Methods to Determine the Value of Biomedical Research (VOBR) at NIAID

LIBERTY WALTON, PUBLIC HEALTH ANALYST
STRATEGIC PLANNING AND EVALUATION BRANCH
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)
FEBRUARY 14, 2018

Background

Reasons to consider VOBR

- NIH Scientific Management Review Board (SMRB) 2014 Report: *Approaches to Assess the Value of Biomedical Research Supported by NIH*
  - SMRB defined the value of biomedical research as:
    (1) The generation of scientific knowledge;
    (2) The impact of scientific knowledge on the health of the public; and
    (3) The broader effects of NIH-funded activities on other aspects of society.
- Accountability for public spending
- Emphasis on results
- Exploratory study to develop and pilot a methodology to assess the value of intramural and extramural NIAID research portfolios

Objectives of the NIAID VOBR Project

1. Develop a methodology for assessing the contribution of NIAID research to five outcome domains

2. Conduct a pilot test of the methodology using two NIAID research portfolios

3. Construct a guidebook describing the procedures NIAID staff can use to conduct similar portfolio analyses in the future

Study Questions

1. What are appropriate ‘core’ indicators of scientific, economic, health, and societal value of return associated with NIAID’s investment in various research areas?

2. Can these indicators be generalized to other NIAID research portfolios?

3. What are the data sources and collection methods needed to access and gather data for each indicator?

4. What data analysis tools are needed? Can these tools be used in other value of return analyses?

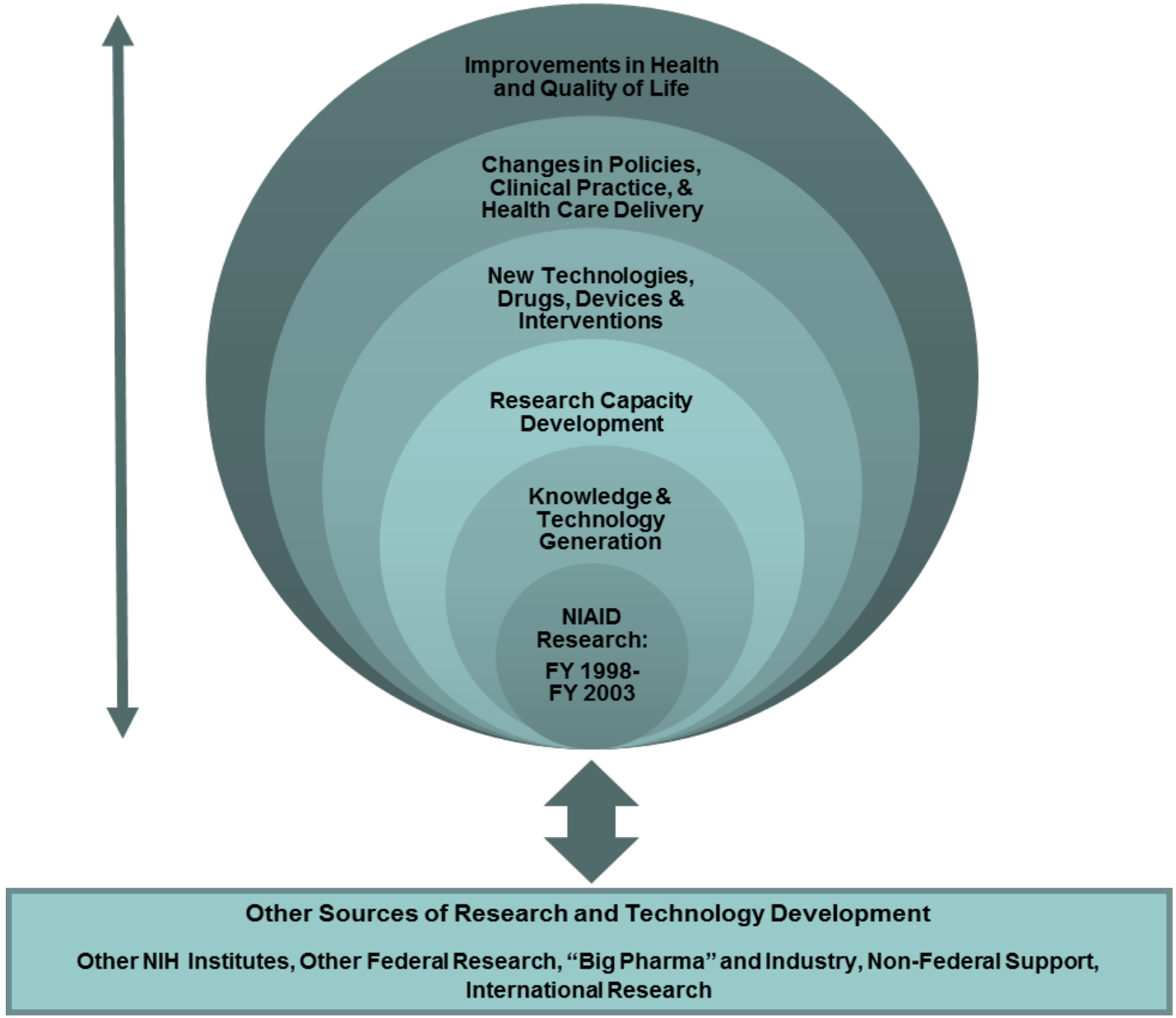
5. How can NIAID’s contribution to longer-term indicators (such as improvements in health) be assessed and appropriately reported?

