

Including Health Economics in Your Specific Aims and Approach

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Outline

- Background
- Specific Aims
- Approach
- Contact details

What cost-effectiveness research question are you interested in?

- Questions the reviewers would like answered in your grant application:
- What is:
 - the intervention?
 - the comparator?
- What outcome measures are appropriate?
- How will you evaluate intervention benefits?
- How will you measure program costs?
- Will you adjust for changes in direct medical costs resulting from the intervention?
- Can you sketch a model/tree that portrays the consequences of the intervention and its comparator?

Introduction

- Start working with a HEIST member early in your grant application process
- Send Ruanne an email request → team notified → matched with a health economist/modeler depending on the question
- Think about whether you want to add costing, modeling or cost-effectiveness analyses to your application
- Do you need a behavior economist?
- We can provide general advice or help with grant writing

The Process* - applies to health economic analyses too

- A good idea
- A good institutional fit
- Assemble a winning team
- Match the idea to a sponsor
- Read the Guidelines
- Contact the sponsor
- Plan in detail
- Develop the budget from the detailed plan
- Read the guidelines again with narrative in mind
- Be persistent - revise and resubmit

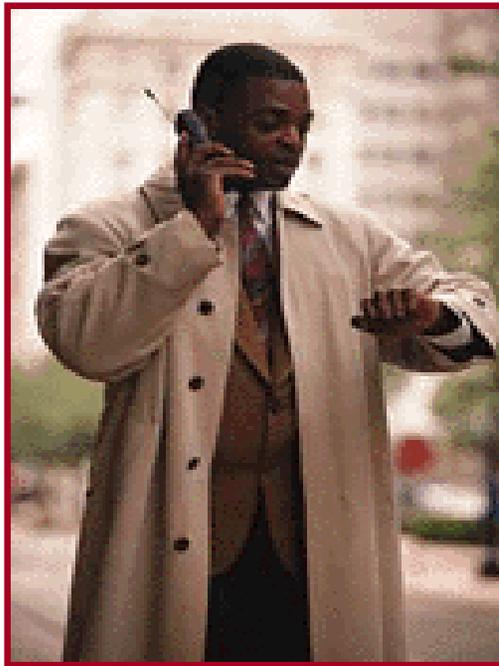
*Adapted from the NIH grant writing slides



More Questions to Ask

- Does the funding agency share your goals?
- Is the funding agency interested in the same populations?
- Has the funding agency funded projects similar to yours?
- Have they made awards to institutions similar to ours?
- Does the agency require matching?
- When will the award be made?

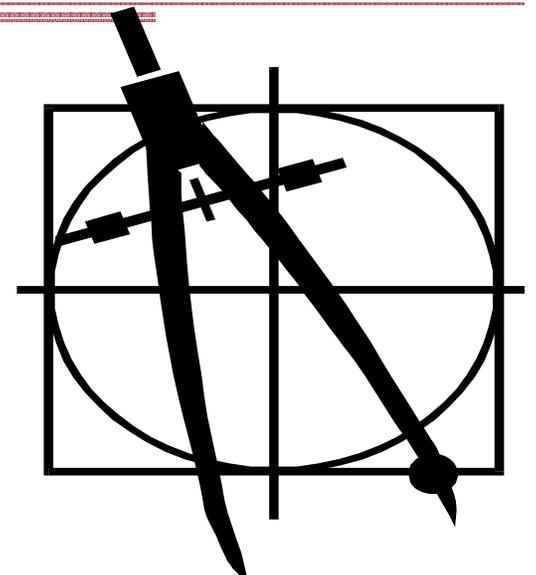
Call the Program Officer



- Health economic analyses are not always required/helpful
- Who will use the results of the economic analysis?

A Grant is not an Idea

It is a Plan



Parts of a Grant Application

- Cover Page
- Table of Contents
- Abstract
- Problem or Needs Statement
- **Goals and Objectives**
- **Methodology**
- Quality of Key Personnel
- Evaluation
- Dissemination
- References Cited
- Budget & Narrative
- Vitae
- Appendices
- Forms, Certifications and Assurances

Specific aims

- The specific aims state the essence of the proposed work in terms of **what** will be accomplished.
- Break the aim down to specific measurable pieces, the outcomes of which can be measured to determine actual accomplishments.

