PEARSON



2011 Researcher-Academic Town Meeting



Melissa C. Duff, PhD, CCC-SLP Researcher-Academic Town Meeting 2011 ASHA Convention San Diego, CA

+ Strategies for a career in clinical research

- ■The early years....
 - Training and building a foundation for a clinical research career

Clinical research

Building a foundation

Training

+ Phases of clinical research

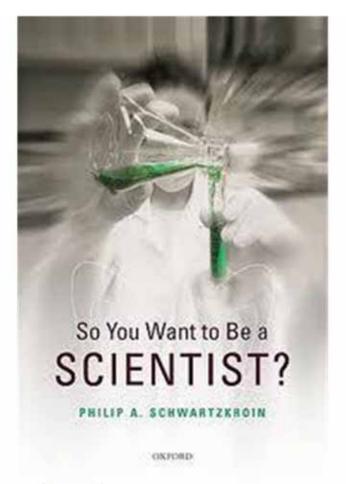
- Pre-trial studies
 - Feasibility studies
 - Early efficacy studies
 - Later efficacy studies
 - Effectiveness studies

+ Phases of clinical research

- I
- Pre-trial studies
- II
- Feasibility studies
- Early efficacy studies
- IV
- Later efficacy studies
- Effectiveness studies

+"... a decade of foundational work before you start intervention studies"

- Understanding the problem/population
- Experience and access to population
- Data analysis and management
- Developing and validating measurement
- Establishing a track record of publications
- Establishing a track record of funding
- Building infrastructure and team of collaborators



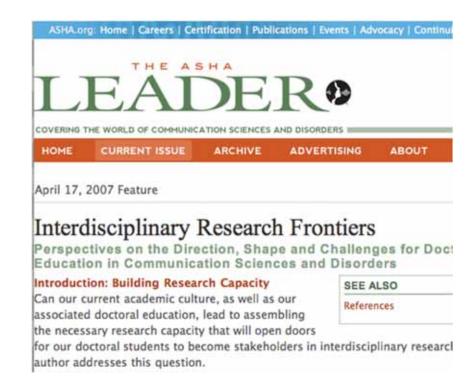
+Training

Doctoral, post-doctoral, early stage investigators

+ Interdisciplinary & Collaborative Training Models

■ Communication Sciences & Disorders

- Developmental science/psychology
- Neuroscience/neurology
- Medicine
- Otolaryngology
- Education/special education
- Linguistics
- Engineering
- Gerontology



+ Interdisciplinary & Collaborative Training Models

■ Formal

Dual degrees, interdisciplinary programs and training grants

■ Informal

 Individually organizing interdisciplinary training experience, selecting mentors

Barriers to Interdisciplinary/Collaborative Training

- Institutional/departmental obstacles
- Physical distance
- Lack of a shared terminology and methods
- Lack of funding to support
- Poor communication between mentors

Opportunities from Obstacles

- Knowledge and expertise in new set of skills and methods
- Developing diverse communication and presentation styles
- Additional peers to vet projects and opportunities for acculturation





CRISIS IN THE DISCIPLINE: A PLAN FOR RESHAPING OUR FUTURE

Report of the

Joint Ad Hoc Committee on the Shortage of PhD Students and Faculty in

Communication Sciences and Disorders

A Committee of the
American Speech-Language-Hearing Association
and the
Council of Academic Programs in Communication Sciences and Disorders

December 2002

+

+ Post-doctoral training

■ TIME!

- To publish your dissertation
- To read, read!
- To acquire new skills and methods
- To get grant writing experience (NIH NRSA F32)
- To build a publication record
- To start new projects and collect new data (pre-trial; feasibility)
- To start mentoring students
- To get mentor training
- To begin new collaborations

Setting

- In field vs. out of field
- Lab vs. clinical setting

Mentor

- Clinician-researcher
- Skilled grant writer/





eligibility



apply online

EXTRAMURAL LRPs FOR RESEARCHERS OUTSIDE NIM

- ▶ CLINICAL RESEARCH
- ▶ PEDIATRIC RESEARCH
- HEALTH DISPARITIES RESEARCH
- CONTRACEPTION AND INFERTILITY RESEARCH
- CLINICAL RESEARCH FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS

