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April 23, 2014

The Honorable Jack Kingston
Chairman
Subcommittee on Labor, Health and Human Services,
Education, and Related Agencies
Committee on Appropriations
House of Representatives

National Institutes of Health: Fiscal Year 2013 Research Funding Allocations across Selected Diseases and Conditions

Dear Mr. Chairman:

The National Institutes of Health (NIH) is the nation's leader in sponsoring and conducting biomedical research related to life processes and many diseases and conditions, including those that are among the leading causes of death both in the United States and globally.[1] In fiscal year 2013, NIH, an agency of the Department of Health and Human Services (HHS), had a budget of over $29 billion, most of which was used to fund research that supports scientists and research personnel working at universities, medical schools, and other research institutions and research performed by NIH scientists in NIH laboratories. Given NIH's role in biomedical research and the size of its budget, Congress and researchers have had long-standing interest in how NIH establishes research priorities and how those priorities guide the allocation of its resources, particularly in relation to various diseases and conditions. Accordingly, we issued a report in March 2014 that included information about NIH's fiscal year 2012 research funding related to diseases and health conditions that are the leading causes of death or the most prevalent chronic conditions.[2]

In response to our March 2014 report, you asked us to provide similar information about NIH's fiscal year 2013 research funding related to these same diseases and conditions when it became available. To accomplish this, we reviewed NIH's Research, Condition, and Disease Categorization system (RCDC) funding data for fiscal year 2013[3] for those categories within RCDC that best matched with leading causes of death in the United States, chronic disease prevalence for adults in the United States, and leading causes of death globally.[4] We interviewed and collected information from NIH officials responsible for RCDC to understand the data gathered and reported on, and determined that the data were sufficiently reliable for the

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[1]According to the Centers for Disease Control and Prevention (CDC), leading causes of death in the United States in 2011 include diseases of the heart, malignant neoplasms, chronic lower respiratory diseases, cerebrovascular disease, and accidents. The most prevalent chronic diseases and conditions include obesity, chronic joint symptoms, hypertension, untreated dental caries, and arthritis.

[2]See GAO, *National Institutes of Health: Research Priority Setting, and Funding Allocations across Selected Diseases and Conditions*, GAO-14-246 (Washington, D.C.: Mar. 31, 2014).

[3]Fiscal year 2013 research funding data was made publicly available in March 2014.

[4]During our previous work, we confirmed the matches between RCDC categories and leading diseases and conditions with NIH.

purposes of this review. More detail regarding our process for determining the leading causes of death and the most prevalent chronic conditions, and the corresponding categories from the RCDC system, is contained in Appendix II of our March 2014 report.[5]

We conducted this performance audit in March and April 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

NIH conducts and sponsors biomedical research through its 27 Institutes and centers (ICs), each of which is charged with a specific mission. ICs' missions generally focus on a specific disease, a particular organ, or a stage in life, such as childhood or old age. The ICs support, plan, and manage their own research programs, and the 24 ICs that fund extramural research each make final decisions on which projects to fund or conduct contingent on the available appropriation or funding.[6] We found in our previous report that the five selected ICs we reviewed set research priorities considering several similar factors, such as the IC's mission, available appropriations, scientific needs and opportunities, gaps in funded research, the burden of disease in a population, and public health need, such as an emerging public health threat that needs to be addressed, like influenza.[7]

In response to 2007 legislation directing NIH to establish an electronic system to categorize NIH's research grants and activities, the agency created RCDC.[8] The system uses a computer-based text-mining tool that recognizes words and phrases in project descriptions in order to assign NIH projects to any of the 237 applicable categories of diseases, conditions, and research areas that were developed for reporting to Congress and the public.[9] As we previously reported, according to NIH officials RCDC serves as NIH's primary computerized reporting

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[5]See GAO-14-246.

[6]NIH funds extramural research projects through a range of mechanisms, such as grants and contracts that are awarded to scientists and research personnel working at institutions outside of NIH. For the purposes of this report, we refer to relevant NIH-funded research as "projects" and do not distinguish between the different types of awards.

[7]The five ICs are National Cancer Institute; National Heart, Lung, and Blood Institute; National Institute of Allergy and Infectious Diseases; National Institute of Diabetes and Digestive and Kidney Diseases; and National Institute of General Medical Sciences.

