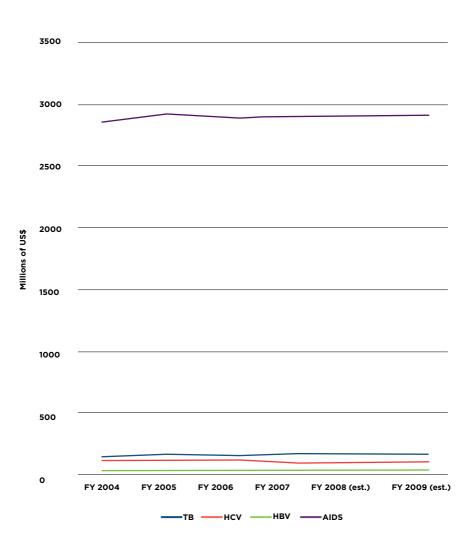


Flat-Lined: How Flat NIH Funding Undermines Research on HIV, Tuberculosis, and Viral Hepatitis

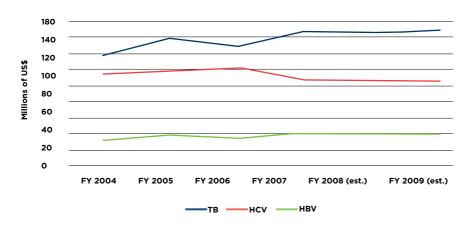
MAY 2009 BY LYDIA H. GUTERMAN **EDITED BY MARK HARRINGTON**

NIH Research Investment for HIV/AIDS and Common Coinfections During Flat Funding, 2004–2009



Note: Data in constant dollars; losses in purchasing power due to inflation not captured.

Zoom View: NIH Research Investment for TB, HCV, and HBV during Flat Funding, 2004-2009

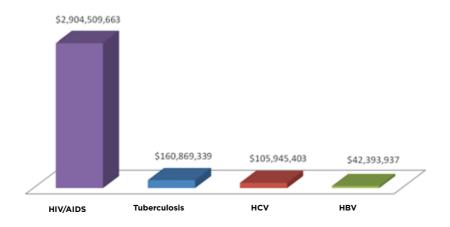


Source: http://report.nih.gov/rcdc/categories

Note: Data in constant dollars; losses in purchasing power due to inflation not captured.

FIGURE 3

Total NIH Research Investment by Disease, 2007



"TAG recommends that the Obama administration commit to at least five years of 15% annual increases in the NIH budget (for fiscal years 2010–2014) in order to regain the momentum that was achieved between 1998 and 2003 when the NIH budget was doubled. This increase will allow for full funding of the NIH Office of AIDS Research's bypass budget, which includes recommended levels for AIDS research funding that will allow new investigators to enter the field while dramatically scaling up the nation's investment in HIV prevention, treatment, and cure research.

TAG recommends that commensurate with the overall NIH increases of 15% annually for at least five years, that research investments in HIV, TB, and viral hepatitis all grow by at least 15% per year."

— "TAG Recommendations to President Obama on AIDS Research and Treatment Policy," 20 January 2009, www.treatmentactiongroup.org/publication. aspx?id=2774.

"Medical miracles do not happen simply by accident. They result from painstaking and costly research—from years of lonely trial and error, much of which never bears fruit—and from a government willing to support that work. From life-saving vaccines, to pioneering cancer treatments, to the sequencing of the human genome—that is the story of scientific progress in America. When government fails to make these investments, opportunities are missed. Promising avenues go unexplored. Some of our best scientists leave for other countries that will sponsor their work. And those countries may surge ahead of ours in the advances that transform our lives.

— President Barack Obama, "Remarks as Prepared for Delivery, Signing of Stem Cell Executive Order and Scientific Integrity," Presidential Memorandum, Washington, D.C., 9 March 2009, http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum.

Table of Contents

E	kecutive :	Summary	•		
	Reco	ommendations	2		
1	Introdu	ction	3		
	1.1	Background	3		
	1.2	U.S. National Institutes of Health Organizational Structure	4		
	1.3	Objectives	4		
	1.4	Methodology	5		
	1.5	Scope and Limitations of the Data	6		
2	Results		7		
_	2.1	Double Counting	7		
	2.2	Research Investment Categories			
	2.3	Hepatitis B Virus (HBV)	10		
	2.4	Hepatitis C Virus (HCV)	13		
	2.5	Tuberculosis (TB)	15		
	2.6	HIV/AIDS	19		
	2.0	111771120			
3	Conclus	sions	25		
4	4 Appendix: List of NIH Grant-Making Institutes and Centers				
5	Referen	ices	27		

Executive Summary

The goal of this funding analysis is to provide a comprehensive picture of the current state of U.S. National Institutes of Health (NIH) research investment in HIV/AIDS and three of its most common coinfections—hepatitis B virus (HBV), hepatitis C virus (HCV), and tuberculosis (TB)—after five years of flat funding at the NIH (2004–2009). For HIV/AIDS research, the NIH Office of AIDS Research (OAR) provided TAG with consistently coded, cross-institute, NIH-wide data, but for HBV, HCV, and TB there is no central, consistent, dollar-denominated, and publicly available reporting mechanism for disease-specific, cross-institute NIH investment. Thus, the 2007 portfolios of hepatitis B, hepatitis C, and tuberculosis research were pieced together from data provided by each of the relevant NIH institutes and centers (ICs).

During the current period of flat funding (2004-2009), slight, nominal annual increases to the NIH budget have been outpaced by rising biomedical inflation, as measured by the biomedical research and development price index (http://officeofbudget.od.nih.gov/UI/GDP_FromGenBudget.htm; see figure 4, "Inflation Eroded Gains in NIH Funding," on page 3). While nominal NIH funding rose from \$27 to \$29 billion between fiscal year (FY) 2003 and the FY 2009 president's budget request, funding adjusted for biomedical inflation has decreased (in constant dollars) by 13.4% since 2003. In constant 2003 dollars, then, the 2009 NIH budget is just about \$23 billion, or \$4 billion less in 2003 dollars than actual funding in 2003 itself (Fauci 2008).