INTRAMURAL LRPS FOR NIH EMPLOYEE RESEARCHERS

- ▶ AIDS RESEARCH
- CLINICAL RESEARCH FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS
- GENERAL RESEARCH (INCLUDING LRP FOR ACGME FELLOWS)

NIH EMPLOYEE STUDENT LOAN REPAYMENT PROGRAM

APPLICANT INFORMATION BULLETIN

REPORTS & STATISTICS

POLICY & GUIDANCE

Home > About the Programs > Clinical Research

PRINT I FONT +/-

SCIENTIFIC BREAKTHROUGHS FROM BENCH TO BEDSIDE

Program Purpose

The purpose of the Clinical Research LRP is to recruit and retain highly qualified health professionals as clinical investigators.

Program Announcement

See Notice for Extramural Loan Repayment Program for Clinical Research (LRP-CR) for program and policy guidance.

Program Eligibility

- Meet general eligibility requirements of the LRPs outlined in the eligibility section of the size
- Have an M.D., Ph.D., Pharm. D., Psy.D., D.O., D.D.S., D.M.D., D.P.M., D.C., N.D., or equivalent doctoral degree from an accredited institution
- Engage in qualified clinical research

Definitions

Clinical Research

Patient-oriented research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, epidemiologic or behavioral studies, outcomes or health services research, or developing new technologies, therapeutic interventions, or clinical trials.



www.lrp.nih.gov

+ Early Stage Investigators

- Increased mentoring opportunities
 - ASHA Mentoring Academic-Research Careers (MARC)
 - ASHA Lessons for Success Research Workshop (LfS)
 - ASHA Clinical Practice Research Institute (CPRI)
- Increase opportunities for mentored experience in research
 - ASHFoundation Clinical Research Grant (mentored treatment research)
 - NIH K Awards
- Establishing independence
 - Defining roles on collaborative teams
 - Tenure







- A foundation of work to support early stage and future clinical research
 - Developing a strategy for productivity and funding while building a programmatic line of research
 - Feasibility and development studies
 - Building a population base, infrastructure, and a team

Iowa Traumatic Brain Injury Registry

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Iowa Traumatic Brain Injury Registry

Population Characterization

- Neuropsychological
- Neuroanatomical

Iowa Traumatic Brain Injury Registry

Foundational Empirical/Feasibility Studies

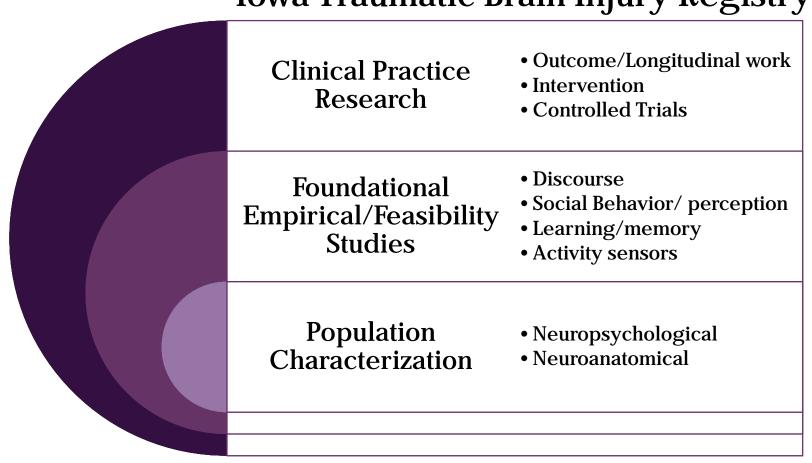
Population Characterization

Possible Population Characterization

• Discourse • Social Behavior/ perception • Learning/memory • Activity sensors

• Neuropsychological • Neuroanatomical

Iowa Traumatic Brain Injury Registry







Training the Next Generation of Clinical Researchers

MARY PAT MOELLER, PH.D.

RESEARCHER-ACADEMIC TOWN MEETING
ASHA NATIONAL CONVENTION
SAN DIEGO, CA
NOVEMBER 16, 2011







Overview: My charge



- Discuss strategies for preparing researchers to contribute to knowledge in prevention, assessment and treatment
- Three premises related to:
 - The need for clinical practice research to progress through systematic phases - How did our early work support a larger, multi-center investigation related to CPR?
 - The importance of research collaborations in CPR What have we discovered about maintaining successful collaborations?
 - Ingredients for developing a career focused on CPR What has worked from our perspective?

