Implementation Science and Scientific Impact Evaluation

Outline

Implementation Science

Scientific Impact Evaluation

Summary

Implementation Science

What does this mean?

- Implementation research is research aimed at developing and testing effective and efficient methods, strategies, and models for integrating or scaling up research-tested health interventions within communities (e.g. schools, villages) or populations. This research enters where scientific findings have moved from the bench to the bedside but have yet to reach the real world.
- Implementation research uses appropriate experimental designs (randomization and controls); quasi-experimental designs (e.g. measuring pre- and post-intervention variables, with control groups and correction for bias); and predictive modeling (testing changes in behavior of complex systems) to study strategies for customizing, adapting, and scaling up interventions to various populations, cultures, and conditions.
- Observational and descriptive studies typically generate hypothesis and identify promising implementation or scale-up strategies that can be tested using these methods.

Implementation Science

Where does it fit?

PHASE III TRIALS

- Assess **Efficacy** and **Safety** of medical interventions
- Ideal settings
- Experimental study designs

PHASE IV TRIALS

- Assess **Effectiveness** and **Impacts** of implementation strategies for medical and public health interventions
- "Real world" settings
- Quasi/experimental study designs

HEALTH SERVICES RESEARCH

- Assess **Quality**, **Cost-Effectiveness**, and **Efficiency, and Performance** of health services & systems
- "Real world" settings
- Observational and interventional study designs

NATIONAL INSTITUTES OF HEALTH

Implementation Science

Why is it needed?

To Bridge the “Know-Do Gap”:

"There is a gap between today's scientific advances and their application - between what we know and what is actually being done. Health systems are under severe pressure and there is an urgent need to generate knowledge for strengthening and improving them.“

- The late Dr. Lee Jong-Wook, Director-General of the WHO, 2004

How does Implementation Science fit into Fogarty's Strategic Plan?

Goal I: Build Sustainable Global Health Research Capacity in Low and Middle Income Countries to extend the frontier of scientific discovery and research

Goal II: Build capacity and develop new approaches to advance implementation and dissemination research

Goal III: Address the growing burden of noncommunicable diseases in the developing world while continuing to support research and research training on communicable diseases and the nexus of the two.

Goal IV: Galvanize the NIH community and US scientists to engage in global health research

Goal V: Build new partnerships and nurture current partnerships to advance Fogarty's strategic goals.

Implementation Science

Some Examples

Studying the safety and effectiveness of simultaneously delivering multiple interventions.

Example: Combined care models for co-morbidities like HIV and TB
Poly-pill therapy for CVD, hypertension, and hypercholesterolemia

Developing methods for integrating new interventions into the delivery of existing ones.

Example: Combining medical, public health & environmental malaria control strategies

Adapting a research-tested intervention to a novel, developing country setting.

Example: Customizing a U.S.-based children's psychological intervention for HIV/AIDS orphans in Uganda.

Implementation Science

Some Examples

Evaluating the downstream impacts of an intervention's implementation.

Example: Impact of school-based deworming on school attendance

Identifying behavior change methods to improve health professionals' performance and uptake of knowledge.

