.

She noted that when collecting policy-relevant data, it is important that participants have informed perspectives about the topics in question. Thus, the team designed research instruments to first provide participants with relevant information about each consent approach. They then assessed participant comprehension and addressed misunderstandings. Finally, they asked questions designed to help participants reflect on issues from multiple perspectives.

Acceptability for all three consent approaches was high: 76 percent for general notification, 96 percent for broad permission, and 89 percent for categorical consent. Broad permission was the most preferred approach overall, at three of the four sites. Nearly all participants would be willing to share non-identifiable data with researchers, but only about half would share identifiable data with researchers. Patients felt more comfortable sharing identifiable information with their own physician if he/she were conducting research, and with researchers in their own health care organization. Older patients were more likely than younger patients to share information in their EHR with researchers, as well as with researchers outside their own physician and health care organization.

After Dr. Brelsford's presentation, several Board members had questions and comments. Dr. Sternberg asked if there were more problems because of social pressure in small communities. Dr. Brelsford said that people in smaller communities were more concerned about the government accessing their information than their own communities and highlighted the importance of trust in building relationships. Ex-officio member Dr. James Olds asked about the data analysis by education level. Dr. Brelsford said they did analyze data according to education and that they didn't find any differences in terms of acceptability and preference by education. She also commented that less-educated people may feel disempowered and ill-equipped to make decisions about data sharing. Dr. Brelsford noted that some participants cited recent government database hacks affecting how they perceive threats to privacy and confidentiality.

IX. BEYOND CONSENT: PATIENT PREFERENCES FOR GOVERNANCE OF USE OF CLINICAL DATA AND SAMPLES

NLM grantee Dr. Sandra Soo-Jin Lee, senior research scholar at the Center for Biomedical Ethics, Senior Fellow at the Center for Innovation in Global Health at Stanford School of Medicine, and affiliated faculty in the Program in Science, Technology and Society at Stanford University, presented qualitative data from her NLM grant on patient preferences for governance of the use of clinical data and samples. She said the study seeks to understand how the public engages with what is "a new model of doing science." She said it reflects a shift in thinking about patients not as human subjects but as active participants. She asked, "How do you bring patients into the discussion?" and "How do they become participants in a way that is meaningful to them?" Her study addresses some of the ethical and social challenges ushered in by this new model of science. Her study also seeks to contribute to the dialogue on honoring the principles of respect and autonomy for participants; to explore the responsibilities and obligations of

stakeholders; and to assess patient attitudes about and preferences for how clinical data and samples are used, stored, and disseminated. Her study was conducted in Northern California and included 20 focus groups, using six videos in English, Mandarin, and Spanish to communicate information on issues, including the meaning of data, integrating data, and what it means to be part of a biobank.

She gave an example about asking about the term biobank, which garnered responses they didn't anticipate. Biobank brought up the idea of financial banks and commerce, a cryobank, an organ or blood bank, and even a gold mine. When they tried the metaphor of a library of medical information instead of a biobank, they found that it resonated because people are familiar with the term "library." In the area of oversight, she said participants' willingness to participate was conditional on the trustworthiness of the research process, the governance approach, and the expectation that information that would be relayed to patients as research was conducted. They would want to know how research actually helps patients. Based on feedback from participants, the research team developed recommendations, including that an oversight board should review and approve data security measures. Data from the focus groups will be used in a randomized pragmatic trial of a biobank that is being launched with Sutter Healthcare Systems in California.

Ex-officio representative Col. Michael Nelson congratulated Dr. Lee on her "non-conventional area of research" and brought up the issues of personal preference vs. acceptability, knowledge, trust, autonomy, and the greater good. He asked about a decentralized model of oversight at the local medical information library level or enterprise level and about accountability of oversight. Dr. Lee noted that oversight is a neglected area in terms of empirical work and creating an oversight committee is not required at Sutter Healthcare and is not a required element of the consent process, but it's important to patients and warrants development. She said that when they probed about willingness to participate, patients were more trusting of their health care system, but were wary of data being available at a federal level or to international researchers. Dr. Lee said that the ability to withdraw was prominent in discussions.