Methods

Steps in the Methodology

1. Develop a conceptual framework
2. Identify indicators and data sources for each metric
3. Collect data
4. Assesses collection methods
    a) Feasibility of using data source
    b) Costs
    c) Strengths
    d) Limitations

Conceptual Framework: Outcome Domains



Criteria for Selecting Indicators to Assess Each Domain

1. Low (or no) cost to access
2. Potential ease of use for NIAID staff
3. Capacity to link indicator to a specific NIH grant

Outcome Domain	Indicator
Knowledge and Technology Generation	Publications—Productivity
	Publications—Research Topics
	Publications—Citation Impact
	Publications—Relative Citation Ratio
	Publications—Quality
	Patents and Licenses—US and International
	International Licensure of Drugs, Vaccines, and Diagnostics
	Subsequent Grants of Principal Investigators
Capacity and Research Infrastructure Development	Publications—Co-Authorship Analysis
	Trainees
	International Clinical Trials
	Inclusion of Research Findings in Curricula and Teaching
New Product Development	New Drug and Medical Device Applications
Policies and Clinical Guidelines	Publications—Citation in Clinical Guidelines and Policy Documents
Improved Health and Well-Being	Changes in Rates of Morbidity, Mortality, and/or Disability

Data Collection Sources	Outcome Domains				
	KNOWLEDGE	CAPACITY	NEW PRODUCTS	POLICIES & PRACTICE	HEALTH & WELL-BEING
NIH Library Bibliometrics Program	✓	✓			
SciVal (Elsevier)	✓				
NIH iCite	✓				
Cochrane Systematic Reviews	✓				
F1000Prime	✓	✓	✓		
NIH ExPORTER	✓	✓			
USPTO PatentsView website	✓				
Citeline	✓	✓			
FDA Orange Book	✓		✓		
NIH IMPAC II QVR	✓	✓			
www.clinicaltrials.gov		✓			
Syllabus Finder		✓			
IDSA Clinical Guidelines				✓	
AHRQ National Guidelines Clearinghouse				✓	
Institute of Medicine (Health & Medicine Division)				✓	
World Health Organization Clinical Guidelines				✓	
PubMed	✓			✓	
CDC					✓
World Health Organizations Statistics					✓
UNAIDS					✓
Global Burden of Disease					✓

Documentation of Data Collection

- Outcome domain and indicator
- Description of the data source
- Type(s) of data sought
- Detailed instructions for data collection
- Nature of the link between the indicator and research portfolio grants
- Limitations and difficulties in using the data source
- Usefulness of the data source
- Recommendations for future use of this data source

Rating of Data Collection

Sources were ranked as low, medium, or high on three characteristics:

- Usefulness
  - The amount of relevant data the data source provides to indicate the value of the portfolio research.
- Ease of Use
  - The amount of time, money, effort, special permissions or specialized skills necessary to obtain and successfully interpret data from the data source.
- Linkability
  - Whether data from this source can be directly linked to a specific portfolio grant and the amount of effort required to link the data.