NIH investment in HBV, HCV, and TB research remains inexplicably low in light of the rapidly increasing global burdens of each of these diseases as epidemics in their own right and as the most common serious HIV-associated coinfections worldwide. Domestically, HBV, HCV, and hepatitis/HIV coinfection contribute a particularly high burden of disease.

In FY 2007, NIH spent approximately 10% of its budget on HIV/AIDS but only 1.1% on HBV, HCV, and TB combined. More than half (52%) of all programs for HIV/AIDS and these three diseases were administered by the National Institute of Allergy and Infectious Diseases (NIAID).

Under flat funding, new initiatives and expansions of research on HIV/AIDS and the three most common coinfections cannot go forward. As the real value of the NIH budget contracts, it is likely that more conservative research proposals by experienced NIH researchers will trump higher-risk (and potentially higher-reward) proposals submitted by early-career researchers. This discourages innovation and has likely already led to missed opportunities for the funding of novel approaches in the prevention and treatment of HIV/AIDS and its common coinfections.

The "Stimulus Bill," aka the American Recovery and Reinvestment Act of 2009 (ARRA), will not, by itself, resolve the problem of longer-term flat funding of the NIH.

- o At first glance, the \$10.4 billion allocated by Congress to the NIH for FY 2009 and FY 2010 in the ARRA, signed by President Obama on February 17, 2009, appears to offer a long-sought remedy to the many years of flat funding that this report discusses. However, upon looking into the details of the act, and after discussions with senior NIH leadership, it is clear that while there will be short-term opportunities under the Act,
- the ARRA was not intended to raise the baseline funding level of the NIH
- · spending from the stimulus will have to be completed by September 2011
- most spending will be determined by individual NIH institute directors (and not by the OAR) based on "recently peer reviewed, highly meritorious R01 applications from scientists across the country," and "new R01 applications... that have a reasonable expectation of making progress in two years." (NIH 2009b)
- o Thus, it remains critical to focus on increasing the baseline NIH funding levels proposed in the president's FY 2009 and FY 2010 budget, expected to be submitted to Congress in April 2009, and in following years, by at least 15% per year for five years, or by at least 10% per year for ten years, over the rate of biomedical inflation.

Recommendations

- 1. To counteract the past five years of flat funding and lost purchasing power and to set the NIH budget back on track, TAG recommends that the overall NIH budget increase by 15% per year for at least five years, starting in 2010.
- 2. Faced with the increasing global burden of HBV, HCV, and TB, the NIH must significantly increase its investment on research in these three diseases.
- TAG has previously recommended (Feuer 2006, 2008") that funding for TB research should increase fourfold to achieve the targets set out in the Global Plan to Stop TB: 2006–2015.
- TAG further recommends that the NIH increase its annual investment in research on hepatitis B virus (HBV) infection fourfold.
- TAG further recommends that the NIH increase its annual investment in research on hepatitis C virus (HCV) infection fourfold.
- 3. To avoid double counting of the same research dollars for multiple diseases, reporting of disease-specific research investment across NIH institutes requires better coordination. NIH-wide, disease-specific awards listings should be available through a centralized reporting mechanism freely available online.

National Institutes of Health. NIH's Role in the American Recovery and Reinvestment Act (ARRA). www.nih.gov/about/ director/02252009statement_arra.htm. (25 February 2009). Accessed 25 February 2009.

ii. Feuer C. Tuberculosis Research and Development: A Critical Analysis. Edited by Javid Syed and Mark Harrington with Bob Huff. Treatment Action Group. New York, October 2006. www.treatmentactiongroup.org/assets/0/16/42/196/202/d733085f-4af3-48bc-8c2e-89084347780e.pdf. Accessed 9 March 2009. Feuer C. TB Research and Development: A Critical Analysis of Funding Trends, 2005-2006: An Update. Edited by Mark Harrington, Bob Huff, and Javid Syed. www.treatmentactiongroup.org/publication.aspx?id=2486; www.treatmentactiongroup.org/WorkArea/linkit.aspx?linkidentifier=id<emlD=2492. Accessed 9 March 2009.

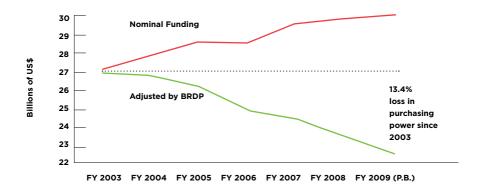
1 Introduction

1.1 Background

For the U.S. National Institutes of Health, the beginning of FY 2009 (1 October 2008) marked the fifth consecutive year of flat funding, with a budget hovering around \$29 billion. The nominal annual increases approved by Congress from 2004 to 2008 have proved insufficient to keep pace with rising biomedical inflation. In the final FY 2009 budget passed by Congress in late February, the NIH budget rose by \$937.5 million to \$30.317 billion—an increase of 3.2%, which, while better than recent years, is still below biomedical inflation and far from meeting TAG's recommended targeted growth of 15% per year. For every year that NIH funding does not increase above the level of biomedical inflation, the NIH budget loses purchasing power and is able to fund less research (Fauci 2008).

FIGURE 4

Inflation Eroded Gains in NIH Funding, Real and Nominal NIH Funding Levels since 2003



Source: A. S. Fauci, "The Research Path to Tuberculosis Control: An NIH Perspective" at the Institute of Medicine Workshop "Addressing the Threat of Drug Resistant TB: A Realistic Assessment of the Challenges," held at The Kaiser Family Foundation's Barbara Jordan Conference Center, Washington, D.C., 2005. (5 November 2008; http://www.iom.edu/?id=59920). Accessed 26 May 2009.

Note: BRDPI = Biomedical Research and Development Price Index

Like the overall NIH budget, disease-specific funding for HIV/AIDS and its most common coinfections has remained basically flat, or has fallen when inflation is considered, during the five years after doubling. Despite the increasing global burden of all four diseases, NIH research investment in these diseases has slipped in real terms, as its purchasing power decreases due to inflation every year.

