160th NICHD National Advisory Council

Advancing Global Maternal and Child Health: Opportunities and Challenges

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Director, NICHD Office of Global Health

Why should NICHD be involved with Global Health Research?

- **Recent health crises:** (e.g., Ebola and Zika virus) impact of increased mobility, travel, migration, use of social media.
- **Unique research needs:** unique vulnerabilities infants, children, and pregnant women face during public health emergencies.
- **Fragile health systems:** demonstrating need for capacity building for more effective local emergency responses to prevent epidemics.

Why should NICHD be involved with Global Health Research?

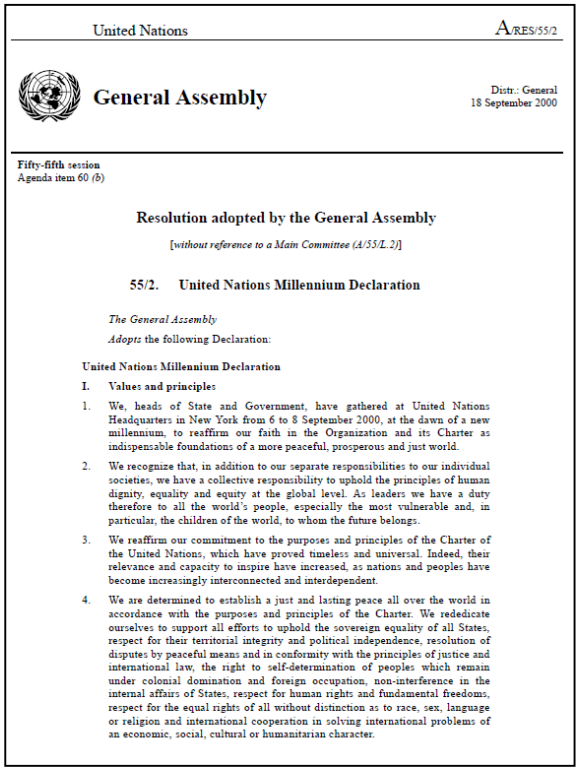
- **Impact of poverty on health**: risk of poor long-term health and developmental outcomes that can often be averted with early, evidence-based interventions.
- **Under-trained and resourced scientists:** to conduct research for a local evidence base for informed health program and policy decisions, and to respond effectively to local health emergencies. Risk of brain drain.
- **Ongoing cycle of inaction:** which prevents children and their families from thriving and reaching their full life potential.

Impact of NIH-supported research on child health and development in US and globally

- **Disease and disability have no borders:** innovative health discoveries that will benefit humanity are welcome developments to our global community, wherever they occur.
- **NIH's peer review system**: awards the best science wherever it is conducted in the world.
- ***JAMA* article**: **"What the United States Has to Gain From Global Health Research,"** Dr. Roger Glass, Director, Fogarty International Center. *JAMA*.2013;310(9):903-904

Background: Millennium Development Goals

September 2000, adoption of the United Nations (UN) Millennium Declaration at UN Headquarters in New York, committing to a global partnership to reduce extreme poverty and setting out a series of time-bound targets - with a deadline of 2015, known as the Millennium Development Goals (MDGs).



United Nations A/RES/55/2

General Assembly

Distr.: General
18 September 2000

Fifty-fifth session
Agenda item 60 (b)

Resolution adopted by the General Assembly

[*without reference to a Main Committee (A/55/L.2)*]

55/2. United Nations Millennium Declaration

The General Assembly

Adopts the following Declaration:

United Nations Millennium Declaration

I. Values and principles

1. We, heads of State and Government, have gathered at United Nations Headquarters in New York from 6 to 8 September 2000, at the dawn of a new millennium, to reaffirm our faith in the Organization and its Charter as indispensable foundations of a more peaceful, prosperous and just world.

2. We recognize that, in addition to our separate responsibilities to our individual societies, we have a collective responsibility to uphold the principles of human dignity, equality and equity at the global level. As leaders we have a duty therefore to all the world's people, especially the most vulnerable and, in particular, the children of the world, to whom the future belongs.

3. We reaffirm our commitment to the purposes and principles of the Charter of the United Nations, which have proved timeless and universal. Indeed, their relevance and capacity to inspire have increased, as nations and peoples have become increasingly interconnected and interdependent.

4. We are determined to establish a just and lasting peace all over the world in accordance with the purposes and principles of the Charter. We rededicate ourselves to support all efforts to uphold the sovereign equality of all States, respect for their territorial integrity and political independence, resolution of disputes by peaceful means and in conformity with the principles of justice and international law, the right to self-determination of peoples which remain under colonial domination and foreign occupation, non-interference in the internal affairs of States, respect for human rights and fundamental freedoms, respect for the equal rights of all without distinction as to race, sex, language or religion and international cooperation in solving international problems of an economic, social, cultural or humanitarian character.

Background: Millennium Development Goals

Targets (between 1990 and 2015):

MDG4: Reduce by two thirds, the under-5 mortality rate:

- **Indicator 4.1** Under-five mortality rate
- **Indicator 4.2** Infant mortality rate
- **Indicator 4.3** Proportion of 1 year-old children immunized against measles

MDG5: Reduce by three-quarters, the maternal mortality ratio:

- **Indicator 5.A** Improve maternal mortality ratio
- **Indicator 5.B** Universal access to reproductive health care

MDG 4 & 5: Current Status

- **MDG 4: Under 5 Child Mortality since 1990:**
  - **Estimated** 48 million lives saved **in children under age five** if the under-five mortality rate had remained at the same level as in 2000
  - **Annual number of under-five deaths** worldwide has declined from 12.7 million in 1990 to 5.9 million in 2015
  - A total of 16,000 children die each day in 2015.

- **MDG 5: Maternal Mortality Ratio since 1990:**
  - **The maternal mortality ratio** has been cut 43.9%, and most of the reduction occurred since 2000.
  - **The global MMR** fell from 385 deaths per 100,000 livebirths in 1990, to 216 in 2015 with 303,000 maternal deaths in 2015.
  - After years of slow progress, only half of pregnant women receive the recommended amount of **antenatal care**.

References: You D et al. Lancet. 2015 Dec 5;386(10010):2275-2286: Alkema L et al. Lancet 2016 Jan 30; 387(10017):462-474.

What's next?

Sustainable Development Goals (SDGs)

- Adopted September 2015 at UN Sustainable Development Summit
- 17 Goals and 169 Targets
- Came into effect on January 1, 2016 with full implementation by 2030

The U.S. Government (USG) and Global Health

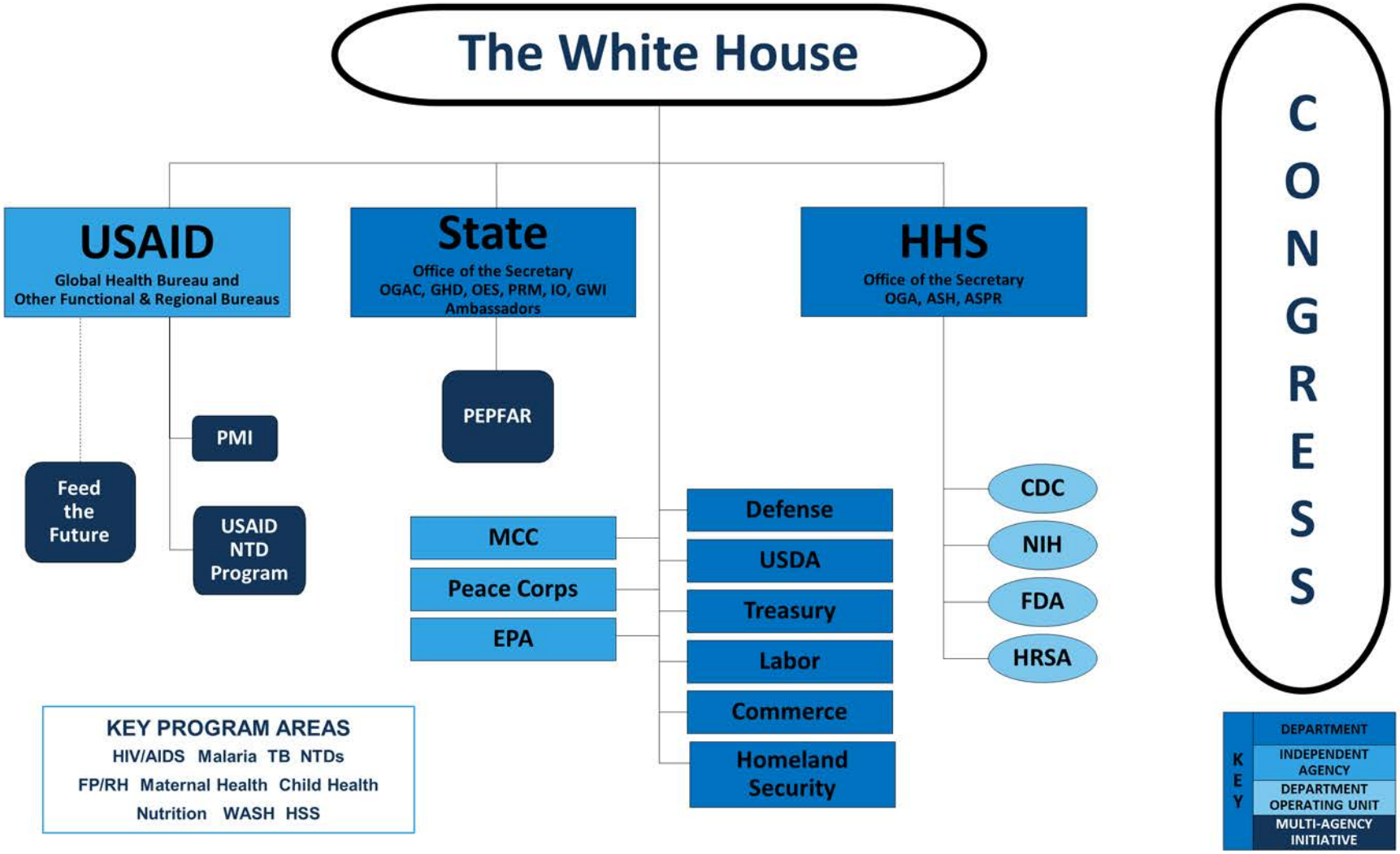
- USG involvement in global health spans over 100 years
- Largest funder and implementer of global health programs world-wide
- Less than 1% of $4 trillion U.S. federal budget spent on foreign aid
- Foreign aid comprised of global health, economic development, and humanitarian assistance
- ~21% of foreign aid budget dedicated to global health

Role of the USG in Global Health

- Operates programs and delivers health services (e.g., PEPFAR, USAID initiatives)
- Provides technical assistance/capacity-building
- Participates in international health bodies (e.g., WHO, UNICEF)
- Conducts research (e.g., NIH, CDC)
- Supports international responses to disasters and other emergencies (e.g., USAID OFDA, USPHS)
- Engages in bilateral and multilateral activities

Figure 1

Organization of USG Global Health Efforts



NOTES: USAID: U.S. Agency for International Development; State: Department of State; OGAC: Office of the Global AIDS Coordinator; GHD: Office of Global Health Diplomacy; OES: Oceans and International Environmental and Scientific Affairs; PRM: Population, Refugees, and Migration; IO: International Organizations; GWI: Global Women's Issues; HHS: Department of Health and Human Services; OGA: Office of Global Affairs; ASH: Office of the Assistant Secretary for Health; ASPR: Office of the Assistant Secretary for Preparedness and Response; PMI: President's Malaria Initiative; NTD: Neglected Tropical Diseases; PEPFAR: President's Emergency Plan for AIDS Relief; MCC: Millennium Challenge Corporation; EPA: Environmental Protection Agency; Defense: Department of Defense; USDA: U.S. Department of Agriculture; Treasury: Department of the Treasury; Labor: Department of Labor; Commerce: Department of Commerce; Homeland Security: Department of Homeland Security; CDC: Centers for Disease Control and Prevention; NIH: National Institutes of Health; FDA: Food & Drug Administration; HRSA: Health Resources and Services Administration; HIV/AIDS: Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome; TB: Tuberculosis; FP/RH: Family Planning/Reproductive Health; WASH: Clean Water, Sanitation, and Hygiene; HSS: Health Systems Strengthening.
SOURCE: Kaiser Family Foundation analysis.