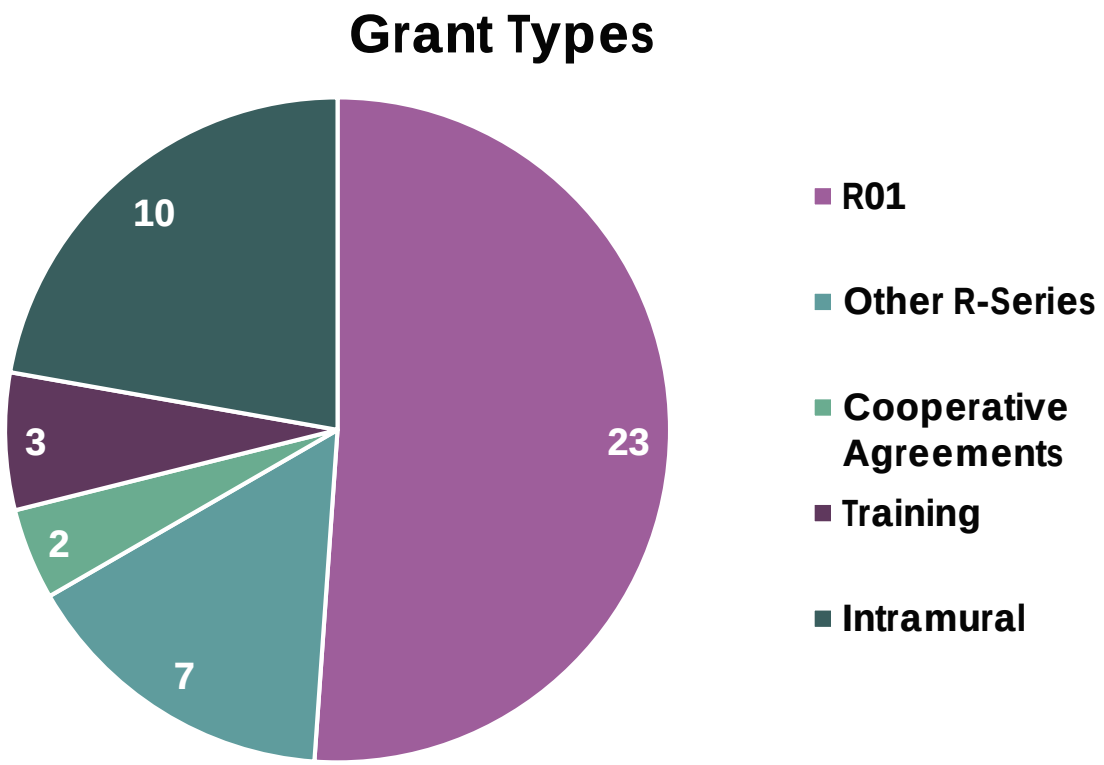
Applying the Methodology

Criteria for Case Study Selection

- Portfolio size (small, under 200 grants)
- Grants active between FY 1998 and FY 2003 (allow time for impacts)
- Exclusion of research center grants (too large and complex) and contracts (insufficient information available)

Characteristics of Coronavirus Portfolio

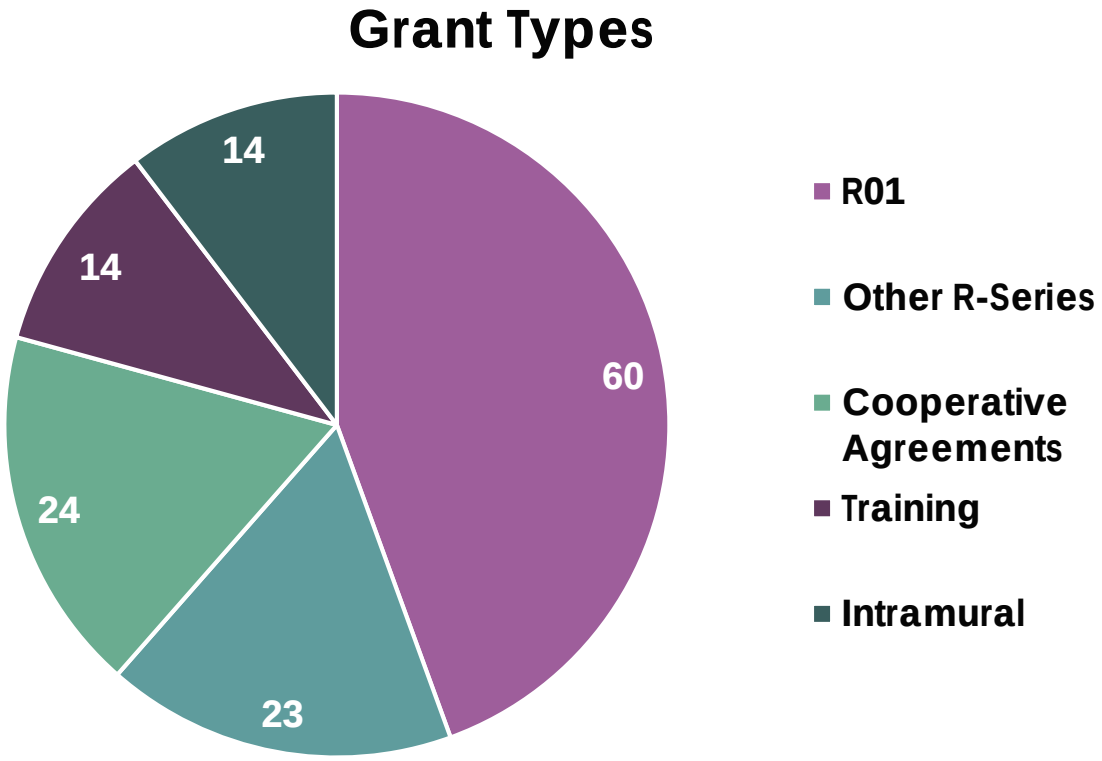
- Cause mild to moderate upper-respiratory tract illnesses (e.g., SARS, MERS)
- Portfolio included 45 active grants
- 23/45 grants (51%) were R01 grants
- Grants were awarded to 31 PIs at 25 research institutions