Flat funding notwithstanding, the NIH remains the global leader in research investment for HIV/AIDS and its most common coinfections. As its purchasing power lags and research budget contracts, the NIH must continue to prioritize the kind of innovative and high-risk research that has yielded major breakthroughs and advances in the past. Now more than at any time since the beginning of the budget doubling in 1998, it is imperative that policy makers, scientists, and activists alike understand how NIH research investment for HIV/AIDS and its most common coinfections is being spent so that disease-specific funding gaps may be identified and targeted advocacy efforts can take shape.

1.2 U.S. National Institutes of Health Organizational Structure¹

The NIH is made up of 27 ICs and the Office of the Director (OD) which coordinates the ICs and houses the OAR, among other offices. The OD and 24 of the 27 ICs fund and administer research awards. For a full listing of NIH ICs, see the appendix.

1.3 Objectives

This report analyzes the 2007 NIH research investment in HIV/AIDS, hepatitis B, hepatitis C, and tuberculosis, and highlights the current underfunding of HIV and its three most common coinfections. The goal of this publication is to promote advocacy for increased funding of these diseases and the overall NIH budget. For each of the four diseases highlighted, this mapping provides an exhaustive analysis of research investment by IC and research category.

^{1.} For a full description of the NIH organizational structure visit http://www.nih.gov/icd/index.html.

^{2.} The 2007 research portfolio was selected for this analysis because 2007 was the most recent year for which full lists of research awards were available.

1.4 Methodology

HIV/AIDS

The OAR provided TAG with a full listing of NIH-funded HIV/AIDS awards for 2007 from the OAR AIDS Research Information System (ARIS) database. The OAR is the coordinating mechanism for HIV/AIDS research investment across the NIH.

HBV, HCV, and TB

Separate Freedom of Information Act (FOIA) requests were submitted to each of the 27 ICs and the OD. For each of the diseases hepatitis B, hepatitis C, and tuberculosis, each IC and the OD was asked to provide complete lists of its 2007 intra- and extramural awards (including disease-specific funding amounts for each award, award number, title, and principal investigator). The individual IC FOIA results were then compiled to create a complete listing of NIH-funded awards for each of the three diseases. Results were cross-checked with the U.S. Department of Health and Human Services Tracking Accountability in Government Grants System (TAGGS) database (http://taggs.hhs.gov), which contains information on many but not all awards and does not include amounts budgeted to the institutes to administer extramural grants, a funding category called research management and support (RMS).

In January 2009, the NIH announced a revised and updated methodology on its "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)" webpage.³ For this report, TAG used the data we received directly from the ICs rather than the revised central NIH figures released in January 2009.

^{3. &}quot;At the request of Congress, the NIH embarked on a process to provide better consistency and transparency in the reporting of its funded research. This new process, implemented through the Research, Condition, and Disease Categorization (RCDC) system, uses sophisticated text data mining (categorizing and clustering using words and multiword phrases) in conjunction with NIH-wide definitions used to match projects to categories. The definitions are a list of terms and concepts selected by NIH scientific experts to define a research category. Due to significant methodology changes, it is likely that annual totals for categories (year over year) will exhibit a noticeable one-time adjustment. The research category levels represent the NIH's best estimates based on the category definitions.

The NIH does not expressly budget by category. The annual estimates reflect amounts that change as a result of science, actual research projects funded, and the NIH budget. The research categories are not mutually exclusive. Individual research projects can be included in multiple categories so amounts depicted within each column of this table do not add up to 100 percent of NIH-funded research.

The FY 2005 and FY 2006 data were produced from a reporting process historically used by NIH. The technical elements of the previous reporting process did not have the ability to produce uniform results and led to wide variability in the way research categories were coded. This process caused inconsistencies in reporting data. RCDC's use of data mining improves the consistency and eliminates the wide variability in defining the research categories reported." NIH 2009a. Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC). http://report.nih.gov/rcdc/categories (15 January 2009). Accessed 21 January 2009.

Here is a table displaying variations in the FY 2007 data reported to TAG by the ICs versus the historical and revised NIH methods via the RCDC:

TABLE 1

	NIH Revised Method	NIH Historical (dollars in millions)	ICs reporting to TAG
HBV	\$ 42	\$ 53	\$ 42
HCV	\$ 108	\$ 100	\$ 106
TB	\$ 166	\$ 188	\$ 161
HIV/AIDS	\$ 2,906	\$ 2,906	\$ 2,905

Source for revised and historical methods: http://report.nih.gov/rcdc/categories

1.5 Scope and Limitations of the Data

There was a 100% response rate for all submitted FOIA requests. The OAR provided a full listing of HIV awards. Thus, the data included in this report provide a complete picture of 2007 NIH research investment in HIV/AIDS, hepatitis B, hepatitis C, and tuberculosis. As such, the figures in this report detailing total disease-specific research investment and disease-specific research investment by IC should be interpreted as absolute findings.

In contrast, figures detailing disease-specific funding amounts by research category should be interpreted as general trends and not as exact figures, as there is variation and inconsistency in how and by whom the award portfolios were coded. All HIV/AIDS awards and all awards administered by NIAID, the largest funder of research in all four diseases highlighted in this report, were coded internally by NIH staff before being released to TAG. The OAR used a seven-code schema and NIAID a four-code schema. On the other hand, all hepatitis B, hepatitis C, and tuberculosis awards from non-NIAID ICs were coded by TAG using a five-code schema. The exact variations between schemas are detailed in section 2.2, "Research Investment Categories." The lack of intercoder reliability and a consistent set of codes by which all awards were sorted mean that the analysis of investment by research category is instructive only in revealing general trends.

