

WRITING SPECTACULAR SPECIFIC AIMS

R² WORKSHOP

OCTOBER 21, 2014

The Cornerstone of a Research Proposal

- What are the objectives of the work?
 - Master Plan of your research.
 - Simple and easy to read.
 - Dense, full-of-jargon, poorly-written Specific Aims will not help the review of your proposal, even if the science is sound!
 - Is a useful summary for obtaining early feedback on your proposal

The Science of Specific Aims

- Unmet scientific need
- Includes project goals, hypotheses to be without fine detail
- Original ideas
- Novelty of design
- Fills a gap in the existing scientific story

The Art of Specific Aims

- Be crystal-clear in your writing!
 - State the conceptual framework
 - Limit scientific jargon
 - Non-experts in the field should understand the aims and why they are important

The Marketing of Specific Aims

- Review committee considerations
 - Not all members read every word of the proposal
 - Many read just the specific aims
- Statement of aims preceded by several paragraphs
 - National and big picture science
 - Clinical and translational importance

The Formula for Specific Aims

I. Introductory Paragraph

Opening sentence containing extremely creative thoughts. This will grab the attention of your reader.

State what is *known* about this issue.

State what is *unknown* about this issue.

State why is this lack of knowledge is important.

Formula, cont'd

2. What, Why Whom Paragraph

State the overall, long-term goal of your mission. This represents any future projections or the continuum of your line of research.

State the overall objective of this application. This is a step to achieving your long term goal.

Steps along the continuum for this research that must be achieved, regardless of how hypothesis tests.

Clearly state your central hypothesis. All vague and unfocused fishing expeditions for information will not adequately fulfill your research mission and appears as an invalid study design.

State your rationale for your hypothesis, or how did you come up with the central hypothesis.

Briefly explain why your research design are the best possible solution for the topic at hand.

Examples

- The overarching goal of this proposal is to estimate associations between prenatal exposure to mixtures of correlated endocrine disrupting chemicals (EDCs) and child neurodevelopment.
- The goal of our research is to determine the mechanism of X (or Y, or Z).
- The overall goal of our research group is to define the role of ...

Mounting evidence suggests that prenatal exposure to these EDCs may be associated with adverse child neurodevelopment, yet previous studies are limited by small sample sizes, inconsistencies in developmental measures, and differences in the timing of exposure and outcome assessments^{1,2}. More importantly, previous research has been hindered by a fundamental methodological problem: the challenge of estimating the neurodevelopmental impact of complex mixtures of highly inter-correlated EDC chemicals, with varying concentrations of constituents and potentially different effects across populations. Only recently have investigators begun developing and applying methods to study the effects of complex environmental chemical mixtures, and these methods have yet to be applied to the study of EDC effects on neurodevelopment. This is a critical research gap, as exposures to EDCs are ubiquitous in the US and other developed countries. The validation of methods for evaluating effects of chemical mixtures has been identified as a high priority by NIEHS and the National Academy of Sciences^{3,4}.

Formula, cont'd

3. Specific Aims

Detail your specific aims that will test your central hypothesis, citing primary and secondary endpoints.

Write in the ACTIVE voice.

Use verbs:

- to explain
- to examine
- to investigate
- to estimate
- to compare

Example

Specifically, we propose to:

Estimate the independent and combined associations between prenatal exposure to mixtures of correlated EDCs metabolite concentrations and age 6-7 year neurodevelopmental endpoints in the SELMA cohort based on the results of a comparative modeling strategy.

Compare the results of four different analytic strategies to model exposure-outcome associations in the SELMA cohort;

Select the strategy(s) that best meets criteria of congruence between discovery and confirmation phases and correct identification of etiologically important components in the simulation phase.

Apply the selected analytic strategy(s) from Aim I to a New York City cohort (CCCEH) to ascertain whether these methods are applicable in a heterogeneous population with different EDC exposure concentrations.

Formula, cont'd

4. Payoff paragraph

Briefly explain why this application is innovative

State plainly and simply the general positive impact that your study will have on science.

Why should the reviewers care

Why you should get funded

Why is it important for the general population

Example

Results will inform future researchers and policy makers about possible developmental risks associated with prenatal exposure to EDCs across populations of children.

Hurricane Sandy Grant

Major climatic events, such as hurricanes, appear to be increasing due to the consequences of global warming. Such events are likely associated with increased psychological stress. On October 29, 2012 Superstorm Sandy, a major hurricane, devastated the mid-Atlantic region of the United States, particularly the New York City/New Jersey area. Along the coastline, houses and businesses were destroyed and residents were evacuated; as of February 2013 some residents were still displaced. In Manhattan, few residents were displaced; those who were quickly returned. However, the storm resulted in serious perturbations to mass transportation, which led to income loss for many. Further, the storm also resulted in long-lasting power outages and shortages of basic supplies such as bread, milk and gasoline.

Pregnant women are considered a vulnerable population. There is increasing evidence that acute psychosocial stressors may be associated with adverse pregnancy outcomes, such as decreases in birth weight and decreases in gestational length. Such outcomes may be the result of acute biological responses to stressors, such as increased production of hormones such as cortisol and increased inflammatory processes. Previous studies in pregnant women following natural disasters find associations with depressive symptoms, anxiety and post-traumatic stress syndrome, and with birth weight, preterm delivery and intrauterine growth restriction; inferences from these are limited, however, because baseline measures of perceived stress were not available and sample sizes were limited.