Dr. Puckrein said that the conversation seemed to be about structured data from EHRs, but unstructured data is the "wild, wild west" in terms of true transparency and availability to patients and those with whom they wished to share the data. He emphasized the need to bring unstructured data together with structured data. At the end of the presentation, Dr. Esther Sternberg commented that it is terrific that the public trusts the term "library," which is a government institution and how those in the medical profession shouldn't use names that seem may be threatening and unfamiliar to the public.

X. NLM-FUNDED CONSUMER AND PATIENT-CENTERED RESEARCH 2006-2015

Dr. Valerie Florance, director of Extramural Programs, used the NIH Precision Medicine Initiative and NLM's anticipated participation in it as a lead-in to her talk about NLM's previous funding of grant projects in consumer and patient informatics.

She looked at projects funded by NLM that involved patient engagement or consumer engagement over the last ten years. Using RePORTER, NIH's Research Portfolio Online Reporting Tools, she searched for research grants between 2006 and 2015 with the search term

“consumer or patient.” RePORTER found 554 projects funded by NLM during this 10-year period for \$158.5 million, which was 46 percent of the budget spent on research, resource and career grants. However, Dr. Florance found that the search term “patient” was too broad, capturing mainly grants about clinician behavior related to patient care. So she re-focused her search on “consumer,” producing a smaller number of projects about patient and consumer use of health information, and barriers to health literacy. The new list contained 89 NLM-funded projects for \$16.8 million or 5 percent of the NLM budget spent on research, resource, and career grants during that period. During this period, NLM ranked sixth of 26 NIH institutes that fund grants for “consumer research.” NLM supported relevant resource grants during this period. In 2010, NLM asked that researchers exploit computer and information technologies to bring health related information and information resources together to help reduce health disparities.

Dr. Florance provided several examples of NLM research projects that focused on consumer health information, including projects focused on terms consumers use to search health information, how breast cancer survivors manage information, an evidence-based tool for simplifying text sent to patients, and educational materials designed for American Indian and Native Alaskan men, who typically do not get screened for colorectal cancer.

NLM Director, Dr. Patricia Brennan was an NLM grantee while at the University of Wisconsin-Madison. Her work focused on providing home-care patients with electronic information and communication resources to better enhance patient care and partnerships with home care nurses.

Currently, NLM is participating in a trans-NIH health literacy project to encourage methodological, intervention, and dissemination research for understanding and promoting health literacy. NLM’s extramural funding investments in this area have been small compared to areas such as clinician decision support and translational bioinformatics. Other than the NLM Resource Grant (G08) to develop information resources to help reduce health disparities, NLM does not have other active funding opportunities focused only on consumers, patients, and health information. However, the newly re-issued NLM Express Research Grants in Biomedical Informatics and Data Science includes new language in the funding announcement to encourage research in this area: “Support for consumer and patient engagement in understanding, accessing, sharing, protecting and using their own health data.”

XI. NLM STRATEGIC PLAN: NEXT STEPS

Board Chair Dr. Robert Greenes and NLM Director Dr. Patti Brennan opened the discussion of next steps in the development of the new NLM Strategic Plan.

Dr. Masys reported that he had developed a draft planning model and timeline for the Strategic Plan based on the previous day’s discussion. In presenting the draft Strategic Plan timeline, he said that timing to completion would be ambitious. The Board will be updated next February. We will need a few months to schedule in person meetings of panels of about 20 to 25 persons for four to five meetings in February and March 2017. The panel discussions will be summarized in about six months for discussion at the May Board meeting. The final report should be ready to present to the BOR for approval on September 12, 2017.

Dr. Greenes said that a period for public comment should be included in the timeline. Dr. Masys agreed and asked Ms. Humphreys if previous long range plans included a RFI phase. She said that they have not. Dr. Greenes asked whether a 90-day comment period was required. Ms. Humphreys said no. Dr. Brennan suggested that RFI comments should be shared with the planning panels so panel members would have the benefit of input in preparing the report.