[8]National Institutes of Health Reform Act of 2006, Pub. L. No. 109-482, § 104, 120 Stat. 3675, 3689 (2007) (adding § 403B to the Public Health Service Act, codified at 42 U.S.C. § 282b). The House committee of reference indicated that this language was intended to address a recommendation made in an Institute of Medicine report to standardize data and information management systems by creating a comprehensive electronic reporting system that would catalogue all of the research activities of the NIH in a standardized format. H. Rep. No. 109-687, at 4 – 5 (2006), referring to Institute of Medicine, *Responding to Health Needs and Scientific Opportunity: The Organizational Structure of the National Institutes of Medicine* (Washington, D.C.; Oct. 16, 1984).

[9]The text mining tool is used in conjunction with NIH definitions—a list of terms and concepts selected by NIH experts to define a research category—to match research projects to categories. Projects may fall into one or more categories. There are additional categories that are not reported publicly for issues such as nanotechnology, for a total of approximately 290 categories.

process to categorize its research funding.[10] The system includes reporting tools that can be used to generate publicly-available, web-based reports on total funding amounts for the research projects related to each RCDC category.

As we previously reported, NIH officials also said that the RCDC was not designed to be able to estimate a total, non-duplicated amount of funding specific to a given disease or condition because RCDC categories are neither mutually exclusive nor exhaustive. Specifically, projects may be reported in multiple RCDC categories—on average, a single project may fall into five or six categories; some categories are inherently related, and therefore an entire RCDC category can also be contained within another category; categories do not exist for all diseases; and, according to NIH officials, 3 to 5 percent of NIH-funded research projects do not appear in any RCDC category.

Results

In fiscal year 2013, NIH reported funding levels that continued to range widely—from $11 million for projects in one RCDC category to about $5.3 billion for another—for the different RCDC categories we examined that corresponded to three different measures of burden of disease: the most frequent causes of death in the United States,[11] the most frequent causes of death globally,[12] and the most prevalent chronic conditions for adults in the United States.[13] Tables 1 through 3 below break out RCDC category funding by these three measures. This is consistent with our March 2014 report, in which we reported fiscal year 2012 funding levels that ranged widely across the 40 RCDC categories we examined, from $13 million for projects in one RCDC category to more than $5.6 billion for another.[14]

Fiscal year 2013 funding levels related to leading causes of death in the United States ranged from $24 million in one RCDC category to about $5.3 billion in another for the corresponding RCDC categories. (See table 1.)

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[10]RCDC tracks projects funded by three different types of NIH funding: extramural research grants, research and development contracts, and intramural research conducted in NIH's own laboratories and clinics. Information on funding totals and projects within each category is available on the NIH website. See "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," accessed March 7, 2014 http://www.report.nih.gov/categorical_spending.aspx.

[11]D. L. Hoyert and J. Xu, National Center for Health Statistics, "Deaths: Preliminary Data for 2011," *National Vital Statistics Reports*, vol. 61, no. 6 (Oct. 10, 2012).

[12]R. Lozano et al., "Global and Regional Mortality from 235 Causes of Death for 20 Age Groups in 1990 and 2010: A Systematic Analysis for the Global Burden of Disease Study 2010," *The Lancet*, vol. 380 (2012).

[13]CDC provided data for the most prevalent chronic conditions based on a variety of sources.

[14]See GAO-14-246.

Table 1: Leading Causes of Death in the United States, 2011, and NIH Research, Condition, and Disease Categorization (RCDC) Categories and Fiscal Year 2013 Funding