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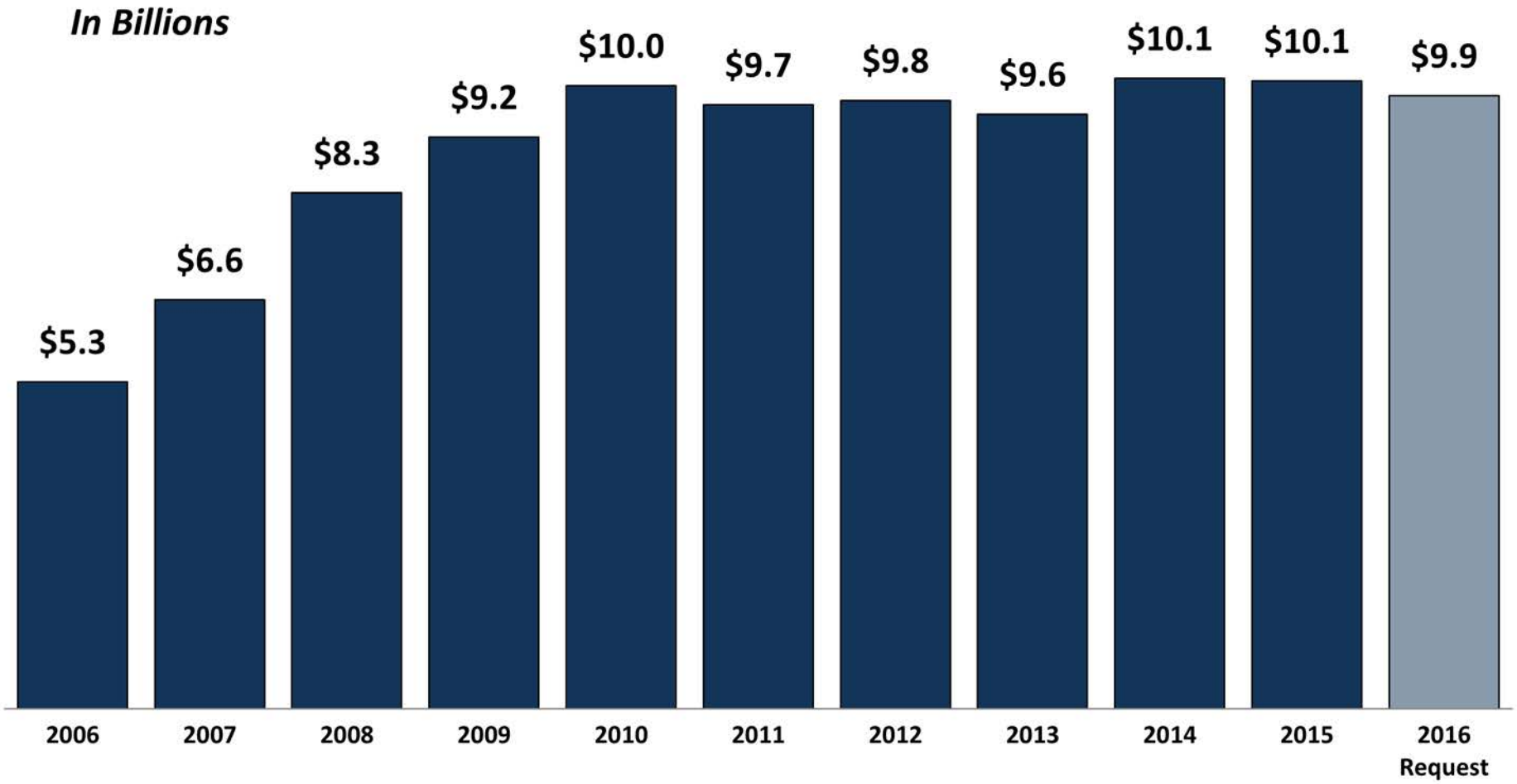
Figure 2

U.S. Global Health Funding, FY 2006-FY 2016 Request



NOTES: Represents total known funding provided through the State Department, USAID, CDC, NIH, and DoD. Includes base and supplemental funding. FY13 includes the effects of sequestration. FY15 is based on funding provided in the "Consolidated and Further Appropriations Act, 2015" (P.L. 113-235) and is a preliminary estimate. Some FY15 and FY16 funding for malaria programs at DoD is not yet known and is assumed to remain at FY14 levels. Some FY15 global health funding provided through the Economic Support Fund (ESF) and Development Assistance (DA) accounts is not yet known; for comparison purposes, FY15 ESF and DA amounts are estimated using the lower level of funding in either FY14 Final or the FY16 Request, which is likely to be a conservative estimate.

SOURCE: Kaiser Family Foundation analysis of data from the Office of Management and Budget, Agency Congressional Budget Justifications, Congressional Appropriations Bills, and U.S. Foreign Assistance Dashboard [website], available at: www.foreignassistance.gov.

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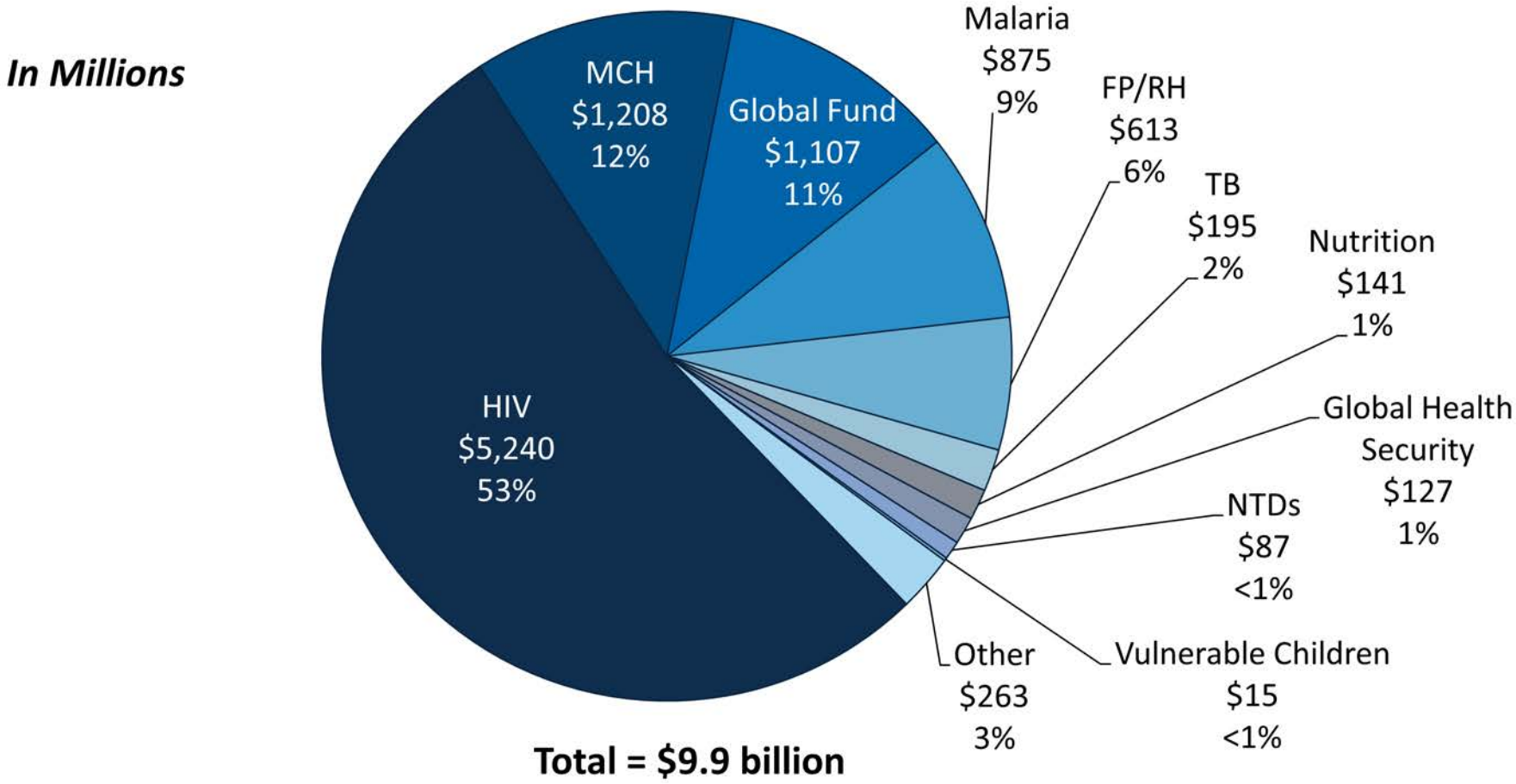
Figure 9

U.S. Global Health Funding, By Sector, FY 2016 Request



NOTES: Represents total known funding provided through the State Department, USAID, CDC, NIH, and DoD. HIV includes funding through State/OGAC, USAID, CDC, NIH, and DoD. Malaria includes funding through USAID, CDC, NIH, and DoD (some FY16 funding for malaria programs at DoD is not yet known and is assumed to remain at FY14 levels). TB, Nutrition, NTDs, and Vulnerable Children include funding through USAID. MCH includes funding through USAID and CDC as well as contributions to UNICEF. FP/RH includes funding through USAID as well as contributions to UNFPA. Global Health Security includes funding through USAID and CDC. "Other" includes funding through USAID, CDC, and NIH as well as contributions to WHO and PAHO.

SOURCE: Kaiser Family Foundation analysis of data from the Office of Management and Budget, Agency Congressional Budget Justifications, Congressional Appropriations Bills, and U.S. Foreign Assistance Dashboard [website], available at: www.foreignassistance.gov.