Dr. Masys agreed that comments should be received early in the process. Ms. Humphreys said it is a common practice across HHS to have open public meetings and then to provide opportunity for public comment at the end. Dr. Brennan suggested that, during the last 30 minutes of the panel meetings, those who would like to comment should be given three-minute segments to do so. Another way to provide for input, she said, would be to post a notice on NLM's website, encouraging public comment. Board members liked this approach as well. Ms. Humphreys said NLM could combine that process along with allowing a portion of the meetings to be open for public input. Dr. Masys said input via social media could be encouraged as well. Dr. Brennan noted that NIH Strategic Planning took place about a year ago. There were three webinars in August 2015 with about 750 participants. An RFI for the framework was devised and discussed with advisory councils. A report was produced without any public panels. NLM is taking a different approach. Ms. Humphreys reminded the Board that any subcommittee of the Board must report what occurred in their meetings to the full board in open session.

Dr. Masys suggested possible planning panel topics including: 1) Creating “the 21st century collection.” Issues to be discussed include whether to index or not, the evolving nature of physical and digital information resources, public-private partnerships, NLM as Author/Publisher and the information resources life cycle, and the relationships with other federal libraries and information providers (e.g., FDA); 2) Enhancing and preserving information resources. Issues to be discussed could include the physical plant, NLM's role in standards for digital content, NLM's role in integration of heterogeneous data to add new value, strategies for archival resilience, and utility reliability, and durability of cloud computing; 3) Accommodating digital and social diversity. Issues to be addressed could include the rise of machines as users, API's for all resources, when to wholesale, when to retail, user personas and evolving digital lifestyles: Millennials, Gens X and Y, Baby Boomers, persons “aging in place,” and the role of social networking technologies in NLM services; and 4) Catalyzing discovery and translational science. Issues to be addressed could include open science leadership, evolving role of NCBI in global biomedical research, support for other NIH ICDs, NLM role in Precision Medicine Initiative and other large scale prospective cohort projects; 5) Supporting and advancing healthcare services and systems. Issues to be discussed could include NLM's role in a Learning Healthcare System, context and user-sensitive health information for clinicians, individuals, families, support networks, a Public Library of Decision Support: infrastructure for systems approaches to developing and maintaining automated clinical and personal decision support; 6) Promoting health literacy and reducing health disparities nationally and globally. Issues to be discussed could include NLM's role in reducing health disparities, NN/LM services, outreach activities, and international programs; 7) Protecting the health of populations. Issues to be discussed could include NLM's role in federal, state, and local public health programs, disaster information services, and support for epidemic surveillance and response; and 8) Promoting informatics and data science. Issues to be discussed here could include extramural program

support of investigator initiated R&D, BD2K (Big Data to Knowledge), the role of internal R&D in Lister Hill Center and NCBI, workforce development.

Dr. Masys suggested that the work plan be sent to members electronically so they can react to or modify this document. Dr. Sternberg said that what is missing is the overarching mission towards which all these goals are working. Dr. Masys said he was glad that she mentioned this because in the planning model, the original group activity he envisioned under number 3 of the planning model was “determining the revised ten-year vision” for 2027 in that group’s domain. Dr. Greenes said that we are searching for the right tag line and Dr. Sternberg and Dr. Masys said that it should be determined in the beginning. Dr. Sternberg asked, “What is the big challenge all agencies are facing right now? And, how does NLM fit into that? What digital, informatics infrastructure is needed?”

XII. REPORT FROM THE NLM DEPUTY DIRECTOR

Deputy Director Betsy Humphreys said that the FY 2016 appropriation included two increases for NLM. One was an increase of \$44.5 million specifically for NCBI and public access activities. This was done to eliminate the need to tap the other ICs to support NCBI’s work. But this increase was actually \$5.8 million less than NLM would have received if the tap from the ICs had continued into FY 2016. NLM also received a general increase of \$13.225 million. To make up the NCBI shortfall, we allocated \$5.8 million from the general NLM increase. NLM did not receive the \$4 million increase included in the President’s budget for ClinicalTrials.gov expansion. NLM negotiated with NIH to receive \$3 million from the ICs for ClinicalTrials.gov.

For FY 2017, we are going to have a continuing resolution. There may be special funding for Zika included in this resolution. We don’t yet know how long the continuing resolution will be.