Rank	Cause of death (Subcategories)[a]	Number of deaths	Corresponding NIH RCDC category	Fiscal year 2013 funding for RCDC category ($ millions)[b]
1	**Diseases of heart**	**596,339**	**Cardiovascular**	**1,964**
	Ischemic heart diseases	374,601	Heart disease – coronary heart disease[c]	404
	Hypertensive heart disease	33,383	Hypertension[c]	222
2	**Malignant neoplasms**	**575,313**	**Cancer**	**5,274**
	Malignant neoplasms of trachea, bronchus and lung	156,614	Lung cancer	208
	Malignant neoplasms of lymphoid, hematopoietic and related tissue	56,263	Lymphoma	233
			Childhood leukemia	67
	Malignant neoplasms of colon, rectum and anus	52,243	Colo-rectal cancer	281
	Malignant neoplasm of breast	41,271	Breast cancer	657
	Malignant neoplasm of pancreas	37,371	Pancreatic cancer	125
	Malignant neoplasm of prostate	27,929	Prostate cancer	286
	Malignant neoplasms of liver and intrahepatic bile ducts	21,519	Liver cancer	71
3	**Chronic lower respiratory diseases**	**143,382**	**Asthma**	**207**
			Emphysema	**24**
			Chronic obstructive pulmonary disease	**102**
4	**Cerebrovascular diseases**	**128,931**	**Stroke**	**282**
5	**Accidents (unintentional injuries)**	**122,777**	**Injury (total) accidents/ adverse effects**	**367**
	Non-transport accidents	85,502	No RCDC match	—
	Transport accidents	37,275	No RCDC match	—
6	**Alzheimer's disease**	**84,691**	**Alzheimer's disease**	**504**
7	**Diabetes mellitus**	**73,282**	**Diabetes**	**1,007**
8	**Pneumonia and influenza**	**53,667**	**Pneumonia and influenza**	**407**
	Pneumonia	52,136	Pneumonia	113
9	**Nephritis, nephrotic syndrome and nephrosis**	**45,731**	**Kidney disease**	**551**
	Renal failure	43,682	Kidney disease	551
10	**Intentional self-harm (suicide)**	**38,285**	**Suicide**	**37**
	Intentional self-harm (suicide) by discharge of firearms	19,766	No RCDC match	—
	Intentional self-harm (suicide) by other and unspecified means and their sequelae	18,519	No RCDC match	—
11	**Septicemia**	**35,539**	**Septicemia**	**88**
12	**Chronic liver disease and cirrhosis**	**33,539**	**Chronic liver disease and cirrhosis**	**282**

Rank	Cause of death (Subcategories)[a]	Number of deaths	Corresponding NIH RCDC category	Fiscal year 2013 funding for RCDC category ($ millions)[b]
13	Essential hypertension and hypertensive renal disease	27,477	Hypertension	222
14	Parkinson's disease	23,107	Parkinson's disease	135
15	Pneumonitis due to solids and liquids	18,090	No RCDC match	—

Source: GAO analysis of data from the Centers for Disease Control and Prevention (CDC) and NIH.

Notes: See D.L. Hoyert and J. Xu, National Center for Health Statistics, "Deaths: Preliminary Data for 2011," *National Vital Statistics Reports*, vol. 61, no. 6. (Oct. 10, 2012).

[a]We identified the 15 leading causes of death in 2011 reported by CDC in its *National Vital Statistics Reports*. Then, we identified subcategories of those leading causes of death. To do so, we used as the cut off the number of deaths for the 15th leading cause of death—which was 18.090 deaths from pneumonitis due to solids and liquids. We included those subcategories of causes of death, for example pneumonia, where the number of deaths reported was greater than 18,090.

[b]RCDC categories are not mutually exclusive. Because of this, NIH officials stated, RCDC is not designed to be used to determine the proportion of NIH funding specific to a given disease or condition.

[c]NIH noted that while this RCDC category was the closest match, it is substantially broader than the disease or condition it was selected to represent.

Fiscal year 2013 funding levels related to leading causes of death globally ranged from $24 million in one RCDC category to about $2.9 billion in another for the corresponding RCDC categories. (See table 2.)

Table 2: Leading Causes of Deaths, Globally, 2010, and NIH Research, Condition, and Disease Categorization (RCDC) Categories and Fiscal Year 2013 Funding

Rank	Cause of death	Corresponding NIH RCDC category	Fiscal year 2013 funding for RCDC category ($ millions)[a]
1	Ischemic heart disease	Heart disease – coronary heart disease[b]	404
2	Stroke	Stroke	282
3	Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	102
		Emphysema	24
4	Lower respiratory infections	Pneumonia	113
		Influenza[c]	304
5	Lung cancer	Lung cancer	208
6	HIV/AIDS	HIV/AIDS	2,898
7	Diarrheal diseases	No RCDC match	—
8	Road injury	No RCDC match	—
9	Diabetes	Diabetes	1,007
10	Tuberculosis	Tuberculosis	240
11	Malaria	Malaria	147
12	Cirrhosis	Chronic liver disease and cirrhosis	282
13	Self-harm	Suicide[c]	37
14	Hypertensive heart disease	Hypertension[b]	222
15	Preterm birth complications	Infant mortality/(Low birth weight)	253
		Perinatal period – conditions originating in perinatal period	486

Source: GAO analysis of Global Burden of Disease Study 2010 data and NIH data.