2 Findings

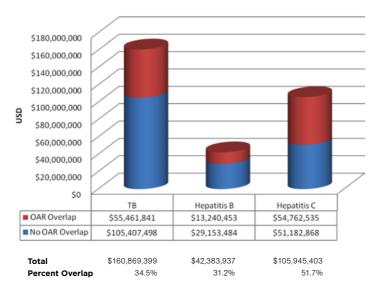
2.1 Double Counting

Due to the lack of a coordinated NIH-wide reporting mechanism, it is likely that many awards reported by ICs as HBV-, HCV-, or TB-specific were also reported by the OAR as HIV/AIDS-specific. The double (and sometimes triple) reporting of the same award/funding under different disease categories, if not adjusted, has the potential to result in apparent exaggeration of the reported real dollar amounts spent on researching the four diseases. To account for this overlap and to identify how much of the HBV, HCV, and TB funding reported by ICs as disease-specific was also counted by the OAR as HIV/AIDS funding, each HBV, HCV, and TB award was checked against the OAR awards and against each other. All awards counted multiple times were cross-checked with the relevant institute.

Overall, just under 40% (\$123,464,829) of the total amount reported by ICs as either HBV-, HCV-, or TB-specific investment was double counted by the OAR as HIV/AIDS-specific investment.

FIGURE 5

Double Counting of Funding by Disease, 2007



Thirty-four percent of total TB research investment dollars, 31% of total HBV research investment dollars, and 52% of total HCV research investment dollars were also reported by OAR as HIV/AIDS research dollars.

2.2 Research Investment Categories

Because the OAR has its own cross-NIH database of research awards, the AIDS Research Information System (ARIS), complete and coded information is available on all NIH-funded AIDS and AIDS-related research from a single source. By contrast, TAG was obliged to identify awards for HBV, HCV, and TB by combining individual FOIA requests to all relevant NIH ICs after a preliminary scan of available online databases such as CRISP (Computer Retrieval of Information on Scientific Projects, http://crisp.cit.nih.gov), its long-delayed and still incomplete successor database RePORT (Research Portfolio Online Reporting Tool, http://report.nih.gov), and TAGGs, none of which contained complete financial information or detailed attributions to the individual diseases on which TAG sought information. For this reason TAG submitted FOIA requests to the individual ICs and cross-checked the responses with the online databases and with the OAR ARIS data.

HIV/AIDS

Before releasing its 2007 HIV/AIDS award lists, the OAR internally coded all awards using seven research categories that correspond with seven major investment priorities outlined in the OAR's 2007 strategic plan (OAR 2006).⁴ The categories are as follows:

• Natural history and epidemiology: includes, but is not limited to, studies of transmission modalities, biological and behavioral factors that influence morbidity and mortality, detailed and correct systems for measuring morbidity and mortality and the presence of comorbid conditions, and systems for measuring the long-term effects of HIV/AIDS treatments.

^{4.} For the full text of OAR's 2007 strategic plan, call +1 301 496 0357. The 2008 and 2009 strategic plans are available online at http://www.oar.nih.gov/strategicplan.

- Etiology and pathogenesis: research efforts to better elucidate (1) how HIV infection takes hold and is maintained in the body and (2) what causes the immune deficiency and serious clinical complications associated with the infection.
- Therapeutics: research dedicated to developing new and better approaches to prevent and treat HIV/AIDS, its comorbidities, and clinical complications.
- **Vaccines:** research and development of prophylactic HIV vaccines to prevent HIV infection and/or to prevent transmission from an infected person and/or to control the progression of HIV/AIDS in an infected person.
- **Behavioral and social sciences:** investment in greater understanding of the contexts in which risk behaviors occur and the determinants of those contexts. Also includes the development of intervention models to break patterns of risk exposure.
- Training, infrastructure, and capacity building: includes, but is not limited to, efforts to develop scientifically sound and culturally specific and sensitive programs for those populations with the largest proportion of newly diagnosed HIV infections. This also includes investment in the training of HIV/AIDS professionals from minority populations.
- **Information dissemination:** efforts to facilitate the timely and efficient exchange of information and the communication of new developments and important tools in the fight against AIDS.

HBV, HCV, and TB

With the exception of NIAID awards, all HBV-, HCV- and TB-specific awards were coded using the following five research categories:

- **Basic science:** undirected, investigator-initiated research that aims to uncover fundamental knowledge of all types of HBV, HCV, or TB.
- Diagnostics: preclinical or clinical trials of diagnostic technologies and algorithms.

- Therapeutics: preclinical or clinical research on treatments and treatment strategies for HBV, HCV, or TB diseases.
- Vaccines: preclinical or clinical research on HBV, HCV, or TB vaccines or vaccination strategies.
- Other, including operational and unspecified: includes randomized controlled studies of existing interventions within routine program settings, as well as epidemiology, surveillance, or targeted evaluation of new or existing interventions to improve disease-specific program performance and reduce disease rates. This also includes research that the administering ICD was unable to further categorize.

NIAID staff internally coded all awards using the following four research categories: basic science, diagnostics, therapeutics, and vaccines. Thus, no NIAID awards are coded using the TAG research category "Other."

2.3 Hepatitis B Virus (HBV)

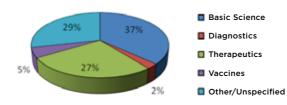
Worldwide, at least 350 million people are chronically infected with HBV (Lee 1997). Untreated HBV can lead to cirrhosis, liver cancer, and liver failure in 15-40% of chronic disease, and is responsible for more than 1 million deaths per year and, currently, 5-10% of liver transplantations. Nearly 10% of the 33 million HIV-positive people worldwide are coinfected with hepatitis B (Alter 2006). End stage liver disease from viral hepatitis coinfection has become a leading cause of death among HIV-positive people in the United States and Europe. HIV accelerates chronic HBV disease progression and the development of drug-resistant mutations.

In the United States, 1.25 million people are estimated to be living with chronic HBV infection (McQuillan 1999). An estimated 10% of the nation's 1.12 million HIV-positive individuals are coinfected with chronic HBV infection.⁵

In 2007, NIH ICs reported a total investment of \$42,393,937 in HBV-specific research. This represents 0.1% of the 2007 total NIH budget.