Regarding NLM personnel, Ms. Humphreys reported that a new director was appointed by NIH Director Dr. Francis Collins, Patricia Flatley Brennan, PhD, RN. Dr. Brennan assumed her new position on August 15, 2016.

Ms. Humphreys said that in FY 2015, NLM had 803 Full Time Equivalent (FTE) staff members. The estimate for FY 2016 was 811 FTEs. Due to the NIH-imposed partial hiring freeze, in effect for most of FY 2016 to provide hiring flexibility for the new NLM Director, we estimate that NLM’s actual use of FTEs in FY 2016 will be 35-40 below 811.

Ms. Humphreys said that Library Operations, has begun the recruitment process for the chief of the Public Services Division and for the head of the National Network Coordinating Office.

Ms. Humphreys mentioned that Dr. Elaine Martin, Director of the New England Regional Medical Library at the University of Massachusetts is moving on to head up the Countway Library at Harvard. Dr. Martin, who has worked at three different Regional Medical Libraries and directed two of them, has been a major creative force within the National Network of Libraries of Medicine, with special emphasis on improving access to information for the public health workforce and on preparing librarians for roles in e-science.

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Departing the NLM after a stellar 37-year career will be Gale Dutcher, MLS, MS, SIS Acting Associate Director. She will retire at the end of September 2016. Among many other contributions, Ms. Dutcher has been a leader in NLM's AIDS information activities and in outreach to underserved minorities.

Two NLM staff members recently left for positions in other agencies. Dr. John Kilbourne, head of the Medical Subject Headings (MeSH) section, resigned in August to join the Veterans Administration. Dr. Kilbourne was the lead on RxNorm. Ms. Deirdre Clarkin, MLS, resigned as deputy chief of the Public Services Division, Library Operations as of August 5, to head the Central Library of NOAA in Silver Spring, MD.

Ms. Humphreys introduced the new NLM Associate Fellows, Ms. Kendra Goodwin, Ms. Megan Kellner, Ms. Tyler Alicia Moses, and Ms. Candace Norton. Also new to the Library are the LHCBC fellows: Ravi Teja Bhupatiraju, MD, PhD, G. Thomas Brown, MD, PhD, Arunima Ghosh, MD, PhD, Satyajeet Raje, PhD, and Haruyuki Tatsumi MD, PhD.

Ms. Humphreys noted that the previous strategic plan emphasized the need for a third building for NLM. Plans developed for that building in 2003 included extensive upgrades to aging infrastructure in NLM's two existing buildings (38 and 38A) and a significant expansion of underground storage space for the NLM collections. When it became evident that construction funds for a new building would not be forthcoming, it was necessary to find other ways to secure more space for staff and collections and to fix building infrastructure, in part by renovations and upgrades to Buildings 38 and 38A. NLM worked with the NIH Office of Research Facilities (ORF) on major projects to strengthen the B2 floor in the Building 38 so it would support compact shelving (and more collection) and to upgrade the electrical capacity within the onsite NLM Data Center. NLM and ORF are now developing plans to address the risks inherent in having a single source of external power and a single source of chilled water for the onsite NLM Data Center. Maintenance and enhancement of infrastructure in Buildings 38 and 38A will require ongoing attention from NLM, irrespective of any Strategic Planning decisions that affect use of these facilities.

Ms. Humphreys noted that the Friends of the NLM (FNLM), Research!America, and the NLM cosponsored "Best Practices of Biomedical Search: Improving Reproducibility and Transparency of Preclinical Research" on June 9-19, 2016. The two-day Bethesda conference included insights from the FDA Commissioner Dr. Robert Califf, two NIH IC Directors, and other knowledgeable speakers.

NLM's 2016 Informatics Training Conference, held at the Ohio State University in Columbus, OH in June, brought together 250 NLM training program participants.

Ms. Humphreys stated that NLM exhibits will be seen in 144 towns in 42 states and two provinces in Canada in 2016. Also, the FNLM, in partnership with the Smithsonian Institution traveling exhibition program will create an exhibit based on NLM's preeminent collection of Arabic medical and scientific manuscripts from the Middle Ages. Former NIH Director Elias Zerhouni will chair this effort and help to fundraise. The Smithsonian will provide initial funding.