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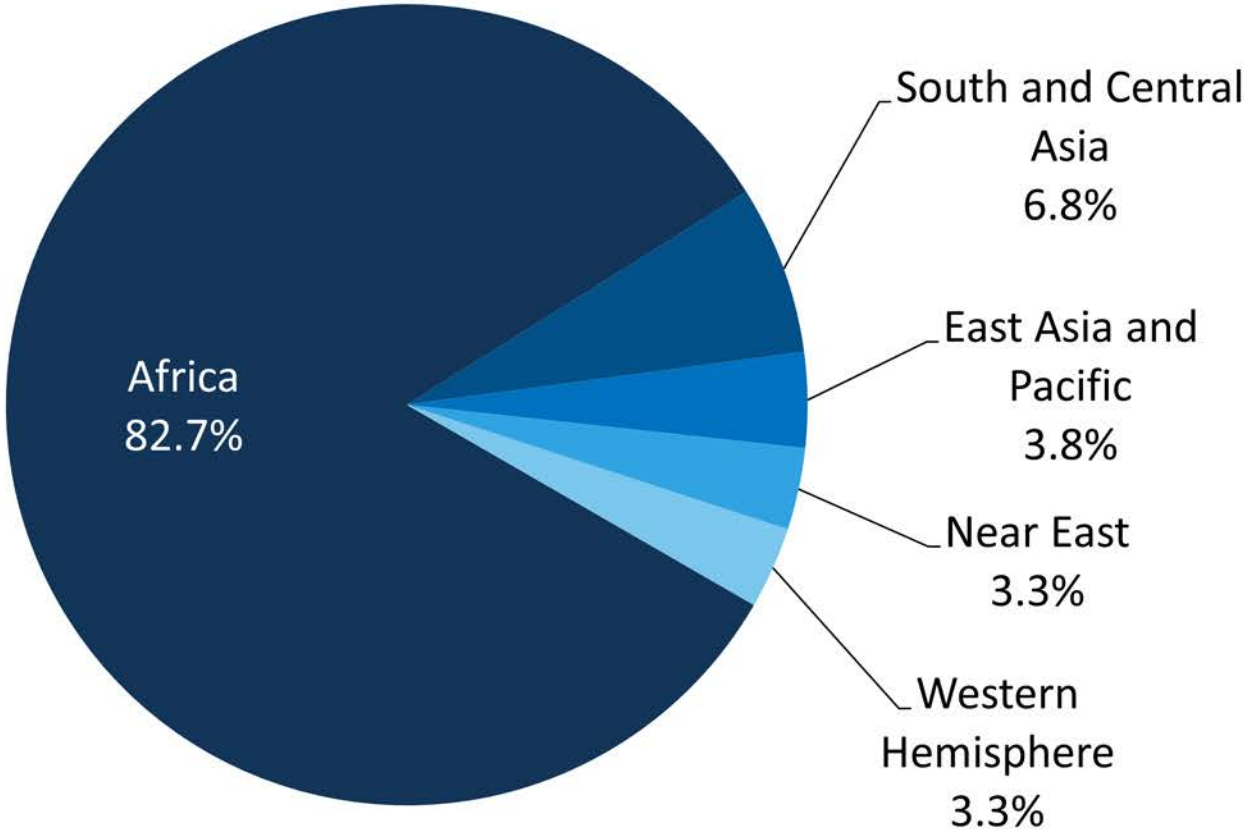
Figure 11

U.S. Global Health Country Funding by Region, FY 2014



Total = $5.9 billion

NOTES: Includes country level funding for global health programs available in the Foreign Assistance Dashboard.
SOURCE: KFF analysis of data from the State Department, Foreign Assistance Dashboard [website], available at: www.foreignassistance.gov; accessed January 2015.

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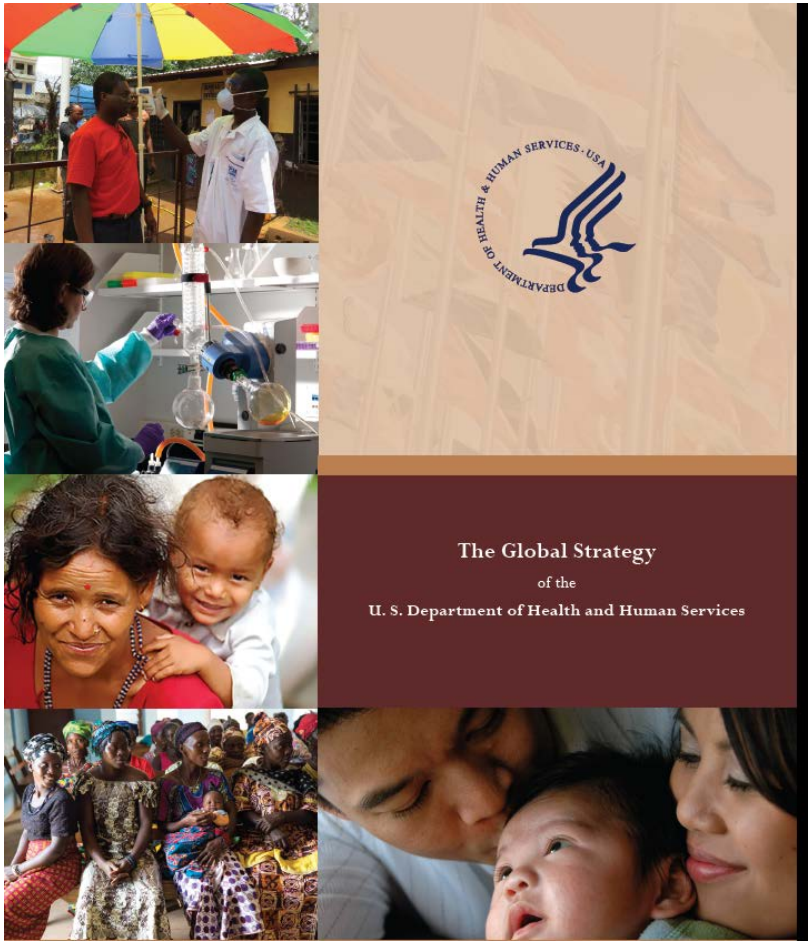
HHS Office of Global Affairs

- Represents the Secretary and HHS in discussions of international matters with U.S. and foreign representatives
- HHS Global Strategy contributes to the achievement of U.S. government goals and principles in the areas of HIV/AIDS, malaria, tuberculosis, neglected tropical disease, maternal and child health, nutrition, safe water, sanitation, food security, and hygiene by focusing on women-centered programming, country ownership, integration and coordination, and health systems strengthening



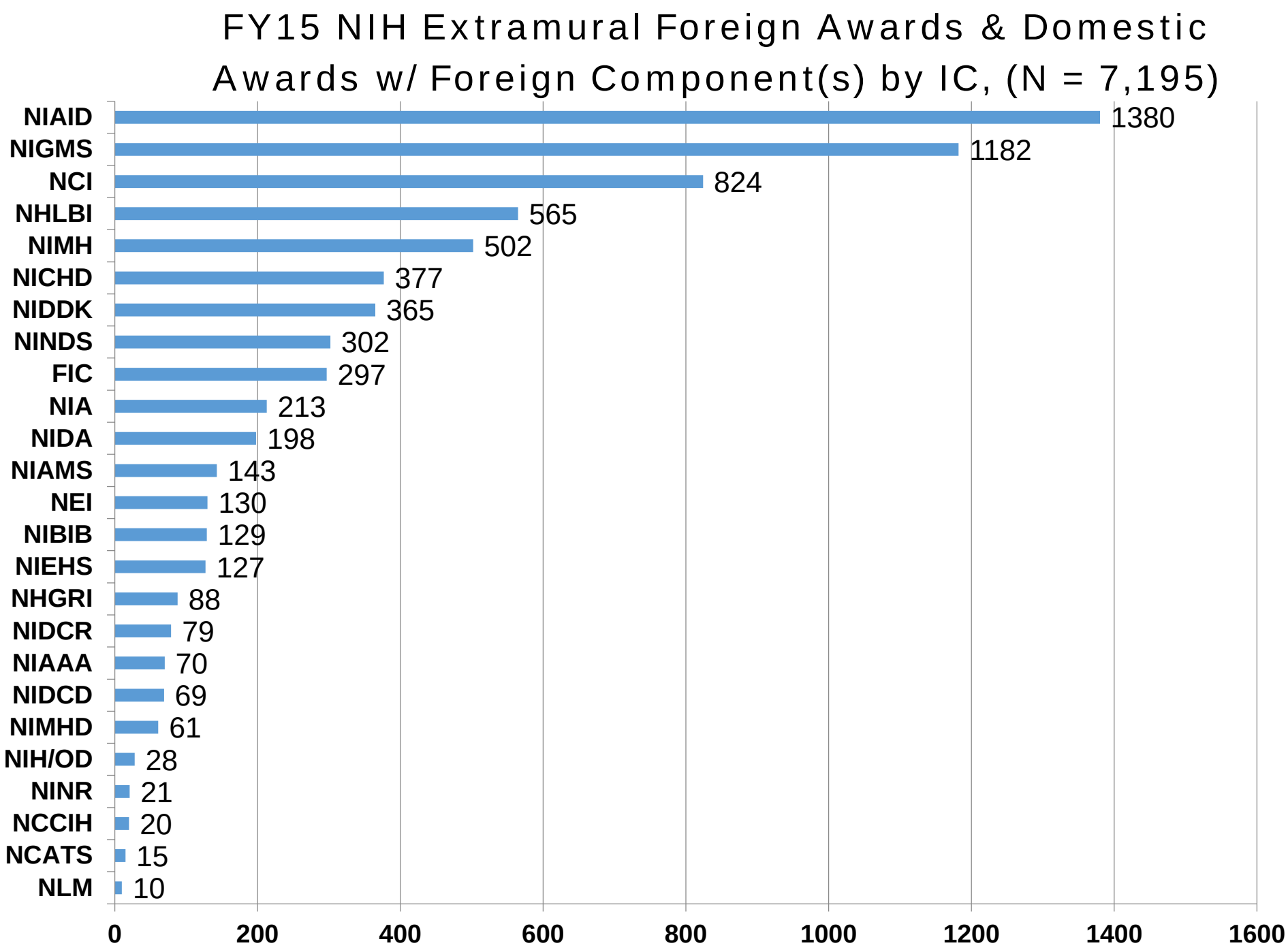
NIH Overview

- Dr. Francis Collins, Director, NIH has identified Global Health as a high priority during his tenure.
- Global health research and training portfolios of the 27 Institutes and Centers are highly variable and disease specific.
- Within USG framework, NIH provides research expertise on global health topics.