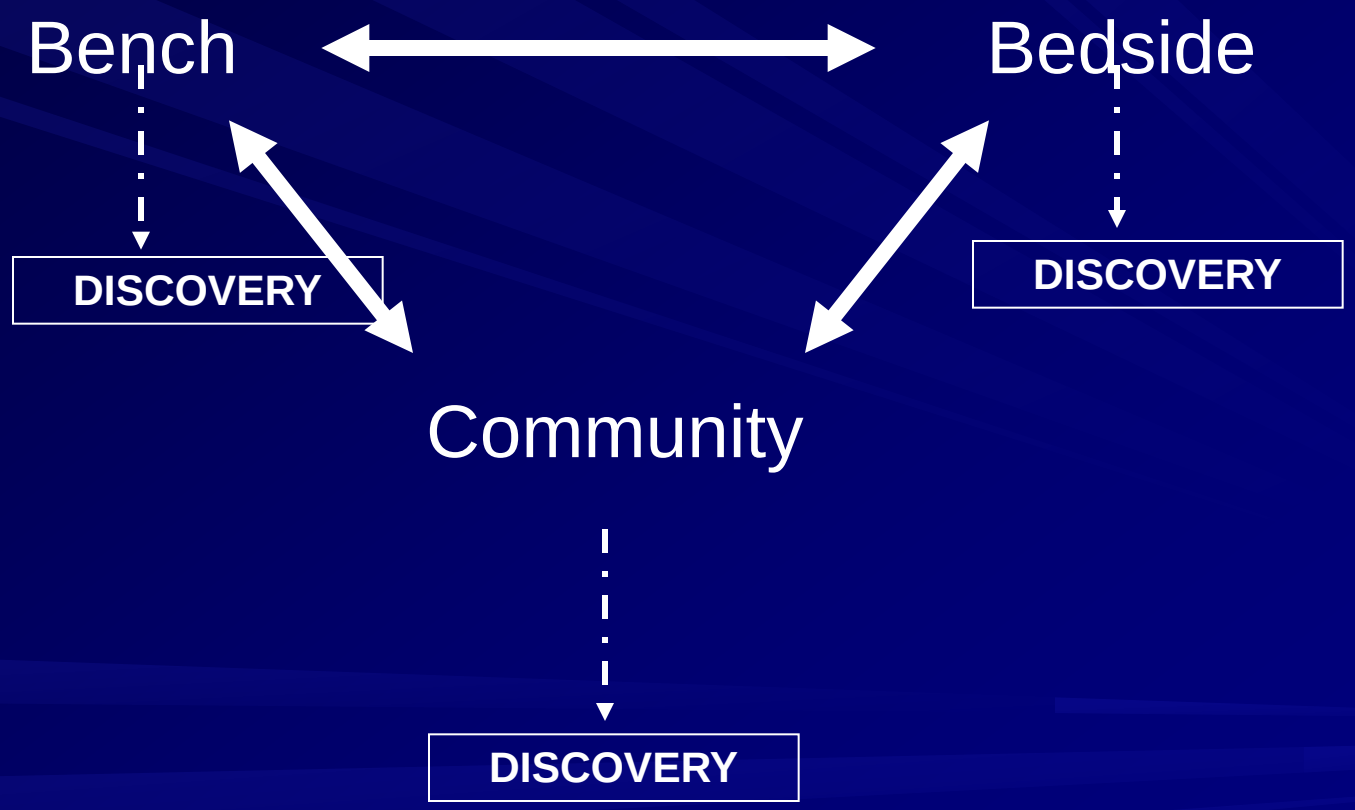
Example: Identifying models for training health workers in stigma reduction to improve patient access to HIV care.

Developing sustainable technology that uses locally available resources and maintenance expertise.

Example: Impact on neonate survival rates of using an isolette built from Toyota car parts and used in secondary health centers.