XIII. HIV/AIDS AND THE NLM

Gale Dutcher, SIS Acting Associate Director, gave a brief historical overview of NLM's involvement with the AIDS epidemic. NLM, she said, has many information sources that includes AIDS-related information (e.g., PubMed/MEDLINE, PubMed Central, GenBank, MedlinePlus and ClinicalTrials.gov, in addition to HIV/AIDS-specific resources)

Over 36 million people were living with HIV at the end of 2015, 1.1 million died of AIDS and 2.1 million new HIV infections occurred in 2015. In the US, the situation is better than in other countries. About 1.2 million people are living with HIV in the US, 13 percent of infected people are unaware of their infection, and about 40,000 newly diagnosed infections were reported in 2014. AIDS is a health disparity issue. Black Americans have the highest burden of disease, youth 13-24 account for 22 percent of newly diagnosed, and gay male African Americans have a one in two lifetime risk of an HIV-positive diagnosis.

In 1981, research in California began to document the AIDS epidemic. In 1983, the CDC established the National AIDS hotline; legislation was passed to provide \$12 million for AIDS-related research and treatment; and, the retrovirus causing AIDS was identified. But, community organizations did the heavy lifting with the affected population, mostly in California, largely organized by gay men.

The big change for NIH came with the passage of the Health Omnibus Programs Extension (HOPE) Act in 1988 (PL 100-607), which created the NIH Office of AIDS Research and required a databank of information on the results of AIDS research and the establishment of a AIDS databank on clinical trials and treatments. (This same legislation also created the NCBI at NLM.) The two databanks came to the NLM. Even before the HOPE legislation, NLM was developing AIDS-related information. NLM had produced an AIDS bibliography beginning in 1983 and Acquired Immunodeficiency Syndrome was added to MeSH that year; AIDSLINE was developed in 1988 (with coverage back to 1980). An AIDS subset was later made available through PubMed. The AIDS Clinical Trial Information Service database, a collaborative effort between the NLM, the FDA and NIAID, was housed at NLM and a telephone service for the public opened in July 1989.

AZT (Zidovudine) was approved in 1987. A call center started to receive calls about treatment and experimental drugs. In 1994, the first federal *practice* guidelines for HIV were issued by the Agency for Health Care Policy and Research, and the AIDS Treatment Information Service was started with support from the NIH (NLM, NIAID, and the Office of AIDS Research (OAR)), CDC, HRSA, and SAMHSA, providing federally approved treatment information about drugs for AIDS and related infections. In 1998, HHS issued the first federal *treatment* guidelines.

In 2002, AIDS*info* was formed by the merger of AIDS Clinical Trials Information Service and the AIDS Treatment Information Service. Other AIDS*info* content includes drug information, both approved and under investigation, with links to HIV clinical trials from ClinicalTrials.gov. Ms. Dutcher said the primary users of AIDS*info* are providers, followed by patients, families, friends, and others. AIDS*info* includes only federal information, but NLM's AIDS*source* includes both federal and non-federal AIDS information.

NLM provides support for the five AIDS-related NIH Guidelines Panels, which are working groups of the OAR Advisory Committee. We also provide access to CDC-supported guidelines. NLM has a content management system that facilitates frequent online panel updates, and archives the content in English. NLM also produces a number of Apps for handheld devices to improve access to this information.

NLM received funds from the HOPE legislation and from NIH Institutes or the OAR. In conjunction with OAR, NLM held a conference in 1993 to learn about information needs from the affected community and their caregivers. This conference led to the provision of free access to AIDSLINE (prior to free access to MEDLINE via PubMed in 1997) and to the creation of NLM's AIDS Community Information Outreach Program to help community organizations obtain the connectivity and equipment they needed to access AIDS information. Over 320 awards have been made since 1994.