Outcome Domain	Coronavirus Case Study Results
Knowledge & New Technology Generation	• 423 research publications (1998-2015) • 20,606 citations through 2015 (48.7 citations per research article) • 12.4% of publications cited at least 3 times as often as other NIH Publications from similar fields • 40 U.S. patents attributed to 13/45 portfolio grants (29%)—no international patents
Capacity & Research Infrastructure Development	• 17 of 31 PIs awarded a total of 82 subsequent grants (56% of grants were related to CoV and 80% were funded by NIAID)
New Product Development	• Inconclusive
Changes in Policies and Clinical Guidelines	• Inconclusive
Improved Health & Well-Being	• Inconclusive

Characteristics of the Pediatric HIV/AIDS Research Portfolio

- Portfolio included 135 grants
- 60/135 grants (44%) were R01 grants
- Grants were awarded to 105 PIs at 75 research institutions



Outcome Domain	Pediatric HIV/AIDS Case Study Results
Knowledge & New Technology Generation	• 2,596 total publications identified between 1998-2015 (of which 2,495 were research articles) • 108,461 total citations through 2014 (43.5 citations per research article) • 13.4% of publications cited 3 or more times as often as other NIH articles from similar fields • 64 U.S. patents attributed to 32/135 grants (24%)- no international patents
Capacity & Research Infrastructure Development	• 63/105 PIs awarded a total of 635 subsequent grants (25% of grants related to pediatric HIV/AIDS, and 38% of grants funded by NIAID)
New Product Development	• Inconclusive
Changes in Policies and Clinical Guidelines	• Inconclusive
Improved Health & Well-Being	• Inconclusive

Overall Usefulness of Data Sources	Data Sources
Data sources found useful	• PubMed, Web of Science, InCites (and NIH Library BSP) • iCite • NIH IMPAC II QVR • USPTO PatentsView website
Data sources that may be useful with some portfolios under some circumstances	• SciVal (Elsevier), also Thomson-Reuters • Cochrane Systematic Reviews • Clinical Trials.gov • Citeline • IDSA Clinical Guidelines (also AHRQ National Clearinghouse, Institute of Medicine) • CDC • World Health Organizations Statistics • Global Burden of Disease
Data sources not found useful	• NIH ExPORTER • F1000Prime • Syllabus Finder • FDA Orange Book

Domain	Indicator	Data source	Usefulness	Ease of Use	Linkability
Knowledge & Technology Generation	Publications (Productivity & Research Topics)	**NIH Library's Bibliometrics Services Program (includes NIH RePORTER, Web of Science, inCites):** https://nihlibrary.nih.gov/Services/Pages/Form/Comments.aspx			
	Publications (Citation Impact)	**SciVal (Elsevier):** https://www.elsevier.com/solutions/scival		Not assessed	
	Publications (Relative Citation Ratio)	**NIH iCite:** www.icite.od.nih.gov			
	Publications (Quality)	**Cochrane Systematic Reviews**			
		F1000Prime			
	Patents and Licenses (U.S.)	**NIH ExPORTER:** http://exporter.nih.gov/ExPORTER_Catalog.aspx?sid=0&index=3			
		USPTO PatentsView website: http://www.patentsview.org/web/			
		FDA Orange Book: http://www.accessdata.fda.gov/scripts/cder/ob/			
		Publications list (from RePORTER search results)			
	Patents and Licenses (International)	**Citeline**			
	Subsequent PI Grant History	**NIH IMPAC II QVR**			