NIH Building 1, Main Campus
Bethesda, MD

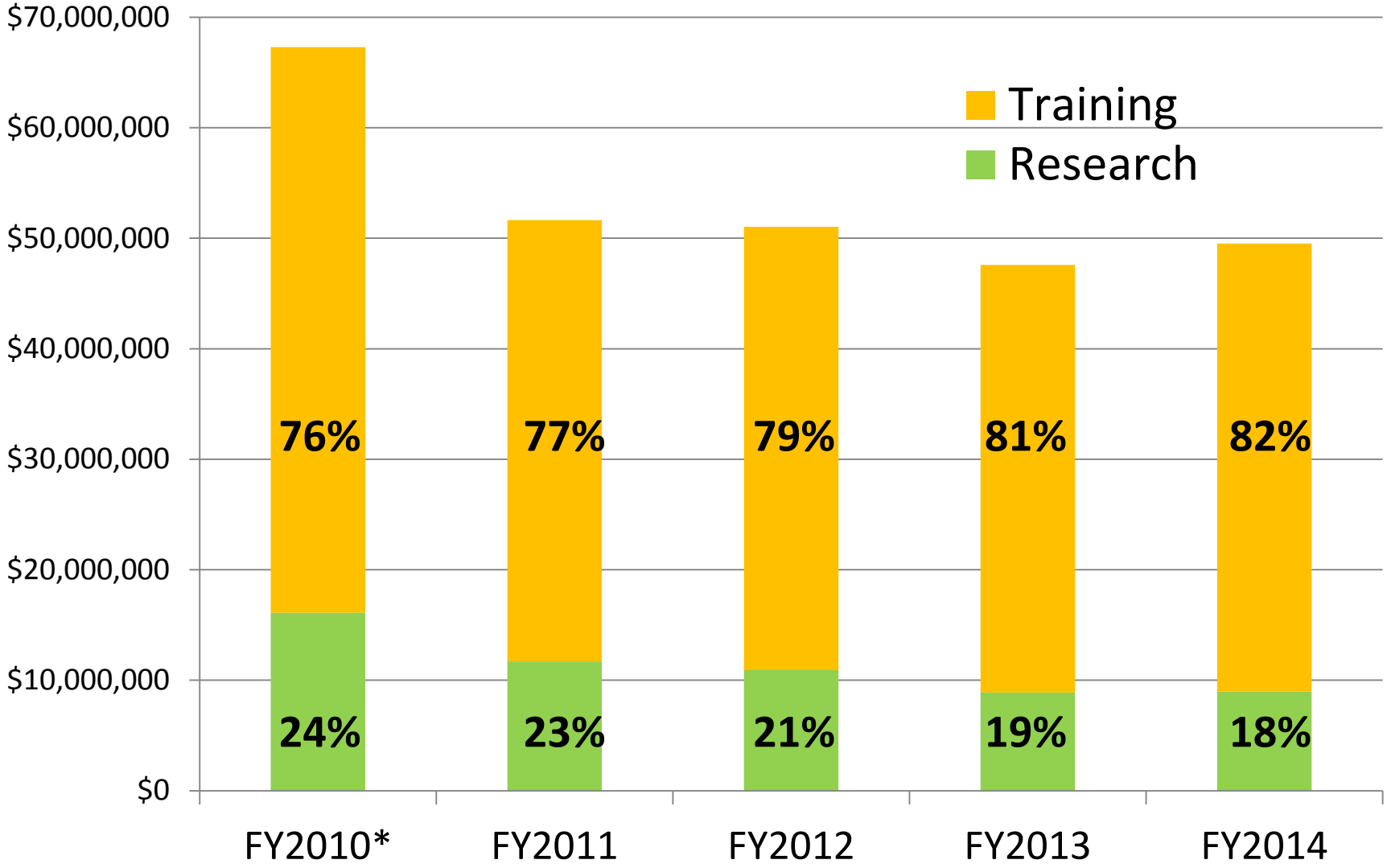
NIH-Wide Global Health Research Portfolio

- 7,195 NIH extramural foreign awards and domestic awards with foreign components in FY ‘15
- 24 ICs plus NIH OD make such awards; all regions have awards
- Great variation in number of awards by IC and by region/country
- 12.7% of foreign awards are to low and middle income countries.


FY15 NIH Extramural Foreign Awards & Domestic Awards w/ Foreign Component(s) by IC, (N = 7,195)
NIAID 1380
NIGMS 1182
NCI 824
NHLBI 565
NIMH 502
NICHD 377
NIDDK 365
NINDS 302
FIC 297
NIA 213
NIDA 198
NIAMS 143
NEI 130
NIBIB 129
NIEHS 127
NHGRI 88
NIDCR 79
NIAAA 70
NIDCD 69
NIMHD 61
NIH/OD 28
NINR 21
NCCIH 20
NCATS 15
NLM 10
0
200
400
600
800
1000
1200
1400
1600

Fogarty Research vs. Training Expenditures

Includes all Fogarty expenditures on FIC extramural programs and non-Fogarty extramural programs

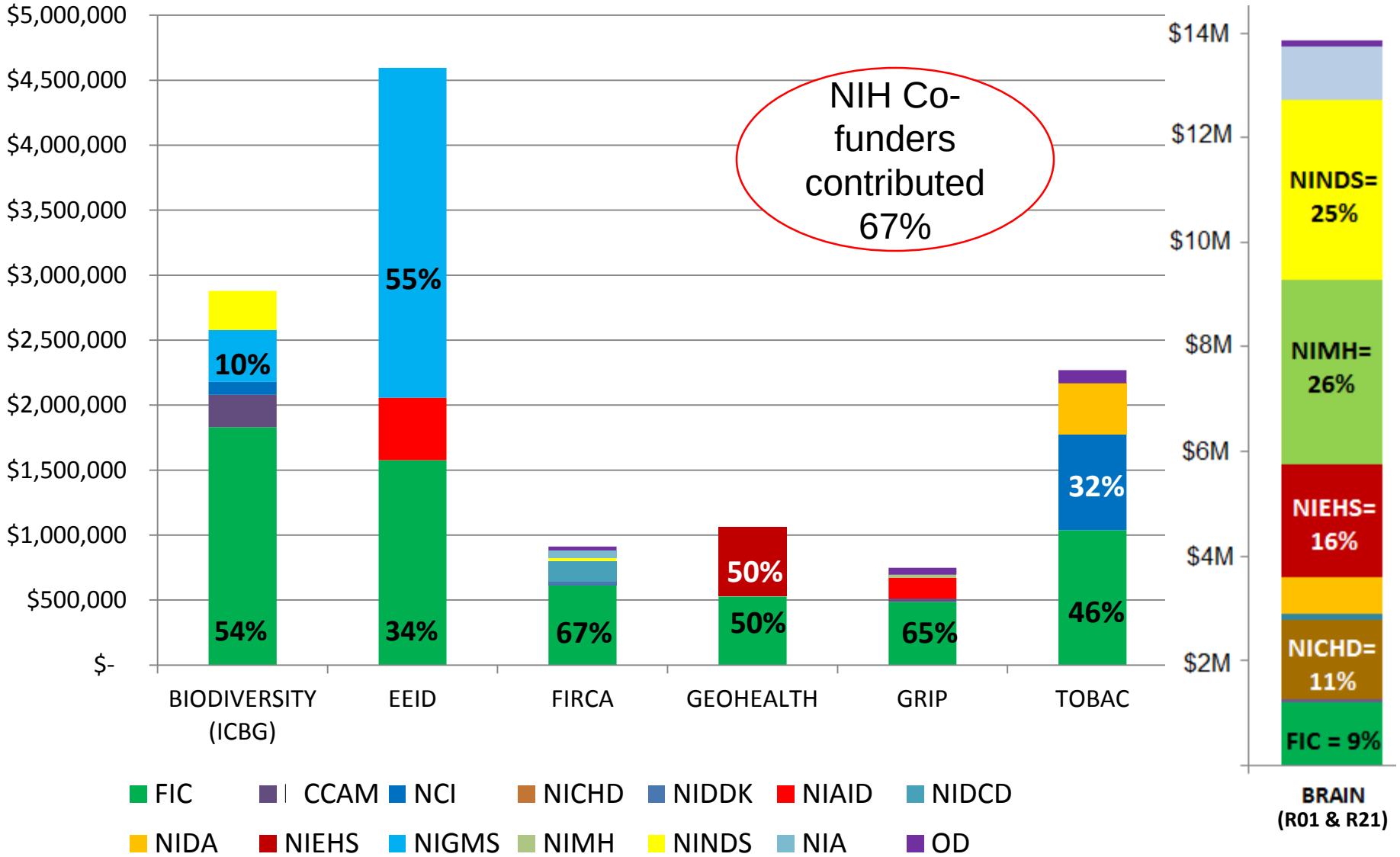


*NOTE: 2010 includes ARRA

Source: FIC Budget Office

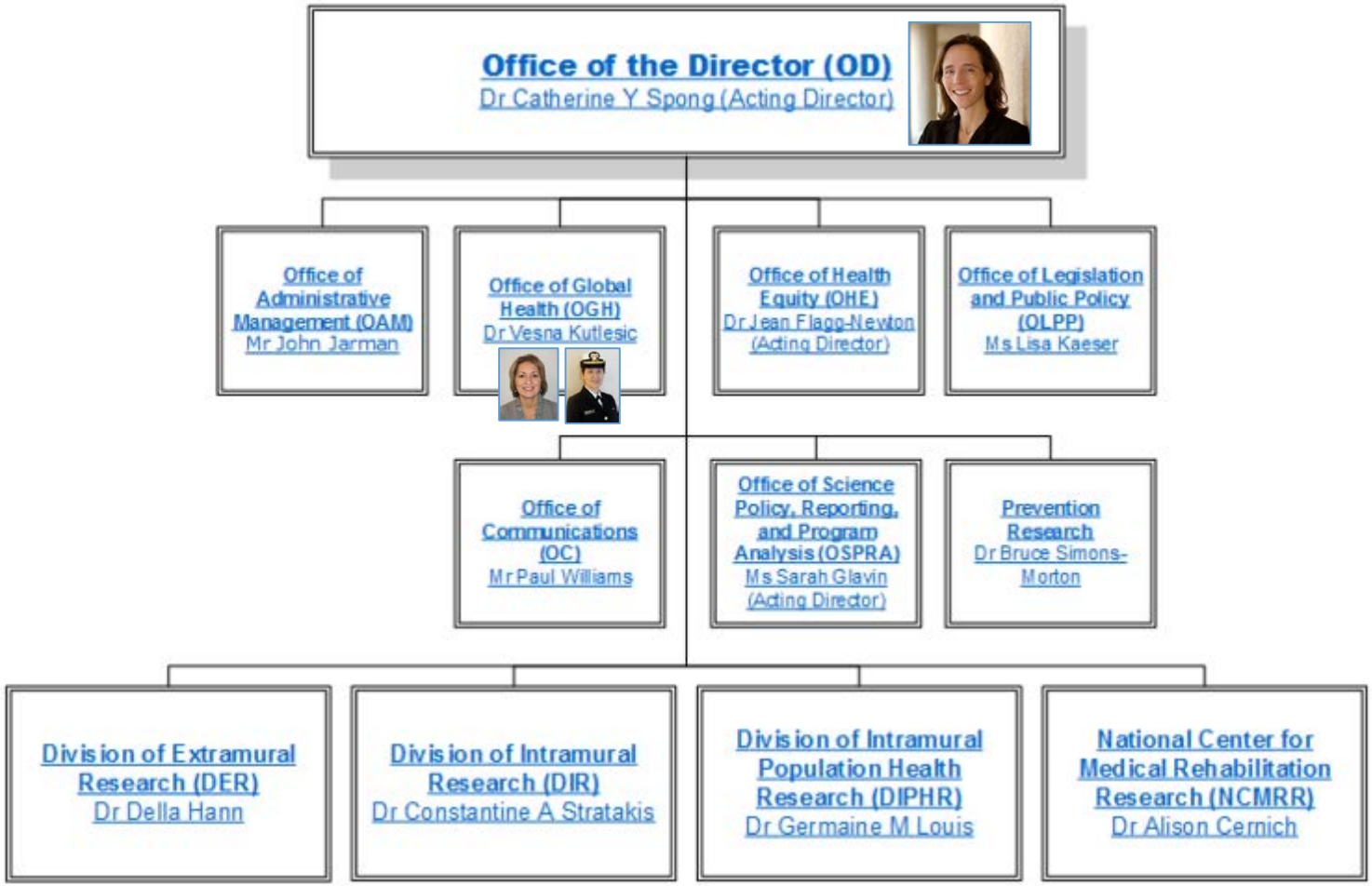
Fogarty Research Portfolio Expenditures (FY 2014)

