NICHD Director’s Report to Council

Diana W. Bianchi, M.D.
September 14, 2017
Outline for Today’s Talk

• Budget Update
  • Continuing Resolution and Budget Update
  • Update on 21st Century Cures Activities

• Staff Updates

• Vision Update
  • Building Bridges
  • Communicating the Message
  • Strategic Planning
• Congress appropriates and passes the budget
• **BREAKING NEWS**: government shutdown averted
• Government will operate through December 8th with a Continuing Resolution, allowing NIH to continue to operate until the regular appropriations acts are enacted
Sept 7, 2017 Breaking News: Senate Approves Increase for NIH’s FY18 Budget

- US Senate's appropriations committee approved a funding bill to increase NIH’s FY18 budget to $36.1 billion (a $2 billion increase from FY17)
- Includes an approximately $50 million increase for NICHD
- Total NICHD budget, if approved by the house and signed by the president, will be $1.426 billion
- No change in overhead (indirect) costs
Where Does the Money Go?

• RCDC stands for “Research, Condition and Disease Categorization”
• NIH keeps the public informed as to how tax dollars are spent
• RCDC is a database NIH has maintained since 2009 to categorize and report the amount of funding on more than 280 topics
• Data are generated using the following process:
  • Scientific experts develop definitions and lists of terms for each category
  • Sophisticated text mining is used to apply definitions to the NIH portfolio
  • Final curation and validation by scientific experts
• NIH does not budget by research category – used to report spending
• Categories are not mutually exclusive
## RCDC Example


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<td>$7</td>
<td>$5</td>
<td>76</td>
<td>8.0% (0.22%)</td>
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21st Century Cures Act

Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC)

Web page created to inform the public: https://www.nichd.nih.gov/about/advisory/PRGLAC/Pages/index.aspx
NICHD Pregnancy and Lactation Literature Analysis 2006-2017: Results for Pregnancy

• RCTs rare in almost all areas
• 5 Exceptions:
  • Gestational diabetes
  • Hypertension
  • Preterm labor
  • Labor pain medication
  • Opioids and tobacco
Interventional Trial Status in the US

*Industry sponsored*

Search terms include:
- Study type: “interventional”
- Study phase: “Early Phase 1; Phase 1; Phase 2; Phase 3; Phase 4”
- Funder type: “industry”

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Site accessed 09 Aug 2017)

Slide courtesy of Christina Bucci-Rechtweg, MD, Novartis Pharmaceuticals Corporation
21st Century Cures Act: Next Generation of Researchers Initiative

- 21st Century Cures Act – Section 2021. Investing in the Next Generation of Researchers
- Dr. Tabak spoke at June’s Council Meeting about the Grant Support Index (GSI)
- Next Generation of Researchers Initiative (NGRI) eliminates the GSI
Definitions

• An **early stage investigator (ESI)** is a Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award.

• An **early established investigator (EEI)** is an investigator who is within 10 years of receiving their first substantial, independent competing NIH research award as an ESI and who will no longer retain their ESI status because they received a substantial award).
Staff Updates
Best Wishes to NICHD Staff Who Are Retiring

• Dr. Germaine Buck-Louis, Director of the Division of Intramural Population Health Research (DIPHR), will begin a new adventure as Dean of the College of Health and Human Services at George Mason University on October 1st. Dr. Constantine Stratakis will serve as Acting Director of DIPHR.

• Dr. Mike Weinrich, Senior Advisor for Device Development, Biotechnology and Bioengineering, will retire at the end of September. He also served as Director of the National Center for Medical Rehabilitation Research at the NIH from 2000 to 2014.
Vision Update

• Building Bridges
  • NICHD/ECHO/NIDA (Opioids)
  • Human Placenta Project
  • All of Us
  • Johns Hopkins Children’s Center Visit
  • Perinatology Research Branch in Detroit

• Communicate the Message
  • Voice of the Patient

• Strategic planning process in early 2018
Building Bridges: Neonatal Opioid Withdrawal (NOW) Syndrome

- Funding from Dr. Francis Collins for Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW)
  - Builds a bridge between NICHD/ECHO/IDeA states network/NIDA/NIGMS
- Breakfast session with Chairman Sessions and Dr. Collins at the US Capitol
- Upcoming: Women’s Congressional Policy Institute Briefing on September 26
- Concept presented to Council later this morning
Building Bridges

4th Annual Human Placenta Project Meeting

July 24-25, 2017
Grantee updates, poster session and demos
https://grants.nih.gov/grants/guide/notice-files/NOT-PM-17-004.html

• Request for information from the public. Due SEPT 22

• What are the most significant precision medicine research questions that could be addressed by inclusion of pediatric populations?

• What are key gaps in pediatric study designs that might be appropriate to address through enrollment of children?

• What are the research resources that the inclusion of children into the All of Us program could generate?
Building Bridges: Johns Hopkins Children’s Center Visit

- Visit on August 30 to Johns Hopkins Children’s Center
- Continuing efforts to identify opportunities for collaboration with local partners in clinical care, intramural research and education
- Tina Cheng, M.D., Chair of Pediatrics at Hopkins, is on the All of Us Pediatric Advisory sub-committee
Building Bridges: Perinatology Research Branch in Detroit

Detroit Mayor Mike Duggan

Congresswoman Debbie Dingell
• Welcome Voice of the Patient speaker, Ms. Megan Connolly!
• She will be speaking about her experience in the NICHD-supported Oncofertility Consortium.
What’s Ahead? Strategic Planning Process

- Strategic planning process in early 2018
- Group of ~50 people
- Will include both internal and external stakeholders
- More information will be forthcoming
Questions?