Domain	Indicator	Data source	Usefulness	Ease of Use	Linkability
Capacity & Research Infrastructure Development	Publications (Co-authorship Analyses)	**NIH Library's Bibliometrics Services Program (includes NIH RePORTER, Web of Science, inCites):** https://nihlibrary.nih.gov/Services/Pages/Form/Comments.aspx			
	Trainees	**NIH IMPAC II QVR** analysis of subsequent grants from portfolio awardees of F and K grants			
	International Clinical Trials	**NIH ExPORTER**			
		www.clinicaltrials.gov			
		Citeline			
	Inclusion of Research Findings in Curricula and Teaching	**Syllabus Finder:** http://www.syllabusfinder.com/		Not assessed	
		F1000Prime: http://f1000.com/prime			

Domain	Indicator	Data source	Usefulness	Ease of Use	Linkability
New Product Development	New Drug and Medical Device Applications	**Manual Publications list search** (from RePORTER search results)			
		F1000Prime: http://f1000.com/prime			
		FDA Orange Book: http://www.accessdata.fda.gov/scripts/cder/ob/			

Domain	Indicator	Data source	Usefulness	Ease of Use	Linkability
Policies & Clinical Guidelines	Citation of Portfolio Publications in References to Clinical Guidelines	**IDSA Clinical Guidelines:** https://www.idsociety.org/IDSA_Practice_Guidelines/			
		AHRQ National Guidelines Clearinghouse: https://guideline.gov/			Not assessed
		Health and Medicine Division (previously Institute of Medicine): http://www.nap.edu/catalog/13058/clinical-practice-guidelines-we-can-trust			
		World Health Organization Clinical Guidelines: http://www.who.int/en/			
		PubMed: http://www.ncbi.nlm.nih.gov/pubmed			

Domain	Indicator	Data source	Usefulness	Ease of Use	Linkability
Improved Health & Well-being	Changes in Rates of Morbidity, Mortality and Disability	**CDC:** http://www.cdc.gov/hiv/library/reports/surveillance/			Not possible
		WHO Statistics: http://www.who.int/en/			Not possible
		UNAIDS: http://www.unaids.org/en/dataanalysis/knowyourepidemic/epidemiologypublications			Not possible
		Global Burden of Disease: http://www.sciencedirect.com/science/article/pii/S0140673612616894			Not possible

Domains	Summary of Recommended Data Sources
Knowledge & New Technology Generation	• NIH, RePORTER, PubMed, Web of Science, InCites (and NIH Library BSP) • SciVal (if funds are available) • iCite • USPTO PatentsView website • Citeline • NIH IMPAC II QVR
Capacity & Research Infrastructure Development	• NIH, RePORTER, PubMed, Web of Science, InCites (and NIH Library BSP) • NIH IMPAC II QVR • Citeline • F1000Prime (best suited for recent, cutting-edge research)
New Product Development	• F1000Prime (best suited for recent, cutting-edge research)
Changes in Policies and Clinical Guidelines	• PubMed
Improved Health & Well-Being	• CDC (MMWR and other disease-specific reports) • World Health Organizations Statistics • WHO Global Burden of Disease DALYs

Conclusions and Recommendations

Conclusions/Recommendations from Pilot Tests

1. The outcome domains selected for the exploratory study are reasonable, but future studies should explore additional indicators and data sources

2. Indicators are useful to the extent that there are benchmarks available against which to interpret them

3. A "one-size-fits-all" approach to valuing NIAID research portfolios is not advisable

Conclusions/Recommendations from Pilot Tests, continued

4. The absence of informed expert opinion by means of interviews with or surveys of NIH Program Officers, PIs, and/or other outside experts critically weakened the study

5. It was possible to demonstrate impacts for shorter-term outcome domains (knowledge and technology generation, research capacity development)

6. Problems were encountered in demonstrating impacts for new products, policies and clinical guidelines and improved health and well-being

Conclusions/Recommendations from Pilot Tests, continued

7) Explore other data collection and analysis tools, such as
    a) NIH Office of Portfolio Analysis (OPA)tools (e.g., iTools, IN-SPIRE)
    b) IC-level tools, for example:
        a) NIAID Outcomes Clustering and Analysis Tool (OCAT)
        b) NIEHS High Impacts Tracking System (HITS)
        c) NIEHS Automated Research Impacts Assessment (ARIA)

Acknowledgements

Thank You!

- **SPEB**
  - Jane Lockmuller
  - Brandie Taylor
  - Larry Solomon
  - Daphne Robinson
  - Adrienne Goodrich-Doctor

- **The Madrillon Group Inc.**
  - Margaret Blasinsky
  - Jack Scott
  - Mary Dufour

Discussion