 $^{5. \}quad \text{Revised domestic HIV prevalence estimates released by the Centers for Disease Control and Prevention (CDC) in October 2008; <math display="block">\text{http://www.cdc.gov/hiv/topics/surveillance/resources/factsheets/prevalence.htm.}$

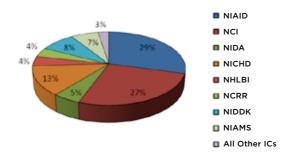
HBV: 2007 NIH Research Investment by Category



Research	нву	% of HBV
Category	\$	Total
Basic Science	15,599,134	37
Diagnostics	1,043,658	2
Therapeutics	11,462,296	27
Vaccines	2,182,632	5
Other/Unspecified	12,106,217	29

FIGURE 7

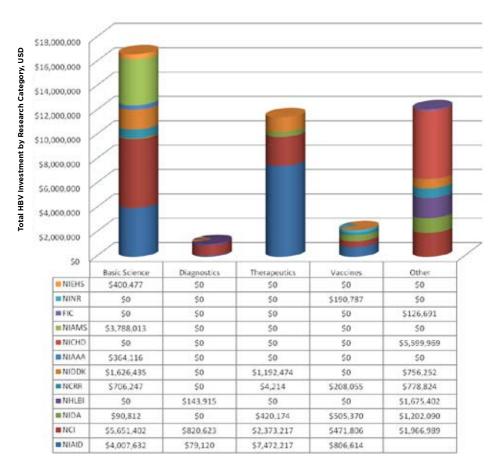
HBV: Percentage of Total NIH 2007 Investment by IC



IC	Total \$	%
NIAID	12,365,583	29
NCI	11,248,037	27
NICHD	5,599,969	13
NIDDK	3,575,161	8
NIAMS	2,788,013	7
NIDA	2,218,446	5
NHLBI	1,819,317	4
NCRR	1,697,340	4
All Other ICs	1,082,071	3

Note: See Appendix for names of institutions listed by acronym.

HBV: Amounts and Proportions of Total NIH Research Investment, 2007



Note: See Appendix for names of institutions listed by acronym.

 $Note: The full 2007 \ NIH \ HBV \ award \ portfolio \ is \ available \ online \ at \ http://www.treatmentaction.group.org/nih-hbv.pdf.$

2.4 Hepatitis C Virus (HCV)

The World Health Organization (WHO) refers to hepatitis C as a "viral time bomb." An estimated 180 million people—3% of the world's population—are infected with HCV, and 3 to 4 million more become infected each year (WHO 2008). Chronic hepatitis C leads to cirrhosis in 20–30% of cases. The annual global death toll from HCV complications (hepatocellular carcinoma and liver failure) is approximately 366,000 (Perz 2006).

In the United States, at least 4 million people have been infected with HCV (Armstrong 2006). HCV-induced liver disease is the leading indication for liver transplantation in the United States, where there are more than 7,000 deaths from HCV complications each year (Wise 2007).

Globally, 4 to 5 million HIV-positive people are coinfected with hepatitis C (Alter 2006). In the United States, more than 30% of the nation's 1.12 million HIV-positive individuals are coinfected with HCV (Sulkowski 2008). Hepatitis C progresses more rapidly, and is harder to treat in HIV-positive people. HCV-associated end stage liver disease has become a leading cause of death among HIV-positive people in the United States and Europe (Weber 2006).

In 2007, NIH ICs reported a total investment of \$105,945,403 in HCV-specific research. This represents 0.4% of the total 2007 NIH budget.

HCV: Percentage of 2007 NIH Research Investment by Category

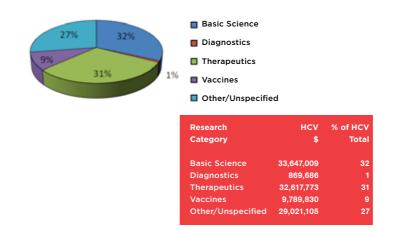
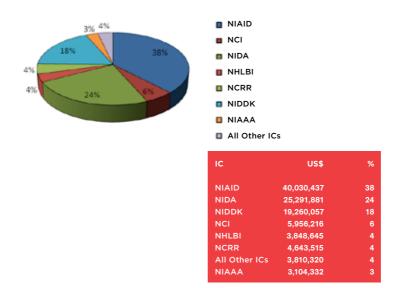


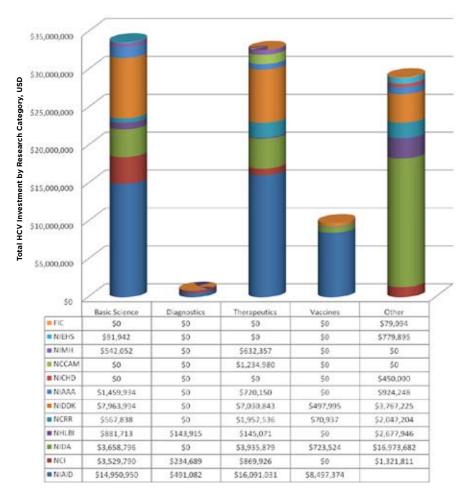
FIGURE 10

HCV: Percentage of Total NIH 2007 Investment by IC



Note: See Appendix for names of institutions listed by acronym.

HCV: Amounts and Proportions of Total NIH Research Investment, 2007



Note: A full listing of 2007 NIH HCV awards is available online at http://www.treatmentactiongroup.org/nih-hcv.pdf.