Includes leveraged expenditures



Source: FIC Budget Office; QVR

NICHD Organizational Chart



Sample of Recent NICHD Science Advances from our NICHD Divisions/Centers

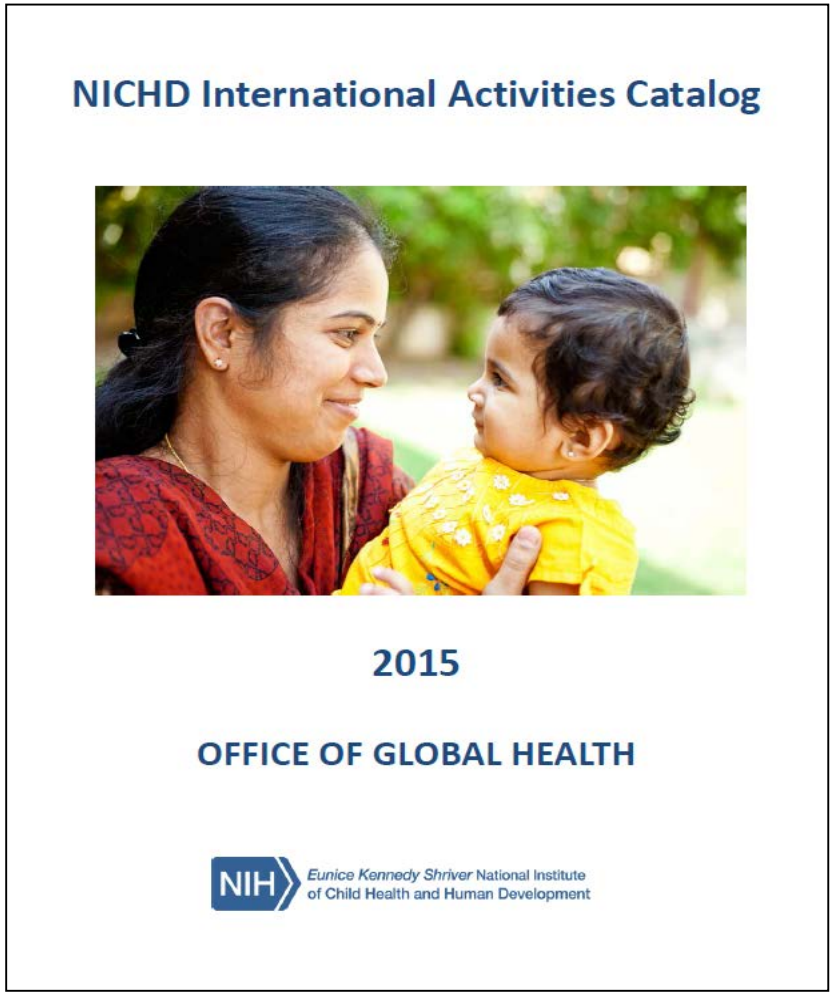
- DIR: South Africa: Combating the evolution of antibiotic resistance in Mycobacterium tuberculosis.
- DER: India: Men engaged in family planning in rural India led to improved contraceptive practices and reduced sexual intimate partner violence.
- DIPHR: Denmark: Determinants and health implications of diabetes in pregnancy on women and their children.
- NCMRR: Foreign Co-PI: Transcranial Direct Current Stimulation in Chronic Spinal Cord Injury

NICHD Office of Global Health

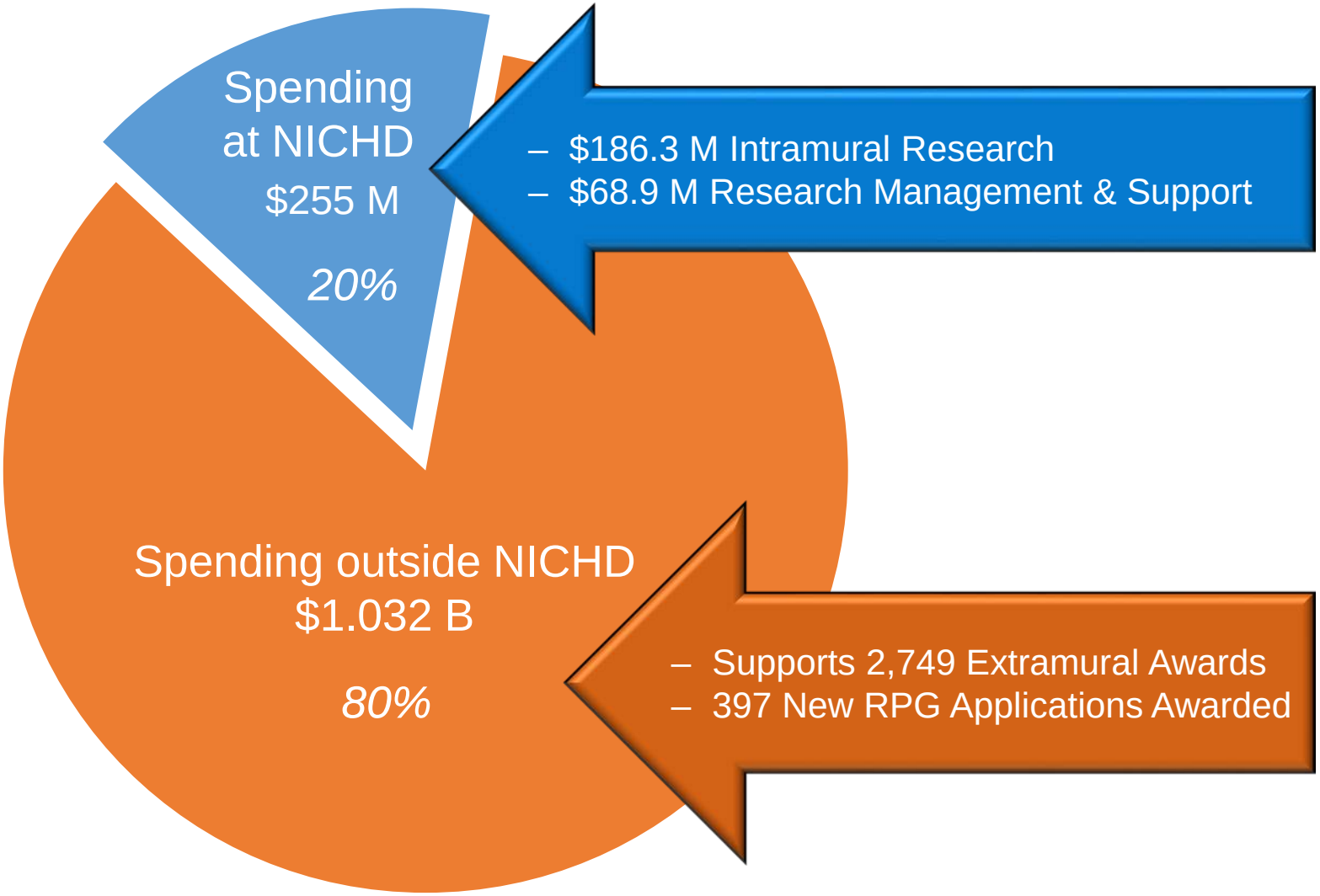
- Providing leadership in the development of cross-cutting policies, plans, and programs related to NICHD's global health research
- Building and maintaining global health partnerships and collaborations
- Assisting the Institute's components in enhancing their international research portfolios and other global health activities

2015 NICHD International Activities Catalog

Available online at:
https://www.nichd.nih.gov/about/org/od/ogh/Documents/NICHD_Intl_Activities_2015.pdf