Implementation Science Triangle

Research at all levels and points



Scientific Impact Evaluation

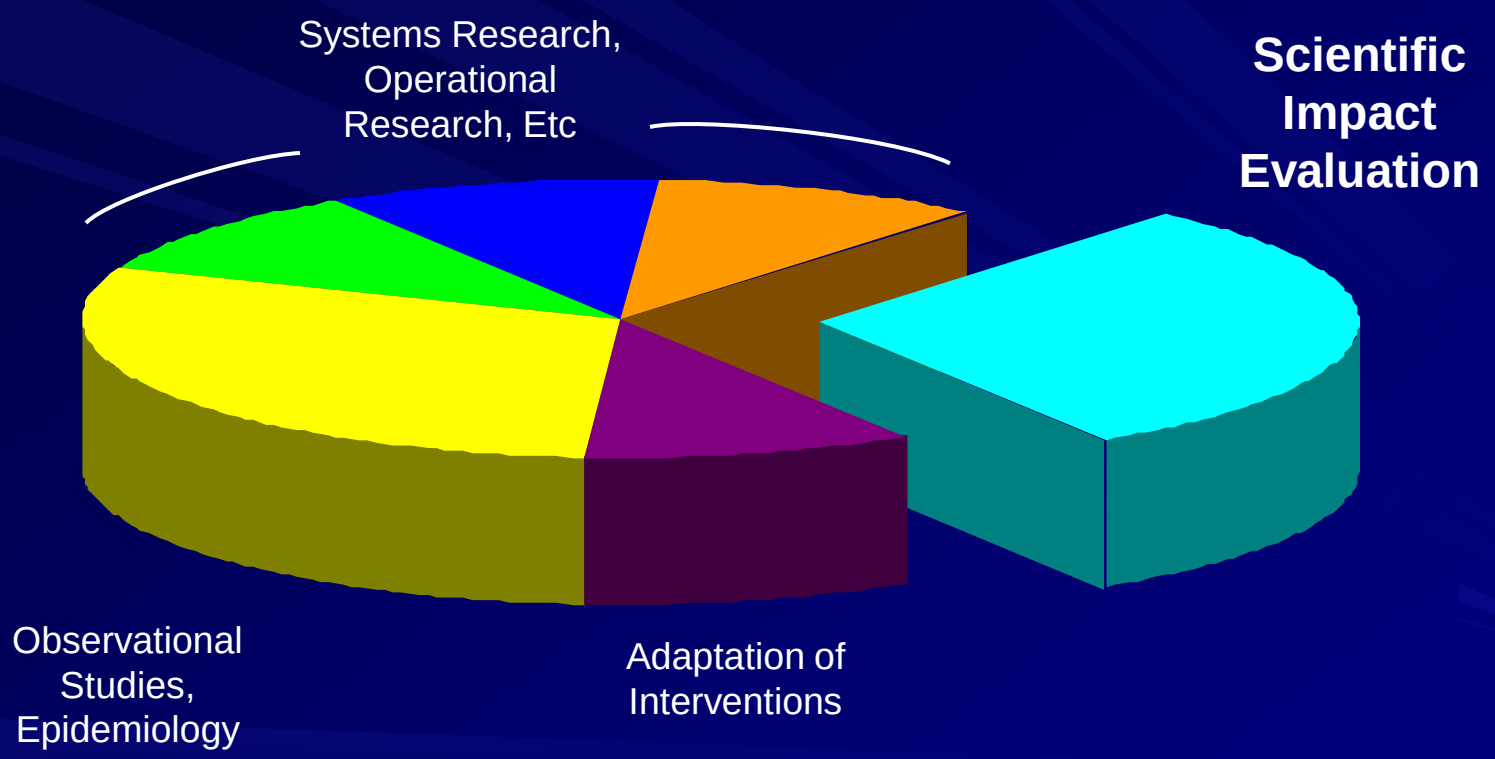
What is it?

Experimental research aimed at evaluating the effectiveness of implementation of an evidence-based medical or public health intervention in the “real world”.

Quantitative, rigorous research using experimental and quasi-experimental designs or predictive modeling.

Scientific Impact Evaluation

A piece of the Implementation Science "Pie"?



Scientific Impact Evaluation

Rigorous Impact Evaluation vs. Other Methods

Experimental (*Rigorous)*

Control groups, randomized design, rigorous statistical analysis allowing identification of the factors responsible for long-term impacts like health outcomes or educational attainment.

- Must be part of the program's planning process
- Can be costlier than non-experimental evaluation

Non-experimental

Retrospective reviews, comparisons, or observational studies enabling assessment of short-term impacts.

- Cannot establish causality
- Not able to distinguish impacts of the intervention from other, external factors
- Difficult to estimate the magnitudes of effects

Scientific Impact Evaluation

Rigorous Scientific Impact Evaluation vs. Other Methods

- "Conceptually, impact evaluation seeks to estimate the effect of a given intervention on an important development indicator by comparing with and without the intervention on the same unit of observation. "

- "Under limited budgets and scarce resources, public policy requires evidence of what works, and what does not. A rigorous impact evaluation can show if things work, and why they work. Effective evaluation will inform policy makers and permit improvements in policies and program implementation"

- OED, World Bank, 2005

Scientific Impact Evaluation

Research Challenges

Novel approaches may be needed to assess the multiple confounding factors common in Phase III and Phase IV research carried out in developing country settings.

New research methods and analytic techniques may be required for rapid, effective scale-up of health interventions done simultaneously in different developing countries.