One recent novel hypothesis relates psychosocial stress and experiences of adverse life events to decreases in leukocyte telomere length (LTL). LTL is associated with chronic diseases, particularly atherosclerotic heart disease, in adulthood and decreased longevity. Little is known regarding the determinants of LTL at birth, which is likely the largest predictor of LTL in adulthood. Given the paucity of literature, it is of interest to determine whether exposure to acute stressors in pregnancy is associated with decrements in LTL at birth.

We were fortunate to be in the process of recruiting 1000 mother-father-newborn trios for a study of prenatal determinants of leukocyte telomere length at birth (R01 HD071180) at the time of Superstorm Sandy. The trios come from prenatal clinics at Columbia University Medical Center in Manhattan and Christiana Health Care Center in Delaware. The protocol for the parent study is remarkable for: comprehensive evaluation of fetal growth by ultrasound from early in pregnancy to parturition; comprehensive measurements of maternal lifestyle, behavior, and health; and the archiving of biological specimens from mothers and newborns. In this R21 application we build upon this study and propose to evaluate the effects of Superstorm Sandy on pregnancy outcomes and LTL in newborns. Because of the timing of recruitment, we are able to evaluate several “exposure windows”, that is no exposure (i.e. birth before the storm), exposure in each trimester and in the three months prior to pregnancy. We also are fortunate to have an unexposed site to serve as a “place” control. For several important reasons, the proposed study improves upon previous work on stress and pregnancy: first, we have both time and place controls and second, we have baseline assessments of stress, social support, anxiety, depression, and resilience. Further, we have sufficient sample size to test our hypotheses. Finally, we are already administering a questionnaire to participants asking about their experiences and stress during the storm.

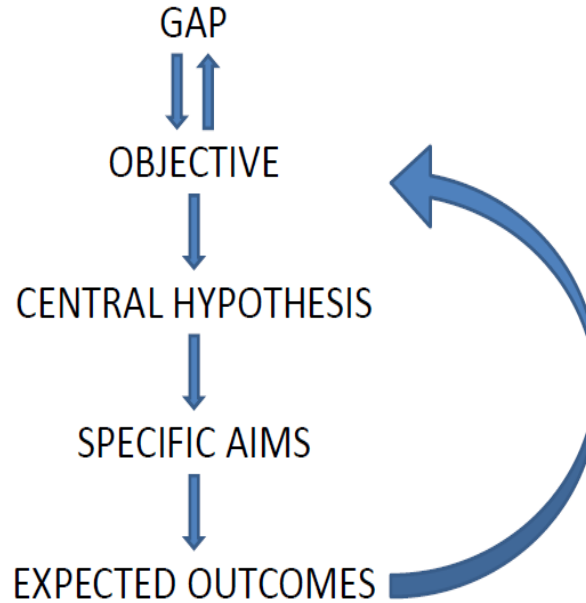
The specific aims are:

1. To examine associations between exposure to Superstorm Sandy and a) decreased length of gestation, b) reduced birth weight, c) reduced birth weight for gestational age, d) decreased head circumference, e) decreased birth length. Secondary aims will examine the associations between exposure in specific trimesters and outcomes and between exposure and dichotomous outcomes such as preterm birth and small for gestational age (SGA).

2. To examine associations between exposure to Superstorm Sandy and LTL in newborns and to examine whether associations, if any, are modified by baseline levels of perceived stress, social support, anxiety, depression and resilience.

Our results have the potential to inform emergency responders and clinicians how best to support and potentially mitigate the effects of psychological stress among pregnant women during and after a major natural disaster. This study will also set the stage for studies to inquire whether exposure to stressful events during the fetal period has long lasting effects on behavior and cognition in children.

Linear Progression of Logic for a Strong Specific Aims Section



www.usuhs.mil/medschool/faculty/ppt/writingspecificaims.pptx

Finally...

- Propose good science
- Write well
- Get feedback

R2 Sessions 2014-2015;

November 2014: Please join the Research Resources Office on Tuesday November 18, 2014 from 2:00 PM - 3:30 PM in Hess Student Commons for a talk with Ms. Elizabeth Tashiro, Associate Dean, Information Technology, MSPH. Ms. Tashiro will discuss "**Data Security And Me**". Time will be allocated for questions and answers. This event is sponsored by the Mailman School Research Resources (R2) Office. To RSVP, please email Craig Kandell at ckk7@columbia.edu.

December 2014: Please join us on Tuesday December 16, 2014 from 2:00 PM - 3:30 PM in Hess Student Commons for a talk with Ms. Rosa Rivera, Director of Sponsored Projects Administration (SPA) and Associate Dean for Grants and Contracts and Ms. Christina McCarthy, Administrator, Department of Epidemiology at the Mailman School. Ms. Rivera and Ms. McCarthy will discuss "**How To Design A Grant Budget and Justification**". Time will be allocated for questions and answers. This event is sponsored by the Mailman School Research Resources (R2) Office. To RSVP, please email Craig Kandell at ckk7@columbia.edu.

Proposed R2 Information Sessions: Proposed R2 Information Sessions (Dates, Times and Speakers TBD):

Fall 2014: **Please watch for Information Sessions on How to Prepare Center Grants!**

January 2015, How To Respond To Summary Statements, Critiques (Formerly Referred To As Pink Sheets) Information Session;

February 2015, IRB Information Session;

March 2015, Biostatistics/Database Management Information Session;

April 2015, Non-NIH Funding Sources Information Session;

May 2015, Post Award Grant Management Information Session;