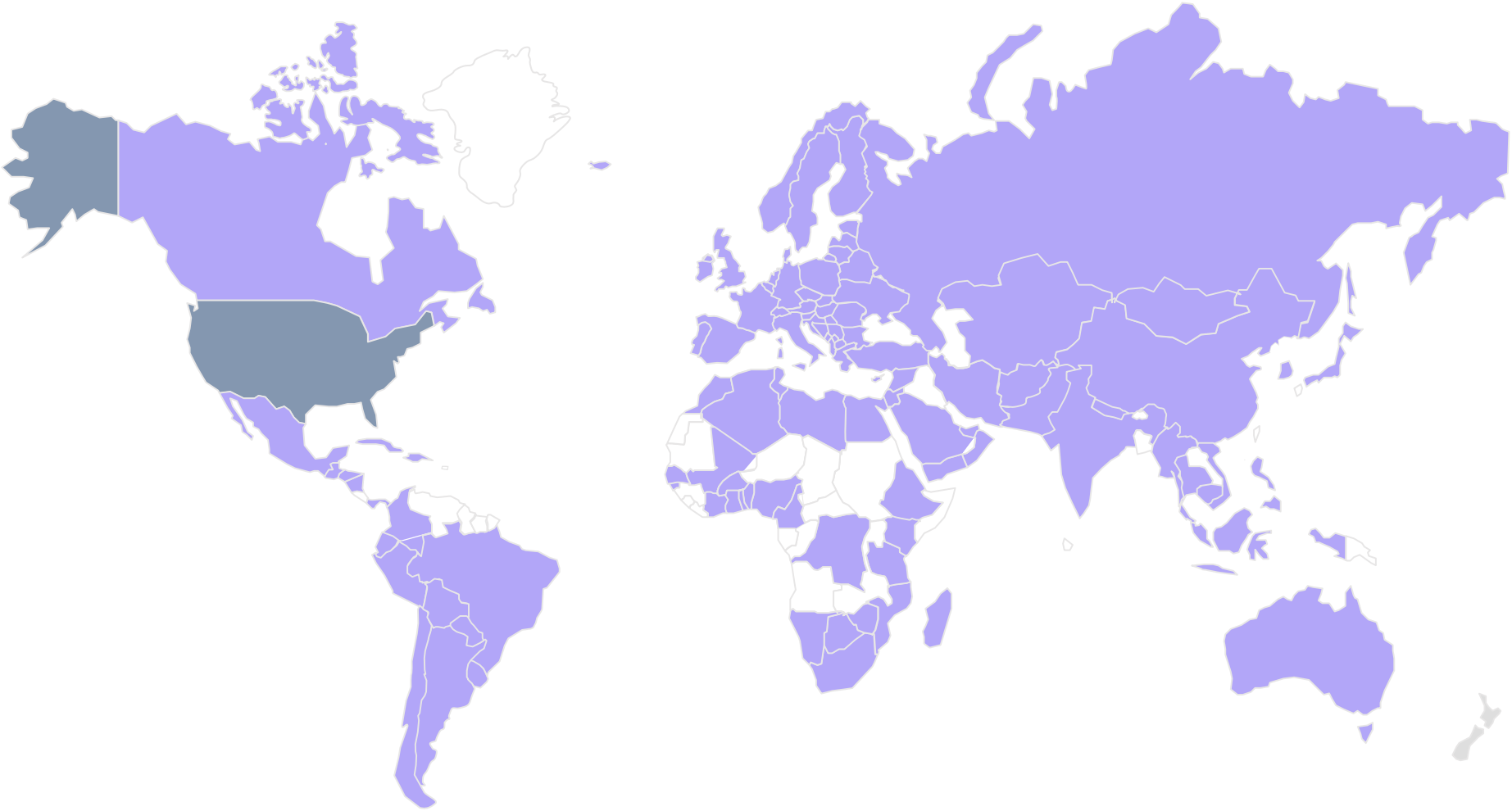
FY 2015 NICHD Funding: $1.29 Billion



NICHD's Total Expenditure for Global Health Related Activities for Fiscal Year 2015…

- Total International Funding: $115,086,116
- 286 funded grants and projects related to global health research
- 138 countries (including unincorporated territories e.g., Hong Kong, Puerto Rico, etc.)

138 Countries with Global Health Related Activities for Fiscal Year 2015



Major Areas of Science Funded and Mechanisms for GH Related Awards in 2015

Health/Science Areas

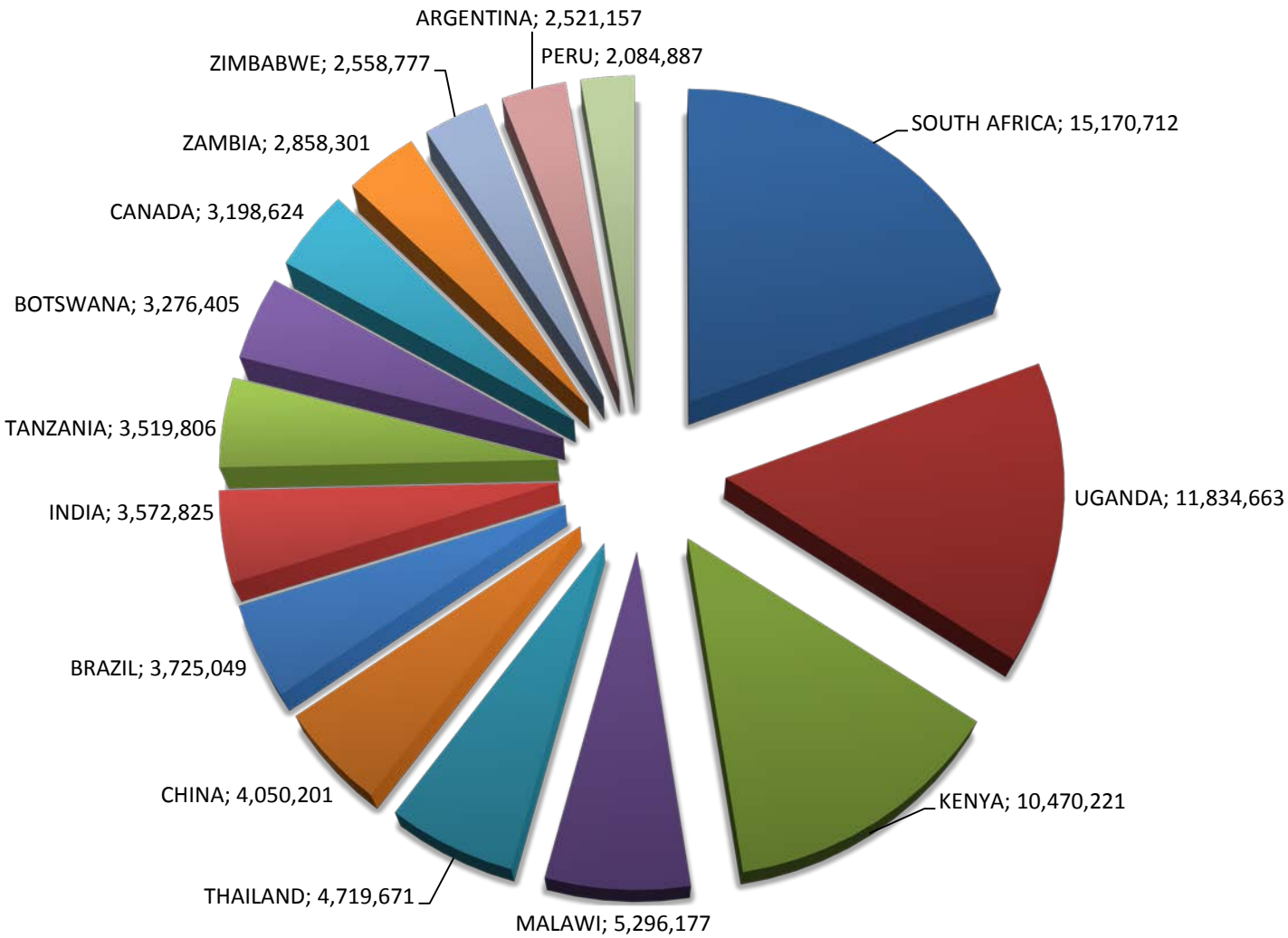
- Maternal, neonatal, and child morbidity and mortality
- Healthy pregnancy, reproductive health, family planning
- HIV/AIDS (including prevention), mother to child transmission
- Infections, malaria, tuberculosis, hepatitis B
- Gastrointestinal diseases, diarrhea in children
- Food insecurity, nutrition, breastfeeding
- Training Activities (e.g., researchers, physicians, nurses, health interventions, research administration…etc.)

Distribution of NICHD GH Awards for 2015

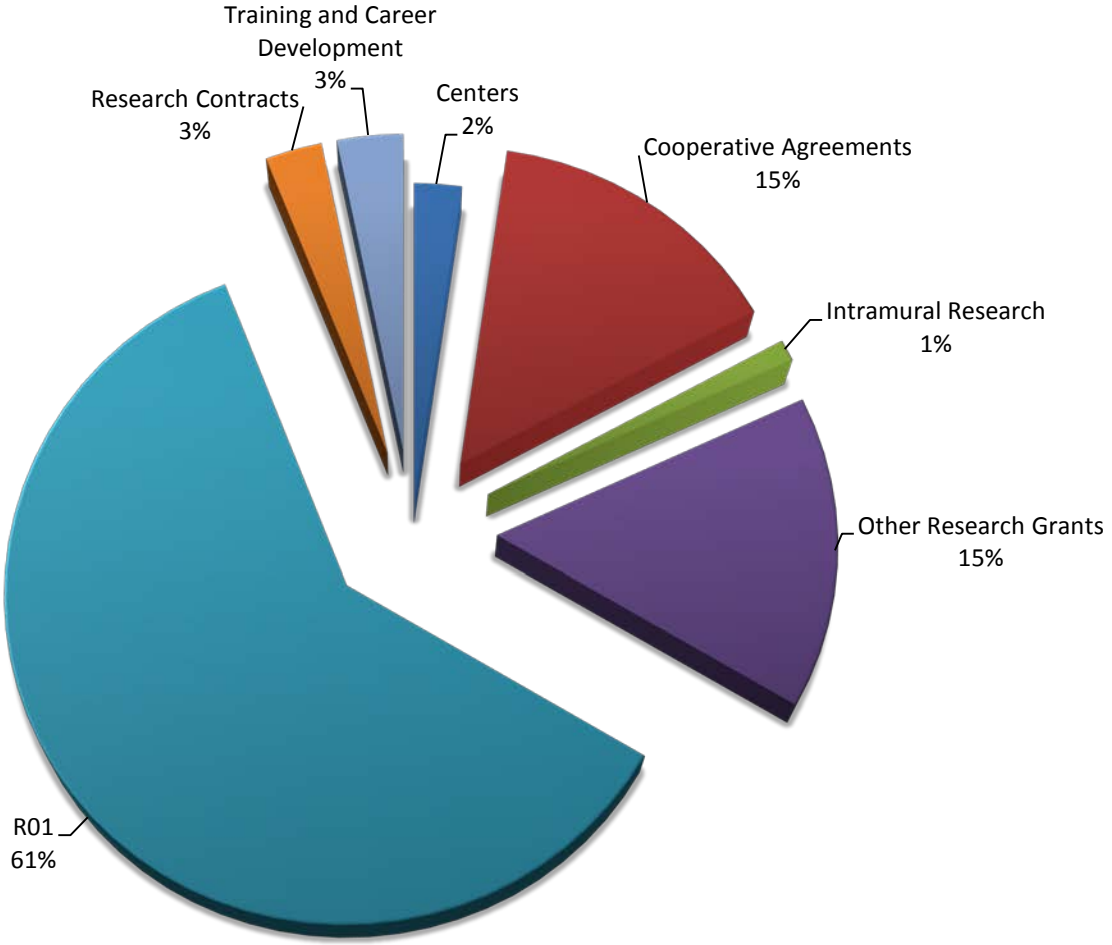
Region	$ Total for all Activities	Percent Total NICHD of GH Activities
Africa	$62,941,196	54.7%
Americas	$19,759,982	17.2%
Eastern Mediterranean	$2,319,237	2.0%
Europe	$9,885,054	8.6%
South-East Asia	$12,157,493	10.6%
Western Pacific	$7,806,628	6.8%
Countries without regions or Unincorporated Territories (e.g. Hong Kong, Puerto Rico...etc.)	$215,886	0.2%

- Total International Funding: $115,086,116

Top 15 Countries That Received NICHD Funding for Fiscal Year 2015



Mechanisms for Global Health Awards in 2015



OGH: Global Health Activities

- **Participation in Interagency and Trans-NIH Global Health Initiatives** (e.g., NIH-BMGF Collaborations; IOM Investing in Young Children Globally Forum; USAID Children in Adversity Initiative)
- **Organizing and Co-sponsoring NIH Global Health Consultations** (e.g., NICHD Global Health Meeting, NICHD Global Injury Meeting, Fogarty Brain Disorders Meeting)
- **Coordination of Visits by Foreign Delegations** (e.g., Cuban Minister of Public Health; Health Minister from Rwanda, Chinese National Science Foundation, Indian Department of Biotechnology)
- **Planning of International Site Visits by Senior NICHD, NIH, DHHS, and Congressional Leadership** (e.g., China, Korea, South Africa, and Tanzania)
- **Dissemination of NICHD Global Health Research Evidence** (e.g., UN, WHO, HHS Global Health Maternal and Child Health policy documents)

New Phase of Cooperation Between NIH and the Bill and Melinda Gates Foundation

The NIH and BMGF have established milestone-driven collaborations in 8 areas:

- Maternal and newborn health
- Contraceptive research
- Child health and development
- Pediatric pneumonia and indoor air pollution
- HIV/AIDS
- Malaria
- Tuberculosis
- HPV/Cervical Cancers

IOM Forum: “Investing in Young Children”

- IOM launched this Forum with over 40 public and private partnering agencies.
- Goal to identify innovative international research and translate this evidence into policies and practices in health, nutrition, education, and social protection for children and their families in resource-limited settings.
- NICHD serves on the Executive Committee and the Mental Health and Development Delays and Disabilities Working Group, and several planning committees for regional meetings.