How to move clinical research into more naturalistic environments– into real world settings with complex medical, behavioral, economic, environmental and social interactions?

Scientific Impact Evaluation

- Rigorous impact evaluation of public health interventions has been extremely limited.
- “Poorly done evaluations may mistakenly attribute positive impacts to a program when the positive results are due to something else.” (Ctr for Global Dev, 2005)
- In low-resource developing country settings we need training as well as new interdisciplinary teams:

Biomedical scientists	Social Scientists	Business Schools
Epidemiologists	Anthropologists	Health Services Researchers
Engineers	Economists	

Scientific Impact Evaluation

Examples of Failures:

"Retrospective studies in Kenya erroneously attributed improved student test scores to the provision of audiovisual aids. More rigorous random-assignment studies demonstrated little or no effect, signaling policymakers of the need to consider why there was no impact and challenging program designers to reconsider their assumptions (Glewwe and others 2004)."

- Center for Global Development, 2005

Scientific Impact Evaluation

Examples of Failure

"The Drug Abuse Resistance Education (DARE) program had been adopted in 75 percent of US school districts because it was believed to be effective; however, evaluations with random assignment demonstrated that **the program was ineffective, wasting financial resources and school time** (Lynam and others 1999; Rosenbaum and Hanson 1998)."

Center for Global Development, 2005

Scientific Impact Evaluation

Examples of Failure

"[Abstinence Education] programs led youth to report views more supportive of abstinence and less supportive of teen sex… however, program and control group youth reported similarly on views of marriage, self-concept, refusal skills, communication with parents…

There is only limited evidence that the programs affected expectations to abstain from sex."

Mathematica Policy Research, Inc. Report for HHS
Five-Year Impacts of Four Title V, Section 510
Abstinence Education Programs, 2005

Scientific Impact Evaluation

Why Scientific Impact Evaluation is Needed:

"Insecticide-treated nets which in the mid-1990s were shown to have the potential to significantly reduce malaria related under-five mortality, have up to now proved difficult to implement on a large scale, and only 6 percent of African children at risk of malaria have access."

Prof Axel Kroeger, WHO TDR

Scientific Impact Evaluation

What's being done?

Dissemination and Implementation Research in Health (R01)

- NIMH
- NCI
- NIDA
- NIDID
- OBSSR
- NINR
- NIAAA
- NIDCR
- NHLBI
- ODS

Wrapping Up

Scientific Impact Evaluation: What should be done?

Increase support for scientific impact evaluation
in developing country health sectors

Develop new approaches, methodologies, research tools

Expand impact evaluation training opportunities in developing countries, to assimilate local knowledge

Promote multi-disciplinarity of research teams,
joining health services, economics, and clinical researchers

Create multi-disciplinary curricula and core competencies

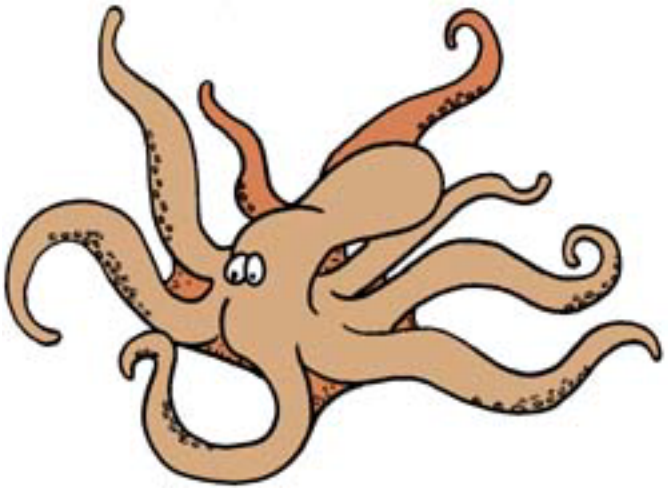
Scientific Impact Evaluation

Potential objectives for a "Scientific Impact Evaluation" Training Program:

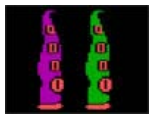
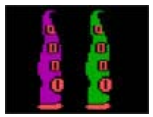
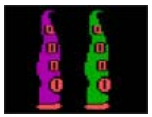
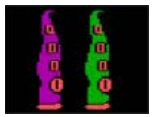
To develop rigorous impact evaluation expertise and resources in developing countries, for assessment of public health and health interventions delivered in low resource settings; and

To identify research evaluation methods, statistical and modeling tools, and experimental approaches for conducting rigorous scientific impact evaluations in developing country settings

Design and Feasibility Study to Evaluate Interdisciplinary Research Work Group (IRWG) Activities: 1 Octopus or 8 Tentacles?