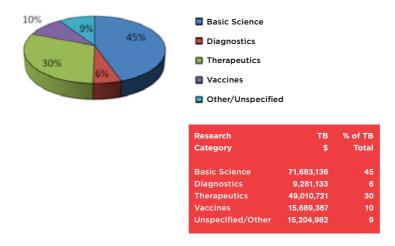
2.5 Tuberculosis

One-third of the world's population is infected with *Mycobacterium tuber-culosis*, the TB bacillus. According to the WHO's *Global Tuberculosis Control 2008* report, in 2006 there were 9.2 million new cases, 709,000 of them coinfected with HIV. (In 2009, the WHO will publish new estimates effectively doubling the number of HIV infected persons with TB disease, based on actual testing data from countries). Though it is a curable disease, TB caused an estimated 1.7 million deaths in 2006. For people with healthy immune systems who are infected with TB, about 10% will develop active TB disease during their lifetime. However, among people with HIV, the risk of developing TB disease increases exponentially. Along with HIV, the emergence of multiple drug-resistant (MDR) and extensively drug-resistant (XDR) TB threatens gains made by TB control efforts and requires new tools to effectively diagnose, treat, and prevent TB (WHO 2008).

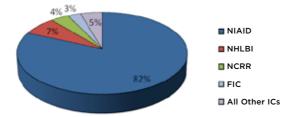
In 2007, NIH ICs reported a total investment of \$160,869,339 in TB-specific research. This represents 0.6% of the total 2007 budget.

FIGURE 12

TB: 2007 NIH Research Investment by Category

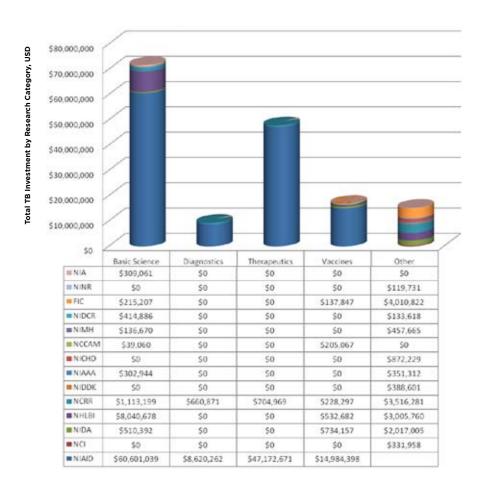


TB: Percentage of Total NIH 2007 Investment by IC



ıc	US\$	%
NIAID	131,378,370	82
NHLBI	11,579,120	7
All Other ICs	7,324,356	5
NCRR	6,223,617	4
FIC	4,363,876	3

TB: Amounts and Proportions of Total NIH Research Investment, 2007



Note: A full listing of 2007 NIH TB awards is available online at http://www.treatmentactiongroup.org/nih-tb.pdf.

2.6 HIV/AIDS

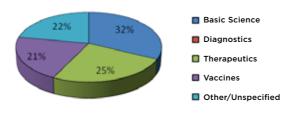
According to UNAIDS and the WHO, at the end of 2007, 33 million people were living with HIV. In that year, 2.7 million new infections occurred and approximately 2 million people died of AIDS (UNAIDS/WHO 2008).

In the United States, at the end of 2006, 1.12 million people were living with HIV, according to the Centers for Disease Control and Prevention's (CDC's) recent upwardly revised prevalence and incidence estimates (CDC 2008). In 2006, approximately 56,300 new HIV infections occurred and 14,627 people died of AIDS in the United States and dependent areas.

In 2007, the OAR reported a total investment of \$2,904,509,663 in HIV/AIDS-specific research. This represents 10% of the total 2007 NIH budget.

FIGURE 15

HIV/AIDS: 2007 NIH Research Investment by Category



Research Code	AIDS	% of AIDS
	\$	Total
Basic Science	938,944,198	32
Diagnostics		
Therapeutics	724,742,313	25
Vaccines	596,775,342	21
Other/Unspecified	644,047,810	22

^{6.} The year 2006 is the most recent for which reported U.S. HIV statistical data is available.

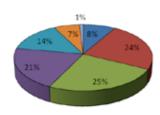
Note: In the following figure, OAR investment totals by strategic planning code were reassigned using TAG research category codes for ease in comparison between HIV/AIDS and HBV, HCV, and TB funding portfolios.

The recoding is as follows:

- Natural History and Epidemiology + Etiology and Pathogenesis (OAR codes) = Basic Science (TAG code)
- Behavioral and Social Science Research + Training, Infrastructure, and Capacity
 Building + Information Dissemination (OAR codes) = Unspecified/Other (TAG codes)
- Therapeutics and Vaccines categories remain the same.

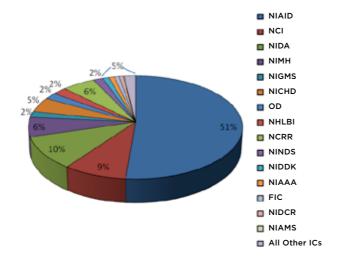
FIGURE 16

HIV/AIDS: 2007 NIH Investment by OAR Strategic Planning Code



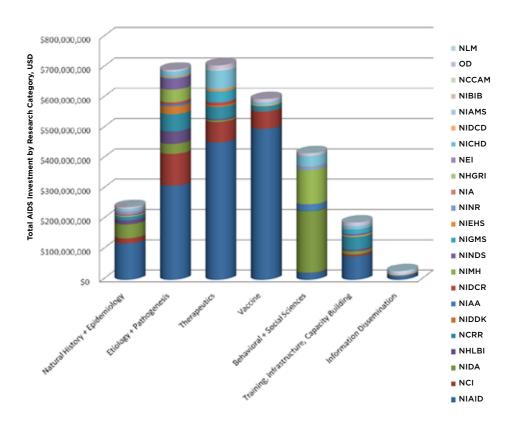
- Natural History + Epidemiology
- **■** Etiology + Pathogenesis
- Therapeutics
- Vaccines
- Behavioral + Social Sciences Research
- Training, Infrastructure,
 Capacity Building
- InformationDissemination
- **OAR Strategic Code** AIDS % of AIDS \$ Total Natural History + Epidemiology 243,940,147 Etiology + Pathogenesis 695,004,051 **Therapeutics** 724,742,313 596.775.342 **Vaccines** Behavioral + Social Sciences 422.319.648 Research Training, Infrastructure. 193.354.014 **Capacity Building** Information 28.374.148 Dissemination

HIV/AIDS: Percentage of Total NIH 2007 Investment by IC



IC	Total \$	%
NIAID	1,490,088,840	51
NIDA	300,162,000	10
NCI	253,666,313	9
NIMH	178,590,000	6
NCRR	160,992,000	6
NICHD	133,555,000	5
NIGMS	53,484,886	2
OD	60,356,000	2
NHLBI	67,341,988	2
NINDS	46,351,000	2
All Other ICs	54,550,000	2
NIDDK	30,897,998	
NIAAA	26,936,688	
FIC	22,983,000	
NIDCR	19,687,950	
NIAMS	4,866,000	

HIV/AIDS: Proportion of Total NIH Research Investment, 2007



OAR Strategic Plan Investment Category

Note: A full listing of 2007 NIH OAR awards is available online at http://www.treatmentactiongroup.org/nih-oar.pdf.