Dr. Taylor observed that we have turned a corner in limiting the transmission and making AIDS a chronic, more stable disease. She said that there are programs in Europe where patients' drug regimens are tracked (via genotypes) so that there is a risk analysis available about what the best drug might be. Is there such a tool here at the NLM? Ms. Dutcher said that it has not been discussed, but is a great idea. Dr. Brennan said NLM is very cautious about accepting identifiable patient data. Dr. Taylor said the attitude in the AIDS community has changed and there has been movement beyond the identification/labeling.

Dr. Walker said that AIDS is a good example of a newly emerging disease and genetic analysis indicates that it probably evolved in the Democratic Republic of the Congo between 1884 and 1924. The first case that was diagnosed was in the Congo in 1959. The first case in the US was a St. Louis teenager in 1969. Several years later it began its transmission around the world.

Ms. Martin said that five years ago there was no recognition of World AIDS Day in Detroit. One of the medical students at her university walked into the library, saw a traveling exhibition from the NLM and approached us about establishing a World AIDS Day in the city. We used some of our outreach funding to help this student do that and it was extremely successful. Ryan White's mother came and spoke. It's a wonderful example of the ripple effect of NLM services.

Dr. Greenes said it is a wonderful example of the unique role that the NLM can play in partnership with other agencies and should be considered in the development of the Strategic Plan.

Dr. Puckrein asked about non-infectious chronic diseases that are prevalent, like diabetes. He said NLM could play a major role in educating the public about this epidemic too. Ex-officio Board member Mr. Christopher Cole agreed and said that, as a national library, we have a level of credibility about what we choose to link to, about what we index, that is incredibly important on the internet.

Following a brief coffee break, Dr. Brennan asked Board members to review the information presented in the Board book about strategic planning and asked if there was general agreement on the charge, process, deliverables, and timeframe.

XIV. CLINICAL TRIALS REGISTRATION AND RESULTS SUBMISSION: STATUS AND NEXT STEPS

ClinicalTrials.gov Director Dr. Deborah Zarin updated members on changes to ClinicalTrials.gov with the passage of The Food and Drug Amendments Act (FDAAA) in September 2007. In 2008, basic results submission was required. But, it is not until this year that the final rule for the submission of results will be published [NOTE: It was published on September 16, 2016, shortly after the meeting]. At the same time, a new NIH Policy will go into effect. FDAAA covers trials of devices, drugs, and biologics regulated by the FDA. The new NIH policy will apply the same reporting requirements to *all* clinical trials funded by the NIH.

Dr. Zarin noted that there have been numerous press stories about the lack of compliance requirements to report clinical trials results. There are serious problems with the clinical research enterprise. Potential participants have trouble finding trials; not all trials or outcome measures or adverse events are published; and changes to protocols are not always acknowledged. In the early 2000s, influential journal articles did not reflect the true state of evidence about some clinical trials. Paxil, Vioxx and Celebrex were examples of cases in which evidence was either suppressed, not reported, or was misleading. This led to trial registration as a requirement for publication in major clinical journals.

There was also the problem of publication bias. This was once thought to be an industry problem. However, we did a study (published in BMJ in 2012) that looked at a cohort of NIH funded clinical trials and found that five years after trial completion, one third had not reported their results. So, you had a traditional system in which: 1) the design and conduct of NIH-funded clinical trials was often left to individual investigators; and 2) individual investigators decided whether, when and how to disseminate results.

The problem persists. Some investigators think that you only have to register if you want to publish, that FDAAA won't be enforced, and that some studies aren't designed to produce meaningful results. These are a few reasons why results are not reported. Two thirds of the time when results are published, they may be misleading.

Dr. Zarin described the functions of the three key components of a robust Trial Reporting System: Prospective Registration, Summary Results Reporting, and Individual Participant Data (IPD) Sharing. Informed interpretation of summary results of trials of any intervention is dependent on comprehensive registration so that the denominator of trials of that intervention is known. Summary results - or a complete overview of trial arms, participants, interventions, outcome measures, and adverse events - are necessary to interpret any IPD that are available, e.g., to know whether all key data for all participants have been included in the available IPD.