Melissa W. Riddle
NIDA & IRWG
June 13, 2007
Roadmap Evaluation Representatives Meeting

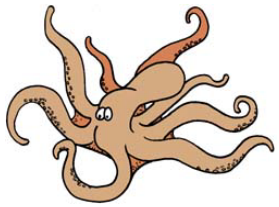
Agenda

Describe the purpose and approach of the IRWG

Highlight the IRWG initiatives

Summarize the design and feasibility phases of the IRWG evaluation

Seek feedback about tricky issues & the overall plan



NIH Roadmap's Interdisciplinary Research Work Group

Purpose

To support significance advances in public health by stimulating research that crosses boundaries defined by scientific disciplines (i.e., "interdisciplinary research" or IR)

Approach

To identify the barriers to IR and support initiatives that remove these barriers

Barriers to IR	IRWG Initiative
Both new and established investigators need IR training	RFAs to establish training programs (T32, T90/R90, K07, R13)
Some IR requires infrastructure	P20 Planning Grants and U54 Consortia

Barriers to IR	IRWG Initiative
System-level disincentives for collaborations within and across disciplines	Multiple PI policy change at NIH
IR bridging basic biological sciences and behavioral and social sciences is most difficult	Initiatives (Admin supp. & RFA) to include behavioral and social sciences

IRWG Training Initiatives

- T32: postdoc IR training
- T90/R90: undergrad, predoc, postdoc IR training; U.S. & international trainees
- K07: IR curriculum development for undergrad, predoc &/or postdoc levels
- R13: IR short-course training for all levels

IRWG Research Consortia (U54)

- Collection of IR research projects and training programs connected by a common focus (e.g., disease process or public health problem) and served by one or more infrastructure cores
  - Topics: Vector-borne diseases; inflammation; neurotherapeutics; engineering organs; antibiotic resistance; stress, self-control & addictions; etc.
  - Mechanisms: R01s, R21s, T90, R90, R25, R13, cores in biostatistics, mouse phenotyping, human subjects, neuroendocrinology, genetics

IRWG Multiple PI Policy Change

- Change in NIH policy to allow for investigators to share PI-ship on grant applications
- Required re-design of NIH's electronic record system
- Implications for funding allocation on applications using the Multiple PI option
- Not necessarily IR, but could facilitate IR

IRWG Behavioral and Social Science Initiatives

- Developing methods and technologies for IR that incorporate behavioral and social science
  - Developing IR methods for diagnosing disorders, translating physical science principles to model disease infectiousness, etc.

- Administrative Supplements to integrate biological or physical sciences and behavioral and social sciences
  - Adding genetics or neuroimaging to behavioral intervention studies
  - Adding behavioral measures or epidemiologic approaches to genetics or basic biological studies

Status of IRWG Initiatives

- T32 — 2 cohorts awarded (FY04 & FY05); **in progress**
- T90/R90 — 2 cohorts awarded (FY05 & FY06); **in progress**
- K07 — 1 cohort awarded (FY05); **completed**
- R13 — 2 cohorts awarded (FY04 & FY05); **completed**
- U54: — review completed; **awards expected 9/07**
- Multiple PI policy — NIH-wide implementation **in progress**
- BSS Admin Supp — awarded (FY05); **in progress**
- Methods R21 — **review scheduled 7/07**

IRWG Evaluation:

Design & Feasibility Phases

Evaluation funds available July, 2006

RFQ issued August, 2006

Contract awarded October, 2006

IRWG Evaluation: Design & Feasibility Study Tasks

- Clarify Initiative Objectives
- Identify and Review Relevant Literature
- Identify and Interview Stakeholders
- Develop Conceptual Framework
- Develop Study Questions
- Identify Key Variables
- Review Existing Data on Methods
- Plan for Data Collection
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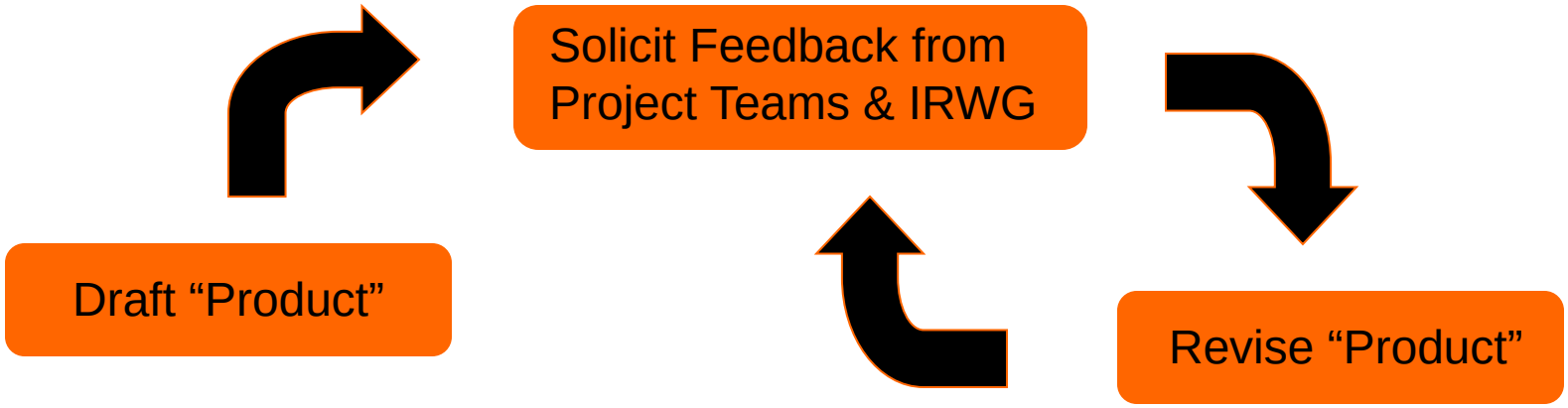
Clarify Initiative Objectives

Identify and Review Relevant Literature

Identify and Interview Stakeholders

Develop Conceptual Framework

Iterative process



Conceptual Framework: T90/R90 Logic Model

Logic Model for IRWG T90/R90: Training for a New Interdisciplinary Research Workforce

[RFA-RM-04-015, RFA-RM-06-006]

Program Goal [language from RFAs]

- Encourage and enable the development of an interdisciplinary workforce by ensuring that undergraduate, pre-doctoral, and postdoctoral students receive the didactic and research experiences necessary to lead and/or engage in integrative and team approaches to solve complex biomedical and health problems
- Support basic and clinical research to develop an interdisciplinary knowledge base for care across the life span, across disciplines, across settings during states of illness and health

Program Objectives [language from RFAs, except where noted]

Support a variety of new and innovative didactic and research experiences designed to provide students with the knowledge and research experiences necessary to develop interdisciplinary solutions to complex health problems and to increase quality and years of healthy life and eliminate health disparities

Encourage the building of training programs for students at the undergraduate, pre-doctoral, and/or postdoctoral levels.

Enable the development of a cadre of interdisciplinary research scientists by capitalizing on the infrastructure of existing multidisciplinary and interdisciplinary research programs

Promote change in institutional culture to support IR training. *[objective from interviews with stakeholders]*

NIH Resources/Activities

Grant funding for development of novel research training and education programs that:

- provide integrated interdisciplinary training for undergraduates, predoctoral and/or postdoctoral trainees, or independent faculty-level investigators
- develop and implement novel training programs focused on new interdisciplinary science
- Provide each group of students with a comprehensive research training experience

New mechanism that allows funding of international students.