Background: An Early Wake-Up Call!!



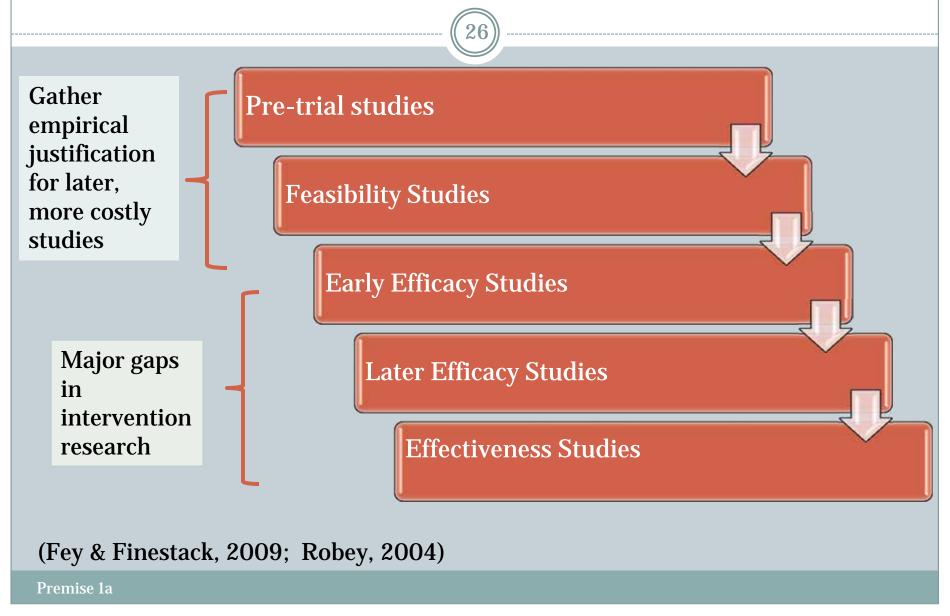
- USPSTF Systematic Review (2004)
 - "The evidence is insufficient to recommend for or against routine screening of newborns for hearing loss..."
 - This motivated outcomes studies (some population-based)
 - Major research needs remain...
 - x In a *new generation* of children, with earlier access to better technologies...
 - In general, there are few studies documenting the efficacy and effectiveness of interventions for this population of children
 - Clinical practice research represents a *critical need* if we are to harness the potential of newborn hearing screening

Premise 1

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TO STRENGTHEN THE EVIDENCE BASE, THERE IS A PRESSING NEED TO APPROACH CPR THROUGH SYSTEMATIC STAGES.

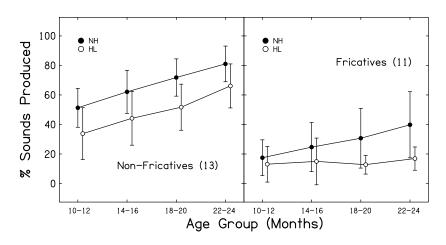
Premise 1: To strengthen the evidence base, there is a pressing need to approach CPR through systematic stages.



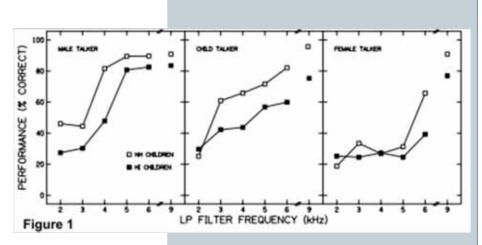
Building on a foundation of early-phase studies...



- Longitudinal studies of early-identified children with hearing loss
 - Language Development Lab + Hearing Aid Research Lab
- Identification of factors influencing early outcomes
- Identifying risks, developing sensitive measures, recognizing gaps



Moeller, et al. Ear & Hearing (2007)



Stelmachowicz, et al., Ear & Hearing (2001)



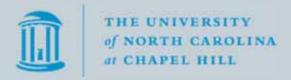
Need to apply health outcomes research methods to a population sample...

In a low-incidence, challenging-to-recruit population It is going to take a village!!