Dr. Zarin reviewed the content of a ClinicalTrials.gov record, which includes a registration section and a results section. NLM does not do peer review, but we do quality control review. The protocol description and results must be clear and informative. The review criteria focus on logic and internal consistency, apparent validity, and meaningful entries. She gave some examples of obviously invalid entries submitted to ClinicalTrials.gov when trials are registered or results are submitted.

ClinicalTrials.gov links to journal articles when they exist, and an increasing number of articles have explicit links back to ClinicalTrials.gov. ClinicalTrials.gov also links out to other reliable sites, e.g., MedlinePlus.gov, Drugs@FDA, Devices@FDA, NIH RePORTER. We imagine ourselves as the informational scaffolding. ClinicalTrials.gov does not house patient specific data but we allow linkages to such data. So, you can use ClinicalTrials.gov to search for trials and to find everything you need to know about a clinical trial.

There are now a plethora of national and international legislative enactments requiring the registration of clinical trials. Today, about 600 new trials are registered in ClinicalTrials.gov each week. We receive about 100 new results entries per week and only about half have related journal publications, which means that this database is a unique source of information about those results. There are now about 23,000 sets of results in ClinicalTrials.gov.

Dr. Zarin showed a *New England Journal of Medicine* article which stated that the data for outcomes not reported in their journal article can be found at ClinicalTrials.gov. When there are numerous outcome measures, it is often not reasonable for a journal to include them all, so pointing readers to the complete source is a reasonable thing to do. ClinicalTrials.gov becomes the archival source for results information.

Challenges remain. We need to improve usability and optimize retrieval for a wide variety of users and clear up confusion about our goals. Dr. Zarin showed a recent *Washington Post* article about a woman who wanted to enroll in a stem cell study. She found out that it was going to cost her \$14,000 to participate. She wanted to know why NIH allowed this to occur. ClinicalTrials.gov does advise prospective research subjects to ask, “Who will pay for my participation?” when they inquire about participation in a trial. However, many trials in ClinicalTrials.gov are not funded or sponsored by NIH. One of the great features of ClinicalTrials.gov is that it provides one-stop access to information about trials funded, sponsored, and conducted by many different organizations in many countries.

What to expect from the Final Rule? Dr. Zarin said the goals are to clarify requirements for regulated community, to interpret ambiguous key statutory provisions, and to convey HHS decisions about additional reporting requirements needed to further the statutory goals. She had a few observations about rulemaking. She said public comments really matter. They often effect the substance of a final rule. For the November 21, 2014-March 23, 2015 comment period, they received about 900 comments and about 110 substantive multi-issue comments.

In summary, Dr. Zarin said that ClinicalTrials.gov is now central to the clinical research enterprise. Organizations that sponsor studies will be held responsible for their conduct and reporting. The time to decide if study is worth reporting is *before* the participants are put at risk, not *after*.

Dr. Masys pointed out that ClinicalTrials.gov has made a powerful contribution to the quality and transparency of the scientific enterprise. He said, “Keep going, you are doing amazingly good work.” His only question of Dr. Zarin, was, “Do you have enough resources?” NLM sits at the nexus of health information, said Col. Cantilina. It is the transparency of information, not the hiding of information that leads to discovery.

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Col. Nelson said he was pleased to hear the emphasis on the accuracy of reporting. He said the quality control that NLM does is critical to the success of ClinicalTrials.gov. Is there feedback to researchers when there is a problem identified so that they correct it? Dr. Zarin indicated that NLM does provide feedback, and NLM often gets results before they are published, so our review helps to scrub and correct the data before they are submitted for journal publication.

XV. ADJOURNMENT

Dr. Greenes adjourned the Board of Regents meeting at 11:45 a.m. on September 14th, 2016.

ACTIONS TAKEN BY THE BOARD OF REGENTS:

- Approval of the May 9-10, 2016 Board Minutes
- Approval of the September 12-13, 2017 Future Meeting Dates
- Creation of Long-Range Planning Subcommittee

Appendix A - Roster - Board of Regents

I certify that, to the best of my knowledge, the foregoing minutes and attachment are accurate and complete.

Patricia Flatley Brennan, RN, Ph.D.
Director, National Library of Medicine

Robert Greenes, M.D., Ph.D.
Chair, NLM Board of Regents