Notes: R. Lozano et al., "Global and Regional Mortality from 235 Causes of Death for 20 Age Groups in 1990 and 2010: A Systematic Analysis for the Global Burden of Disease Study 2010", *The Lancet*, vol. 380 (2012).

[a]RCDC categories are not mutually exclusive. Because of this, NIH officials stated, RCDC is not designed to be used to determine the proportion of NIH funding specific to a given disease or condition.

[b]NIH noted that while this RCDC category was the closest match, it is substantially broader than the disease or condition it was selected to represent.

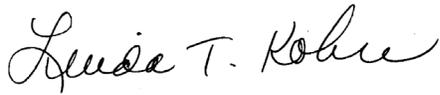[c]NIH noted that while this RCDC category was the closest match, it is substantially narrower than the disease or condition it was selected to represent.

Fiscal year 2013 funding levels related to the most prevalent chronic diseases for adults in the United States ranged from $11 million in one RCDC category to about $5.3 billion in another for the corresponding RCDC categories. (See table 3.)

Table 3: Chronic Disease Prevalence for Adults, United States, and NIH Research, Condition, and Disease Categorization (RCDC) Categories and Fiscal Year 2013 Funding

Rank	Chronic diseases and conditions (Subcategories)[a]	Number of adults impacted (in 1,000s)	Corresponding NIH RCDC category	Fiscal year 2013 funding for RCDC category ($ millions)[b]
1	**Obesity**	**Not reported**[c]	**Obesity**	**812**
2	**Chronic joint symptoms**	**68,749**	**No RCDC match**	**—**
3	**Hypertension**	**58,959**	**Hypertension**	**222**
4	**Untreated dental caries**	**Not reported**[c]	**Dental/oral and craniofacial disease**[d]	**480**
5	**Arthritis diagnosis**	**53,782**	**Arthritis**	**231**
			Lupus	**92**
			Fibromyalgia	**11**
6	**Asthma - ever had**	**29,041**	**Asthma**	**207**
7	**Heart disease (Total)**	**26,485**	**Heart disease**	**1,230**
	Heart disease (coronary)	15,300	Heart disease – coronary heart disease	404
8	**Diabetes**	**20,589**	**Diabetes**	**1,007**
9	**Any Cancer**	**19,025**	**Cancer**	**5,274**
	Breast cancer	3,221	Breast cancer	657
	Prostate cancer	2,280	Prostate cancer	286
	Cervical cancer	1,188	Cervical cancer	98
10	**Asthma - still has**	**18,869**	**Asthma**	**207**
11	**Stroke (cerebrovascular diseases)**	**6,171**	**Stroke**	**282**
12	**Emphysema**	**4,680**	**Emphysema**	**24**
13	**Epilepsy**	**2,300**	**Epilepsy**	**129**

Source: Centers for Disease Control and Prevention (CDC) and GAO analysis of NIH data.

Notes: CDC provided data for the most prevalent chronic conditions based on a variety of sources.

[a]CDC provided us with a list of the 13 most prevalent chronic diseases and conditions, and four subcategories.

[b]RCDC categories are not mutually exclusive. Because of this, NIH officials stated, RCDC is not designed to be used to determine the proportion of NIH funding specific to a given disease or condition.

[c]Only the prevalence rank was provided for this chronic condition. CDC provides links to data and statistics on multiple health topics, including obesity and oral health at www.cdc.gov/DataStatistics.

[d]NIH noted that while this RCDC category was the closest match, it is substantially broader than the disease or condition it was selected to represent.

Agency Comments

We provided a draft of this report to HHS. The Department provided technical comments, which we incorporated as appropriate.

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As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of the Department of Health and Human Services, the Director of the National Institutes of Health, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report were Karen Doran, Assistant Director; George Bogart; Carolyn Feis Korman; Cathy Hamann; Natalie Herzog; and Amy Leone.

Sincerely yours,

Linda T. Kohn
Director, Health Care

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