US Ebola Response and Research Agenda

- LCDR Margaret Brewinski Isaacs, MD, MPH, provided clinical care to health care workers affected by the Ebola virus in Liberia and conducted trainings on infection control in Sierra Leone.
- Presented at the American College of Preventive Medicine and the Howard County (Maryland) Emerging Infectious Diseases Symposium.
- Spoke on MCH Ebola considerations at NIH-hosted, USG Ebola Research Meeting.

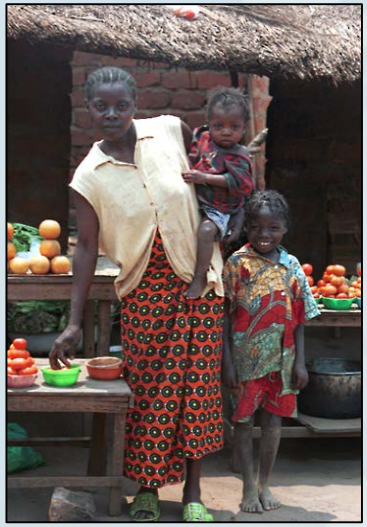
USG “Children in Adversity” Initiative

- OGH representatives serve on the technical working group in line with Public Law 109-95: Assistance for Orphans and Other Vulnerable Children in Developing Countries Act
- A description of this initiative aimed at developing a research agenda and whole-of-government strategy for work with children in adversity in LMICs was published in the *Lancet* and a special issue in *Child Abuse and Neglect*.
- A strategy document was developed, the “Action Plan on Children in Adversity” and launched at the White House.

NICHD Global Health Consultation Meeting

NICHD Global Health Consultation on Child Neurodevelopment, Nutrition, and Inflammation

- Children born into poverty are at heightened risk of poor health and developmental outcomes - need for bridging of the child survival and child development fields
- Meeting included 80 researchers and representatives from multiple NIH ICs, BMGF, OGA, CDC, USAID, WHO, World Bank, Sackler Institute, Grand Challenges Canada.
- *Pediatrics* journal supplement in fall 2016 on cross-cutting assessment issues and key developmental periods. Will explore new research opportunities with partnering agencies.



NICHD Supported Global Health Research

NIH Zika Cohort Study

- Multi-site, multi-country prospective observational cohort study
- Objective: to assess the strength of association with Zika infection during pregnancy and adverse maternal/ and full spectrum of fetal outcomes while controlling for potential confounders
- Protocol in development
- Enrollment target: June 2016

PAR-16-106 - Rapid Assessment of Zika Virus (ZIKV) Complications (R21)

- Open March 20, 2016 and expires on March 1, 2019
- Applications accepted on a rolling basis, beginning on April 20, 2016

Provides an expedited (rapid) funding mechanism for research on Zika virus (ZIKV) and its complications given the urgent need to determine whether ZIKV infection causes microcephaly and other congenital abnormalities in babies and the potential rapid spread of ZIKV to the United States.

International Maternal Pediatric Adolescent AIDS Clinical Trials

- Purpose:
  - Reduce mother-to-infant transmission of HIV
  - Evaluate pharmacological treatment for HIV-infected children, adolescents, and pregnant women
  - Evaluate vaccines for the prevention of HIV transmission in adolescents

- Funding in multiple countries including: Botswana, Brazil, India, Malawi, South Africa, Thailand, Tanzania, Uganda, and Zimbabwe

International Epidemiologic Databases to Evaluate AIDS

- Purpose: generate large data sets to address high priority research questions and streamline HIV/AIDS research
  - Collect and define key variables
  - Harmonize data
  - Implement methodology to pool data
- NICHD supports inclusion of patient data on infants, children, adolescents and pregnant women

Global Network for Women and Children's Health Research

- Aims to build research partnerships to conduct research on feasible, cost-effective, sustainable interventions to address the major causes of perinatal morbidity and mortality of women and children in the developing world
- Consists of teams of US mentors at US universities and international teams in the Democratic Republic of the Congo, Guatemala, India (2 sites), Kenya, Pakistan, and Zambia.
- More information: https://gn.rti.org/

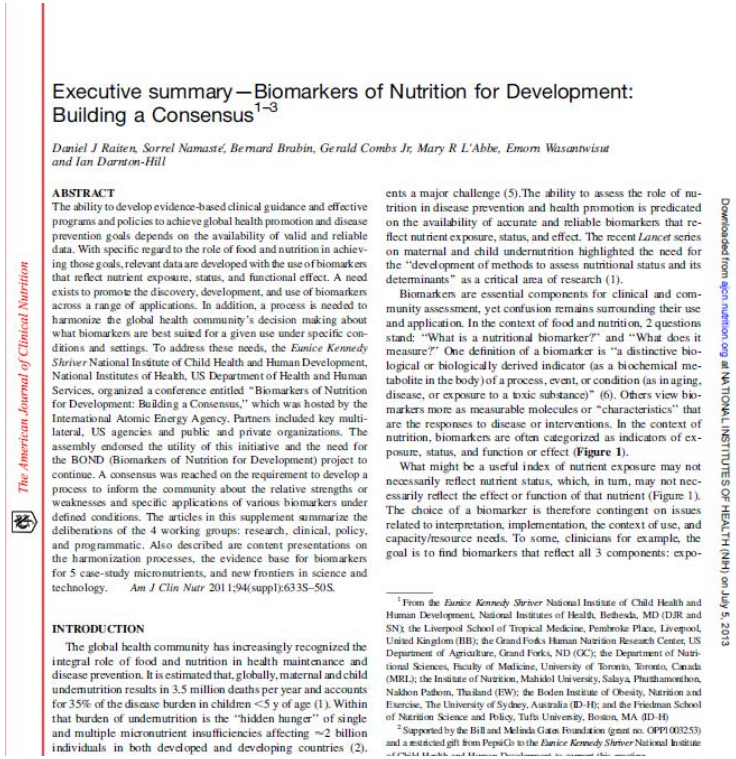
Global Network for Women and Children's Health Research

Sample Topics

- **Registry of all births and deaths in 100 clusters** → population based studies and outcome evaluation
- **FIRST BREATH resuscitation trial**
- **Emergency OB and Neonatal Care trial** (access to care, improve birth preparation and community stabilization, OB and neonatal transport and quality hospital care)
- **Antenatal Steroid Trial** (use FIRST Breath and EmONC as platform to save preterm babies and moms)
- **Complementary feeding trial** in 4 countries to improve linear growth and cognitive outcome

Biomarkers of Nutrition for Development (BOND)

- Collaboration to develop a unified approach to examine the scientific basis for choosing appropriate biomarkers
  - Assess the function and effect of diet and nutrition on health and disease
  - Support the development and evaluation of evidence-based programs and policies to improve diet and nutrition
  - Produce a web-based resource available to the global health community



The American Journal of Clinical Nutrition

Executive summary—Biomarkers of Nutrition for Development: Building a Consensus[1–3]

Daniel J Raiten, Sorrel Namasté, Bernard Brabin, Gerald Combs Jr, Mary R L'Abbe, Emorn Wasantwisut and Ian Darnton-Hill

ABSTRACT

The ability to develop evidence-based clinical guidance and effective programs and policies to achieve global health promotion and disease prevention goals depends on the availability of valid and reliable data. With specific regard to the role of food and nutrition in achieving those goals, relevant data are developed with the use of biomarkers that reflect nutrient exposure, status, and functional effect. A need exists to promote the discovery, development, and use of biomarkers across a range of applications. In addition, a process is needed to harmonize the global health community's decision making about what biomarkers are best suited for a given use under specific conditions and settings. To address these needs, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, US Department of Health and Human Services, organized a conference entitled "Biomarkers of Nutrition for Development: Building a Consensus," which was hosted by the International Atomic Energy Agency. Partners included key multilateral, US agencies and public and private organizations. The assembly endorsed the utility of this initiative and the need for the BOND (Biomarkers of Nutrition for Development) project to continue. A consensus was reached on the requirement to develop a process to inform the community about the relative strengths or weaknesses and specific applications of various biomarkers under defined conditions. The articles in this supplement summarize the deliberations of the 4 working groups: research, clinical, policy, and programmatic. Also described are content presentations on the harmonization processes, the evidence base for biomarkers for 5 case-study micronutrients, and new frontiers in science and technology. *Am J Clin Nutr* 2011;94(suppl):633S–50S.

INTRODUCTION

The global health community has increasingly recognized the integral role of food and nutrition in health maintenance and disease prevention. It is estimated that, globally, maternal and child undernutrition results in 3.5 million deaths per year and accounts for 35% of the disease burden in children <5 y of age (1). Within that burden of undernutrition is the "hidden hunger" of single and multiple micronutrient insufficiencies affecting ≈2 billion individuals in both developed and developing countries (2), ents a major challenge (5). The ability to assess the role of nutrition in disease prevention and health promotion is predicated on the availability of accurate and reliable biomarkers that reflect nutrient exposure, status, and effect. The recent *Lancet* series on maternal and child undernutrition highlighted the need for the "development of methods to assess nutritional status and its determinants" as a critical area of research (1).