Specific aims

- Objectives discuss **who** is going to do **what**, **when** they will do it, and **how** it will be measured.
- Discuss desired end results of the project.
- But not how those results will be accomplished.
- They are action oriented and often begin with a verb.
- Arrange them in priority order.
- In a research proposal the objectives are the hypotheses, they are less specific, but reinforce that the project is conceptually sound.

Specific aims

- Show that you understand the problem
- Demonstrate that this is an important problem to solve, also at regional and national level
- Clearly describe the aspects of the problem that your project will address, and what gaps this will fill
- Describe the theoretical or conceptual basis for your project and your knowledge of the issues surrounding your proposed project
- Include statistical data, if appropriate
- Demonstrate that your approach is creative or innovative
- Describe how this project fits into the already existing goals of the organization

Specific aims: Questions to Ask

- What significant needs are you trying to meet?
- What is the current status of the needs?
- Will this project help meet the need?
- What really needs to be done?
- What services will be delivered? To whom? By whom?
- Is it possible to make some impact on the problem?
- What gaps exist in the knowledge base?
- What does the literature say about the significance of the problem, at a local, state, regional, national level?
- Is there evidence that this project will lead to other significant studies?
- What previous work has been done to meet this need? Was it effective?
- What will be the impact of this study?

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Motivating example: What is the most cost-effective method to promote voluntary male circumcision in Uganda (Linkages study)?

- **Target population:** HIV- uncircumcised men ages 18-49
- **Options:**
 1. Healthcare worker MC promotion at time of HIV test
 2. Healthcare worker promotion plus SMS follow-up encouraging MC within 1 month
 3. Healthcare worker promotion plus follow-up at 1 and 2 months to encourage MC and address barriers to uptake
- Option 3 may be the most effective but it is likely to incur the most costs.

Let's write a specific aim:

- Aim 1
 - To determine the uptake of MC referral by 3 months among HIV-uninfected men 16-49 years of age, with either promotion at point of HIV testing, SMS follow-up or lay-counselor follow-up visits
- Aim 2
 - ...

Pairing health economic aim with effectiveness aim

- Aim 2:
 - To evaluate the (i) incremental cost, by MC demand stimulation strategy, and the (ii) incremental cost-effectiveness, by MC demand stimulation strategy, per HIV infection and HIV related death averted.

Pairing health economic aim with effectiveness aim

- Aim 1:
 - To determine the uptake of MC referral by 3 months among HIV-uninfected men 16-49 years of age, with either promotion at point of HIV testing, SMS follow-up or lay-counsellor follow-up visits
- Aim 2:
 - To evaluate the (i) incremental cost, by MC demand stimulation strategy, and the (ii) incremental cost-effectiveness, by MC demand stimulation strategy, per HIV infection and HIV related death averted.
- Clearly link effectiveness and health economic aim

Pairing health economic aim with effectiveness aim

- To evaluate the (i) incremental cost, by MC demand stimulation strategy, and the (ii) incremental cost-effectiveness, by MC demand stimulation strategy, per HIV infection and HIV related death averted.
- Can also include hypothesis:
 - Demand creation strategies will be cost-effective per HIV infection and HIV-related death averted
- Can also include brief approach
 - Costing, modeling, and cost-effectiveness

Pairing health economic aim with effectiveness aim

- To evaluate the (i) incremental cost, by MC demand stimulation strategy, and the (ii) incremental cost-effectiveness, by MC demand stimulation strategy, per HIV infection and HIV related death averted.
- Key feature:
 - Incremental cost – measured in the study
 - Cost-effectiveness – modeling to measure health outcomes
 - ICER – combining costs and cost-effectiveness

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 - Details go in the approach section

Describe where the data will come from and how the analysis will be done for Aim 2:

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- Effectiveness of each intervention
- Prevalence of HIV in Uganda, current uptake of MC, ART coverage
- Sexual behavior, age-structure of the population, background mortality rate.
- Costs of interventions and standard of care (ie MC procedure, HIV testing, ART, hospitalization)
- Costs averted by preventing future cases of HIV through MC

Data sources:

- **Ongoing study data**
 - Current clinical trial or cohort study
- **Published peer-reviewed data**
 - Specific clinical trial or cohort (single study evidence)
 - Literature reviews (e.g. Pubmed): Examine evidence from multiple studies
 - Meta-analyses: pooled evidence from multiple studies
 - Systematic reviews: highest quality reviews or meta analyses
 - Cochrane Collaboration, Cochrane library
- **Unpublished data**
 - In country expert opinion
 - Ministry of Health
- **NGO reports**
 - UNAIDS, WHO life tables, WHO-CHOICE website, International drug price indicator Guide, Clinton Health Access Initiative (ART prices)

Published sources:

- Costs of MC, HIV/AIDS treatment, and OIs

The cost of providing comprehensive HIV treatment in PEPFAR-supported programs

Nicolas A. Menzies^{a,b}, Andres A. Berruti^{a,b}, Richard Berzon^c,
Scott Filler^a, Robert Ferris^c, Tedd V. Ellerbrock^a
and John M. Blandford^a

Medical male circumcision for HIV/AIDS prevention in Uganda – the cost of disposable versus re-usable circumcision kits

Trop Doct January 2012 42: 5-7,

HIV prevention costs and program scale: data from the PANCEA project in five low and middle-income countries

Elliot Marseille^{*1}, Lalit Dandona², Nell Marshall¹, Paul Gaist³,

- HIV transmission rates

HIV-1 transmission among HIV-1 discordant couples before and after the introduction of antiretroviral therapy

Steven J. Reynolds^{a,b}, Frederick Makumbi^c, Gertrude Nakigozi^d, Joseph Kagaayi^d, R. H. Gray^e, Maria Wawer^e, Thomas C. Quinn^{a,b}, and David Serwadda^c

VIRAL LOAD AND HETEROSEXUAL TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1

THOMAS C. QUINN, M.D., MARIA J. WAWER, M.D., NELSON SEWANKAMBO, M.B., DAVID SERWADDA, M.B., CHUANJUN LI, M.D., FRED WABWIRE-MANGEN, PH.D., MARY O. MEEHAN, B.S., THOMAS LUTALO, M.A., AND RONALD H. GRAY, M.D., FOR THE RAKAI PROJECT STUDY GROUP

Male Circumcision and Risk of Male-to-Female HIV-1

Transmission: A Multinational Prospective Study in African HIV-1 Serodiscordant Couples

Jared M. Baeten¹, Deborah Donnell², Saidi H. Kapiga^{4,5}, Allan Ronald⁶, Grace John-Stewart¹, Mubiana Inambao³, Rachel Manongi⁵, Bellington Vwalika³, and Connie Celum

- Disability adjusted life years for HIV/AIDS

Common values in assessing health outcomes from disease and injury: disability weights measurement study for the Global Burden of Disease Study 2010

Joshua A Salomon[†], Theo Vos, Daniel R Hogan, Michael Gagnon, Mohsen Naghavi, Ali Mokdad, Nazma Begum, Razibuzzaman Shah, Muhammad

Ongoing study:

- **Randomized clinical trial**
 - Linkages Study—3 arms of MC promotion
 - Trial will be used to estimate uptake (efficacy) and incremental costs of each intervention
- **Advantages of using a prospective trial – describe these in the approach section:**
 - Detailed costs—not normally recorded
 - Time and motion studies—capture staff time spent on different aspects of intervention
 - Identify areas of inefficiency (wasted resources or time) & modify protocol
 - First-hand assessment of trial quality
 - Quick turnaround of CEA for policymakers

Limitations of data sources:

- **Generalizability**
 - Population chosen for cohort, self-selection into clinical trial
 - Scale-up
- **Time frame**
 - Length of follow-up may be shorter than time horizon of CEA (can be partially addressed through modeling)
- **Study design**
 - Observational studies may contain selection bias, confounding
 - Clinical trials can have differential loss to follow-up, frequently unblinded which can induce bias, varying quality
- **Effectiveness vs. efficacy**
 - Estimates of MC uptake from an RCT may not indicate real world intervention performance (addressed by obtaining real world estimates of intervention uptake)
 - Costs may also be different in the real world (can separate out intervention costs)

Important to recognize limitations in data and vary uncertain parameters in sensitivity analysis

Research Objectives

- Generation of new knowledge
- Hypothesis or research questions
- generally short
- Example:
 - determine the impact of sheep ranching on the wild puma population in Peru
 - identify the needs of the farmers in preventing loss of sheep due to puma predation
 - formulate ranching guidelines to meet the needs of the farmer and the wild puma

Approach: The “How”



Approach

- Usually, this is the area allotted the most points
- Write this section first





Approach

- Often the most detailed and lengthy section
- What specific activities will allow you to meet your objectives
- Task oriented, specific, detailed
- Essential that you demonstrate all the steps necessary to complete project with each flowing logically from the previous to the next.



Questions for Approach

- Walk the reader through your project
- Describe the activities as they relate to the objectives
- Develop a time line and/or organizational chart
- How will the activities be conducted?
- When?
- How long?
- Who?
- Where?
- What facilities?

Approach

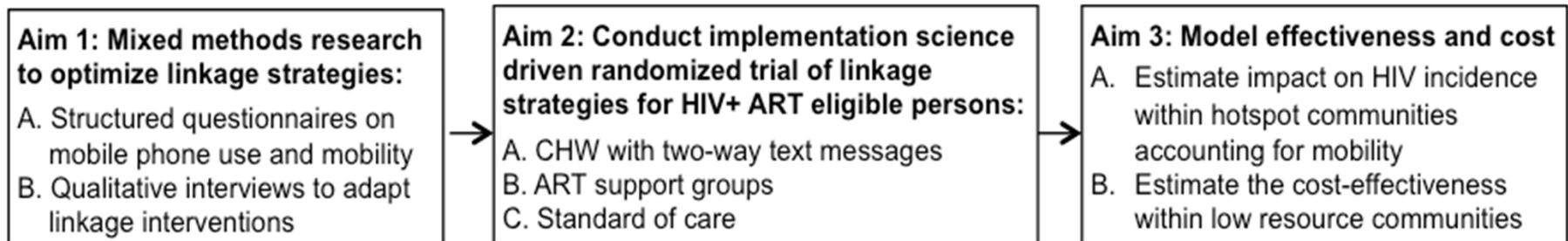
- If methodology is new or unique explain why it is better than that previously used
- Specify research design and why it was chosen.
- Include descriptions of variables and their relationships.
- Define all important terms
- Provide descriptions of data sources including subjects, how they will be selected, the size of subject pool, and the size of the sample.
- Describe all procedures
- Include pilot instruments and data when possible
- Step-by-step work plan

Approach sections

- Overview of Research Design and Methods
- Study site
- Health economic aim
 - Overall goal
 - Modeling
 - Model design
 - Data sources, parameterization, validation, assumptions
 - Model outcomes
 - Costing approach
 - Estimating cost-effectiveness

Approach

- Overview of Research Design and Methods for all aims
- Show that the aims are linked



- Study site
 - Include monthly income
 - Experience with conducting health economic analyses



Health economic aim

- Overall goal for health economic aim
- ...



Health economic aim

- Overall goal for health economic aim
- We aim to provide estimates of impact (change in HIV incidence) and cost (total costs and cost-effectiveness) for use by public health decision-makers to inform HIV treatment and prevention policies.

Modeling

- Model design
 - Compartmental vs. stochastic
- Data sources
 - Clinical trial, observational study, literature
 - Demographic and behavioral data from the study
- Parameterization
 - Existing data sources
- Validation
 - Independent data set
- Assumptions
 - Expected impact on results
- Model outcomes
 - Health units