TABLE 2

HIV/AIDS: Amounts of Total NIH Research Investment by IC and Research Category, 2007

IC	2007 TOTAL \$	NATURAL HISTORY + EPIDEMIOLOGY	ETIOLOGY + PATHOGENESIS	THERAPEUTICS	
NIAID	\$1,490,088,840	\$119,935,876	\$309,850,867	\$452,756,905	
NIDA	\$300,162,000	\$45,992,518	\$33,288,161	\$5,633,020	
NCI	\$253,666,313	\$16,408,754	\$104,532,447	\$67,253,016	
NIMH	\$178,590,000	\$4,429,118	\$41,601,557	\$13,245,282	
NCRR	\$160,992,000	\$8,852,935	\$56,381,320	\$39,292,606	
NICHD	\$133,555,000	\$8,824,194	\$13,501,873	\$58,469,111	
NHLBI	\$67,341,988	\$13,373,822	\$41,358,693	\$4,388,429	
OD	\$60,356,000	\$5,783,620	\$4,116,232	\$13,285,981	
NIGMS	\$53,484,886	\$0	\$2,792,912	\$35,492,172	
NINDS	\$46,351,000	\$4,335,037	\$35,730,629	\$1,085,195	
NIDDK	\$30,897,998	\$27,926	\$26,055,251	\$4,814,821	
NIAAC	\$26,936,688	\$2,053,379	\$6,165,435	\$159,636	
FIC	\$22,983,000	\$4,530,936	\$2,301,119	\$4,401,452	
NIDCR	\$19,687,950	\$242,747	\$7,746,330	\$9,572,737	
NINR	\$12,114,000	\$321,570	\$0	\$1,041,900	
NEI	\$10,585,000	\$7,734,687	\$1,978,841	\$871,472	
NIEHS	\$7,513,000	\$0	\$1,807,630	\$5,177,836	
NLM	\$7,376,000	\$0	\$0	\$0	
NHGRI	\$6,835,000	\$35,000	\$2,422,000	\$1,787,000	
NIA	\$5,392,000	\$217,404	\$1,067,943	\$862,732	
NIAMS	\$4,866,000	\$0	\$2,289,811	\$1,985,070	
NCCAM	\$2,285,000	\$0	\$0	\$2,127,940	
NIDCD	\$1,412,000	\$840,624	\$15,000	\$0	
NIBIB	\$1,038,000	\$0	\$0	\$1,038,000	

VACCINE	BEHAVIORAL + SOCIAL SCIENCES	TRAINING, INFRASTRUCTURE, CAPACITY BUILDING	INFORMATION DISSEMINATION
\$497,054,414	\$21,901,654	\$76,683,920	\$11,905,204
\$1,010,739	\$202,064,773	\$9,959,102	\$2,213,687
\$56,868,724	\$1,326,691	\$6,776,365	\$500,316
\$434,542	\$113,310,002	\$5,494,499	\$75,000
\$13,690,012	\$2,777,087	\$39,998,040	\$0
\$8,207,564	\$34,805,800	\$9,653,758	\$92,700
\$1,241,562	\$1,484,164	\$5,495,318	\$0
\$10,881,430	\$8,181,571	\$11,616,594	\$6,490,572
\$755,424	\$0	\$14,444,378	\$0
\$0	\$0	\$5,200,139	\$0
\$0	\$0	\$0	\$0
\$0	\$17,907,341	\$650,897	\$0
\$1,317,569	\$5,421,278	\$4,998,146	\$12,500
\$1,180,871	\$615,265	\$330,000	\$0
\$113,777	\$9,834,144	\$494,440	\$308,169
\$0	\$0	\$0	\$0
\$527,534	\$0	\$0	\$0
\$0	\$0	\$600,000	\$6,776,000
\$2,591,000	\$0	\$0	\$0
\$309,061	\$1,976,442	\$958,418	\$0
\$591,119	\$0	\$0	\$0
\$0	\$157,060	\$0	\$0
\$0	\$556,376	\$0	\$0
\$0	\$0	\$0	\$0

3 Conclusions

Given the huge and ever-increasing global burden of HIV/AIDS and associated coinfections, the 10% of the total NIH budget spent on HIV/AIDS research and the 1.1% spent on HBV, HCV, and TB research programs combined is unacceptably low. Just keeping pace with inflation would require annual increases in spending on each disease of 3–4%. Unless flat funding is reversed with the appropriation by Congress of significant, steady, sustained, multiyear annual increases to the NIH budget of at least 10–15%, new and increased investment in research on HIV/AIDS and its most common coinfections will be hampered. Until NIH resumes a period of healthy and predictable growth, its capacity to foster innovative and transformative research in all fields will continue to shrink.

NIH Research Investment in HBV, HCV and TB Disproportionate to Disease Burden

In FY 2007, the NIH invested \$122 million in research on smallpox and \$105 million in research on anthrax, despite the eradication of smallpox in 1979 and the extremely low global burden of anthrax-related morbidity and mortality (NIH 2008). In contrast, 2007 NIH investment in TB, HCV, and HBV totaled only \$160 million, \$105 million and \$42 million, respectively, despite the fact that tens of millions of individuals are infected with TB and/or viral hepatitis and millions die from these diseases every year. NIH investment in TB and viral hepatitis is disproportionately small relative to global disease burden. Whereas it is indeed critical to invest in preparedness for a biological weapons attack (smallpox and anthrax), investment in TB and viral hepatitis must be increased to reflect the real and increasing toll these diseases are taking on a global scale.