Biomarkers are essential components for clinical and community assessment, yet confusion remains surrounding their use and application. In the context of food and nutrition, 2 questions stand: "What is a nutritional biomarker?" and "What does it measure?" One definition of a biomarker is "a distinctive biological or biologically derived indicator (as a biochemical metabolite in the body) of a process, event, or condition (as in aging, disease, or exposure to a toxic substance)" (6). Others view biomarkers more as measurable molecules or "characteristics" that are the responses to disease or interventions. In the context of nutrition, biomarkers are often categorized as indicators of exposure, status, and function or effect (**Figure 1**).

What might be a useful index of nutrient exposure may not necessarily reflect nutrient status, which, in turn, may not necessarily reflect the effect or function of that nutrient (Figure 1). The choice of a biomarker is therefore contingent on issues related to interpretation, implementation, the context of use, and capacity/resource needs. To some, clinicians for example, the goal is to find biomarkers that reflect all 3 components: expo-

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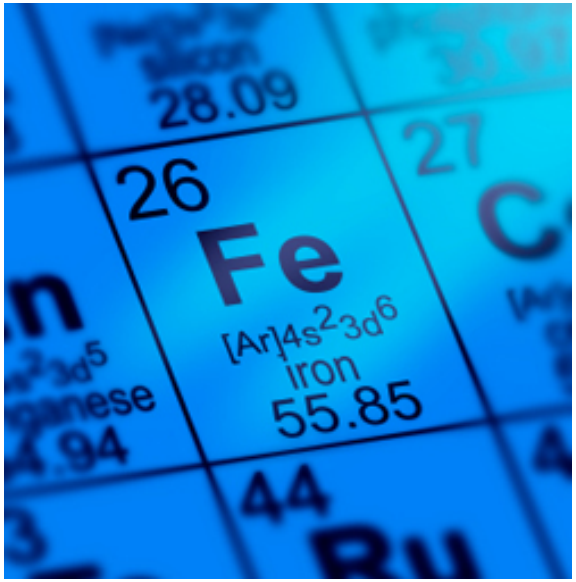
Iron & Malaria Project

- Purpose: establish best practices to prevent and treat iron deficiency in populations where malaria and other infections are endemic
  - Define mechanisms of immune function by which iron may interact with infections
  - Identify biomarkers of exposure, status, and function for prevention and treatment of iron deficiency
  - Determine the safety and effectiveness of iron preparation and iron-related interventions for preventing and treating iron deficiency



Positive Outcomes For Orphans

- **Goal**: provide evidence to communities, policymakers, and funding agencies for optimal and feasible care options for orphans and abandoned children
- Longitudinal research study of children age 6 and above

  Effects of life events, placement, caregiver characteristics, and cultural settings on:
  - Behavior and emotional adjustment
  - Learning and development
  - Health outcomes
- Six study sites:

  Kenya, Cambodia, Tanzania, India (2 sites), and Ethiopia

Population Dynamics

- **Social and Behavioral Science Capacity Building**: the Partnership for HIV/AIDS Research in Kenya, Botswana, Uganda, South Africa, Russia, Indonesia, China and Vietnam.

- **The Role of Women's Empowerment**: reproductive health risks and outcomes and in and socio-economic well-being. Studies are being undertaken in India, Bangladesh and various nations in Africa.

- **Fertility and family planning**: included in this portfolio are high risk behaviors that lead to STD's and AIDS.

- **Population growth, migration and environmental change**: all impact family size and both collective and individual health.

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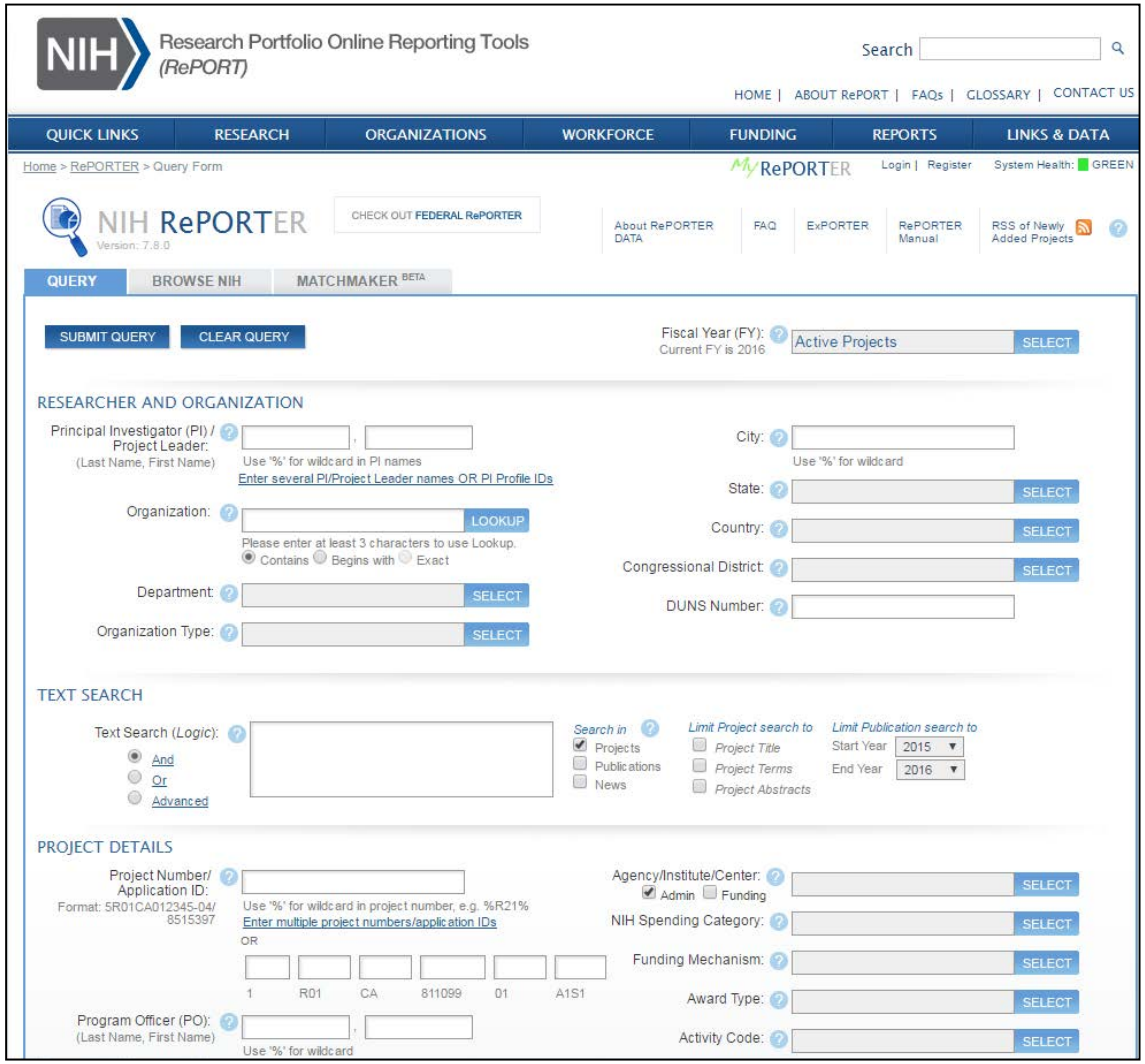

NIH RePORTER – Matchmaker – NEW FEATURE

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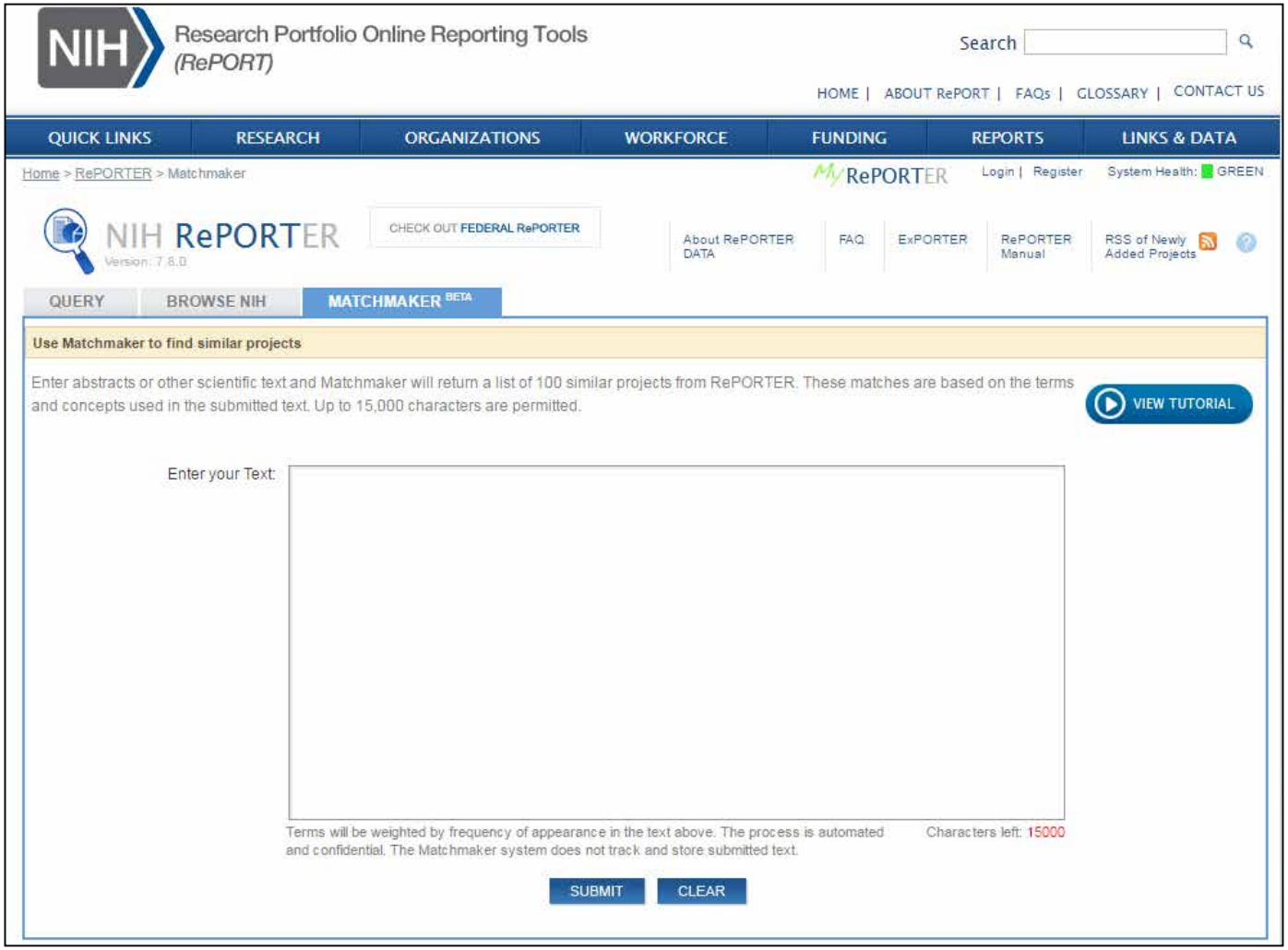

Questions?