Step 1: Forming a team with overlapping & complementary interests, goals and skills



Longitudinal, health-outcomes research expertise Child language research expertise Operational Infrastructure Biostatistics & Data management





Outcomes research related to clinical management of children with HL Expertise in pediatric hearing loss & pediatric amplification Population access

To address the more complicated story...

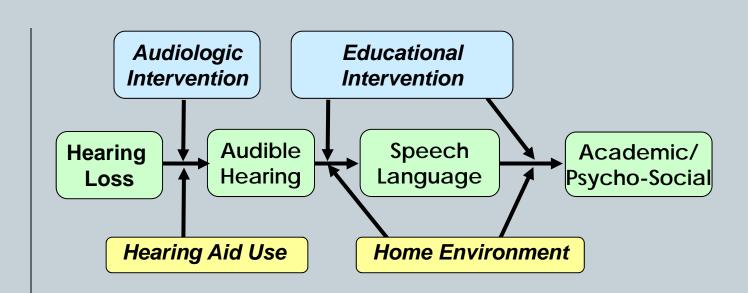
29)

Multi-center, multi-disciplinary longitudinal outcomes study

Clinical Moderators

Mediators & Outcomes

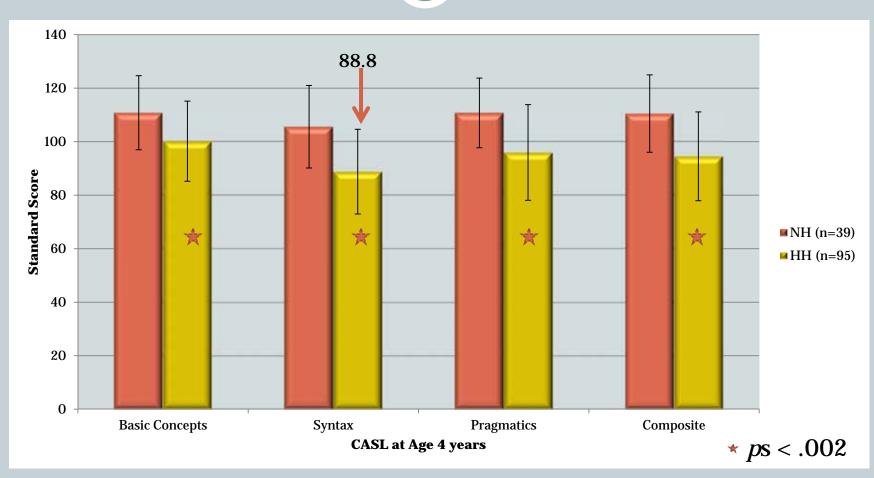
Non-clinical Moderators



306 children who are hard of hearing; 112 children with normal hearing

Identifying vulnerabilities: Phonology & Syntax?





Premise 2

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TO MAINTAIN STRONG COLLABORATIONS, CONSIDER ADOPTING MODELS FROM THE FIELD OF *LEADERSHIP*.

Behaviors of Effective Teams

Invest in quality control & project tracking

Committed to achieving clear goals

Hold one another accountable

Focus on

Lack of territoriality across sites

Commit

Mine the conflict

Engage in Conflict

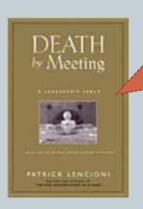
Develop Trust

Ground rules for inclusive communicationStrengths-based management

Adapted from: Lencioni (2002) The Five Dysfunctions of a Team

Leadership Resources Supporting Collaboration

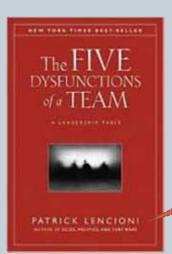




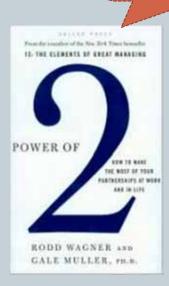
- •Be willing to ask, "Is this working?"
- •Find more efficient processes
- •Our solution: subgroup meetings; strategic focus to large group meetings



- •Complementary strengths
- •Clear, common mission
- •Communication



- •Channel competition toward the study goals
- •Create single entity transcending sites
- •Hold team/members accountable



Premise 3:

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TO FOSTER SUCCESSFUL CAREERS IN CPR, WE NEED:

- 1. CLOSER ALIGNMENTS BETWEEN LABORATORIES & CLINICS
- 2. STRATEGIC SUPPORTS FOR POST DOCS AND EARLY STAGE INVESTIGATORS
- 3. ADDITIONAL OPPORTUNITIES FOR MENTORED RESEARCH EXPERIENCES

Closer alignments between laboratories & clinical programs

- My story...a road less travelled?
 - Research mentoring WHILE in the clinic
 - Late career PhD
 - Worked at an organization that valued the creation of multidisciplinary research teams
 - Research labs closely linked to clinical programs
- Applicable models from this experience?
 - Program directors with clinical + research experience
 - Opportunities for post docs and early stage investigators to gain relevant clinical experiences
 - Involvement of clinicians as laboratory Research Assistants & members of research teams
 - Train clinical staff in EBP concepts; critical consumers of research & appreciate links from research to practice

Strategic supports for post docs and early stage investigators

- Formal and informal supports that have been successful:
 - Regular contact with senior researchers in 4 regularlyscheduled journal groups
 - Grant writing infrastructure and systematic mentoring process
 - Peer "writing groups" accountability for regular writing & opportunities for feedback (mentor oversight)
 - Collegial scientific lecture series— promotes cross-lab discussions and collaborative opportunities
 - Cross-lab sharing of "in progress" studies
 - Senior investigators "mentor the mentors"

Increase Opportunities for Mentored Clinical Research Experiences

NIDCD

- Network of short-term research traineeships for AUD students (T35 grant)
 - o BTNRH, VA Center in Portland, OR, Vanderbilt U, Wash U
 - Two to three month mentored research experience (summer)
 - o 19/19 trainees present at AAS meeting
 - o 25% of participants entered or plan to enter PhD programs
- Provides post-docs with student mentoring experiences
- Extend this effective model to SLPs?

Increase Opportunities for Mentored Clinical Research Experiences

- Linking AUD students with clinical-research settings for Capstone Projects
 - Insist that students conduct empirically-based, hypothesis testing projects as part of the degree requirements
 - Consider clinical-research settings as partners in this enterprise
- Cultivate externship opportunities that combine clinical and research experiences
- Provide graduate coursework devoted to translational and clinical practice research
- Identify CPR interests early
 - Tailor curricular demands?
 - Provide role models who emphasize the value of CPR
 - Provide externships in research settings

In Summary...Key Premises Revisited

- **Premise 1:** To strengthen the evidence base, there is a pressing need to approach CPR through systematic stages.
- **Premise 2:** We accelerate CPR agendas through collaborative science; but to maintain strong collaborations, consider adopting models from the field of *leadership*.
- **Premise 3:** To foster successful careers in CPR, we need closer alignments between laboratories & clinics, strategic supports for early stage investigators, and additional opportunities for mentored CPR experiences.

Thanks





Any questions?

References:

Lencioni, P (2002). *The Five Dysfunctions of a Team.* San Francisco: Jossey-Bass.

Lencioni, P. (2004). *Death by Meeting*. San Francisco: Jossey-Bass.

Wagner, R. & Muller, G. (2009). Power of 2: How to make the most of partnerships at work and in life. NY: Gallup Press.



Time to Fire Up the Voltage to your Thinking Caps







Here's What We're Doing.....



- Select a topic or topics for discussion at your tables
- 20 minutes for table discussion
- 30 minutes for reports and questions for the panelists.
- 3 minute time limit per speaker

Strictly enforced!

Discussion Topics

- 1. How can institutions foster interdisciplinary clinical research opportunities for doctoral students, postdoctoral fellows and young faculty?
- 2. Clinical practice research represents a continuum from early stage feasibility studies, through randomized clinical trials in controlled settings, to randomized trials in actual practice settings. How can institutions encourage studies along the continuum and help researchers select the appropriate stage for their research?
- 3. What strategies should investigators follow to make their funding applications for clinical research attractive to reviewers?
- 4. Mentoring the mentors: What can programs/departments do to help individuals learn strong mentoring skills?
- 5. What models of mentoring have been effective at your institution for helping doctoral students, postdoctoral fellows, and junior faculty develop and continue clinical research?

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