4 Appendix: List of NIH Grant-Making Institutes and Centers

NIH Grant-Making Institutes and Centers

http://www.nih.gov/icd/index.html

NIH Institutes

National Cancer Institute (NCI)

National Eye Institute (NEI)

National Heart, Lung, and Blood Institute (NHLBI)

National Human Genome Research Institute (NHGRI)

National Institute on Aging (NIA)

National Institute of Alcohol Abuse and Alcoholism (NIAAA)

National Institute of Allergy and Infectious Diseases (NIAID)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

National Institute of Child Health and Human Development (NICHD)

National Institute on Deafness and Other Communication Disorders (NIDCD)

National Institute of Dental and Craniofacial Research (NIDCR)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

National Institute on Drug Abuse (NIDA)

National Institute of Environmental Health Services (NIEHS)

National Institute of General Medical Sciences (NIGMS)

National Institute of Mental Health (NIMH)

National Institute of Neurological Disorders and Stroke (NINDS)

National Institute of Nursing Research (NINR)

National Library of Medicine (NLM)

NIH Centers

Center for Information Technology (CIT)

Center for Scientific Review (CSR)

John E. Fogarty International Center (FIC)

National Center for Complementary and Alternative Medicine (NCCAM)

National Center on Minority Health and Health Disparities (NCMHD)

National Center for Research Resources (NCRR)

NIH Clinical Center (CC)

5 References

Alter M. Epidemiology of viral hepatitis and HIV coinfection. J Hepatol. 2006;44:6-9.

American Association for the Advancement of Science. NIH budget flat in 2009 proposal. AAAS R&D Website, http://www.aaas.org/spp/rd/nih09p.htm. Accessed 5 December 2008.

Armstrong GL, Walsey A, Simard EP, et al. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. Ann Intern Med. 16 May 2006; 144(10):705-714.

Centers for Disease Control and Prevention. Fact sheet: new estimates of U.S. HIV prevalence, 2006. Available online at http://www.cdc.gov/hiv/topics/surveillance/resources/factsheets/prevalence.htm. Accessed 5 December 2008.

Fauci A. The research path to tuberculosis control: an NIH perspective. Paper presented at the Institute of Medicine Workshop "Addressing the Threat of Drug Resistant TB: A Realistic Assessment of the Challenges" held at the Kaiser Family Foundation's Barbara Jordan Conference Center, Washington, D.C., 2005. 5 November 2008. Available online at http://www.iom.edu/?id=59920. Accessed 5 December 2008.

Lee WM. Hepatitis B virus infection. N Engl J Med 1997;337:1733-45.

McQuillan GM, Coleman PJ, Kruszon-Moran D, Moyer LA, Lambert SB, Margolis HS. Prevalence of hepatitis B virus infection in the United States: the National Health and Nutrition Examination Surveys, 1976 through 1994. Am J Public Health. 1999;89:14–18.

National Institutes of Health. Estimates of funding for various diseases, conditions, research areas. Available online at http://www.nih.gov/news/fundingresearchareas. htm. Accessed 5 December 2008. Site now updated at http://report.nih.gov/rcdc/categories/. Accessed 25 February 2009.

National Institutes of Health. NIH's role in the American Recovery and Reinvestment Act (ARRA). Available online at http://www.nih.gov/about/director/02252009statement_arra.htm. Accessed 25 February 2009.

Office of AIDS Research, National Institutes of Health. *National Institutes of Health fiscal year 2007 plan for HIV-related research*. 2006. Available online at http://www.oar.nih.gov. Accessed 5 December 2008.

Perz JF, Armstrong GL, Farrington LA, et al. The contributions of hepatitis B virus and hepatitis C virus infections to cirrhosis and primary liver cancer worldwide. J Hepatol. 2006 Oct;45(4):529-38; Ann Intern Med. 2006 May 16;144(10):705-14.

Sulkowski MS. Viral hepatitis and HIV coinfection. J Hepatol. 2008 Feb;48(2):353-67.

UNAIDS/WHO. Global Summary of the AIDS Epidemic, December 2007. Published July 2008. Available online at http://www.who.int/hiv/data/2008_global_summary_AIDS_ep.png. Accessed 5 December 2008.

Weber R, Sabin CA, Friis-Moller N, et al. Liver-related deaths in persons infected with the human immunodeficiency virus: the D:A:D study. Arch Intern Med. 2006;166:1632-41.

Wise M, Bialek S, Finelli L, et al. Changing trends in hepatitis C-related mortality in the United States, 1995–2004. Hepatology 2008 Apr;47(4):1128–35.

World Health Organization. *Global Tuberculosis Control 2008*. Available online at http://www.who.int/tb/publications/global_report/2008/summary/en/index.html. Accessed 3 December 2008.

World Health Organization. Initiative for Vaccine Research. Hepatitis C. Available online at http://www.who.int/vaccine_research/diseases/viral_cancers/en/index2. html. Accessed 24 November 2008.

ACKNOWLEDGMENTS

Warm thanks to all the National Institutes of Health (NIH) staff members who tracked down and provided the data necessary for this analysis. Special mention goes to the Freedom of Information Act coordinators and staff at the 27 NIH institutes and centers and the Office of the Director who over the course of many months processed multiple requests and ran special data queries. For their assistance in data gathering and their guidance as this project took shape, special thanks are due to Christine Sizemore at the NIH National Institute of Allergy and Infectious Diseases and Bob Eisinger at the NIH Office of AIDS Research, Final thanks to the board, staff, and donors of TAG whose generous support made this work possible.

Treatment Action Group

611 Broadway, Suite 308 New York, NY 10012 Tel 212 253 7922 Fax 212 253 7923

tag@treatmentactiongroup.org www.treatmentactiongroup.org