Institutional Activities

Funding for trainees (undergraduates, predoctoral, postdoctoral, independent faculty-level investigators)

Program elements

- Faculty support for program/curriculum development
- Specific plans for recruitment, selection, and retention of students
- Diversity recruitment and retention plan
- Requirements do not extend time to degree
- Lab rotations and/or internships that are interdisciplinary in nature
- Develop courses with interdisciplinary focus
- Mentoring or co-mentoring by faculty in multiple disciplines
- Ample opportunity for meaningful student/faculty/ guest speaker interactions
- Opportunities to develop leadership/teambuilding skills
- Training in responsible conduct of research
- High-quality academic career advice

Identify, recruit, select and retain a diverse group of students

Conduct ongoing program evaluation, including monitoring of student progress

Short-Term Outcomes (1-2 years)

New research education and training programs in interdisciplinary research that provide a comprehensive research training experience are established. (Programs contain elements listed under activities)

Funded trainees (undergrad, grad, postdoc, international, independent faculty-level investigators)

A diverse group of students from different disciplines is recruited.

Increased collaboration among students and faculty from different disciplines

Students work in teams on interdisciplinary projects.

Students have opportunities to network with faculty and other scientists from multiple disciplines.

Students develop interdisciplinary knowledge base and research skills through coursework, lab rotations, internships.

Changes in institutional policies to reduce IR training barriers

Intermediate/Long-Term Program Outcomes (3+ years)

Students trained to integrate multiple disciplines and prepared to solve complex biomedical and health problems begin moving to next phase in pipeline (e.g., undergraduates into graduate programs; doctoral students into postdocs and/or workforce; postdocs into workforce)

Institutionalization of policies that support interdisciplinary training collaborations (e.g., shared allocation of resources)

Institutionalization of successful features of training program features (e.g., incorporation of curricula, novel training platforms, training infrastructure)

Continued IR research in areas related to training programs

Definitions (NOAA Coastal Services Center, 2004)

Program Goal: overarching aims that encompass all aspects of the program
Program Objectives: intended impacts or results of the program on participants
Resources: time, money, human resources, office space, utilities, equipment, supplies, management and partner support, etc. needed to accomplish the program
Activities: what is done in order to achieve the desired outcomes, produce the necessary outputs, or obtain resources
Short-Term Outcomes: expected immediate impacts of the program.
Intermediate/Long-Term Outcomes: intended impacts following an earlier knowledge, attitudes, or skills change as well as ultimate impacts or objectives of the program

Develop Conceptual Framework: T90/R90 Logic Model Excerpts

Program Objectives

[language from RFAs, except where noted]

(intended impacts or results of the program on participants)

Support a variety of new and innovative didactic and research experiences designed to provide students with the knowledge and research experiences necessary to develop interdisciplinary solutions to complex health problems …

Encourage the building of training programs for students at the undergraduate, pre-doctoral, and/or postdoctoral levels.

Promote change in institutional culture to support IR training. *[objective from interviews with stakeholders]*

Develop Conceptual Framework: T90/R90 Logic Model Excerpts

Activities

(time, money, human resources, office space, utilities, equipment, supplies, management and partner support needed to accomplish the program)

NIH

- Grant funding for development of novel research training and education programs that provide integrated interdisciplinary training for undergraduates, predoctoral and/or postdoctoral trainees, or independent faculty-level investigators…
- Allow funding of international students

Institutions

- Faculty support for program/curriculum development
- Specific plans for recruitment, selection, and retention of students
- Mentoring or co-mentoring by faculty in multiple disciplines

Develop Conceptual Framework: T90/R90 Logic Model Excerpts

Short-Term Outcomes
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Key Decisions to be Made

- 1 Octopus or 8 tentacles?

  -comprehensive evaluation vs. initiative-specific evaluations?

  -initiative-specific during design phase

- Inclusion of NIH process?

  -design phase is all-inclusive

- When should we aim to begin the comprehensive evaluation?

Contributors

- Abt Associates (Evaluation Contractors)
- IRWG chairpeople & project teams
  - Dr. Larry Tabak, NIDCR
  - Dr. Pat Grady, NINR
  - Dr. David Schwartz, NIEHS
- NIH Evaluation Community
  - Genevieve deAlmeida-Morris, NIDA's P&E Officer
  - Evaluation Branch