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2009 Researcher-Academic Town Meeting

Clinical Practice Research in Speech-Language Pathology: The Final Frontier

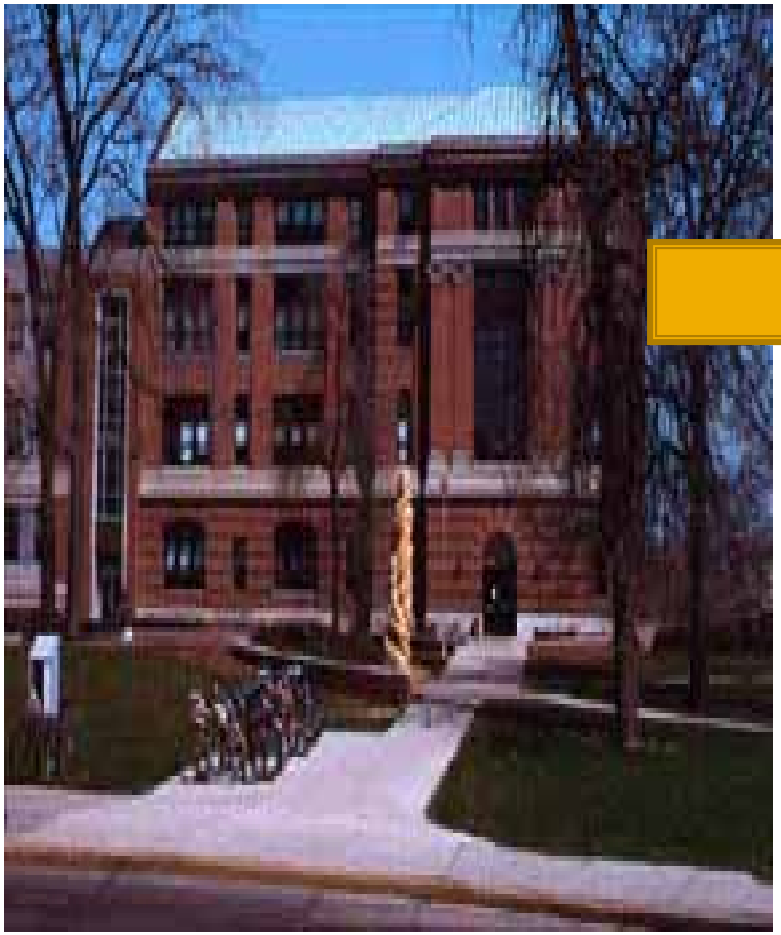
Laura Justice
The Ohio State University

2009 Researcher-Academic Town Meeting
Nov 18 2009

My Charge

to describe the **needs** and **challenges** of clinical practice research and how they might be addressed by individuals who want to pursue this type of research

A Personal Journey from "Bench to Bedside"



Framework and Premises

Preschoolers' literacy skills are consistently and significantly related to later reading achievement

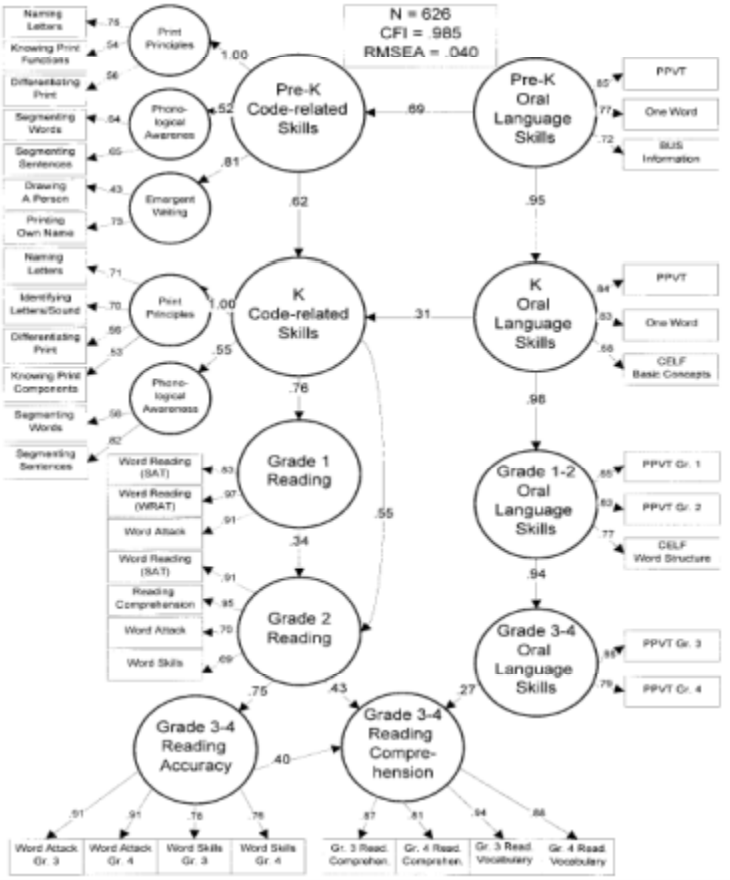
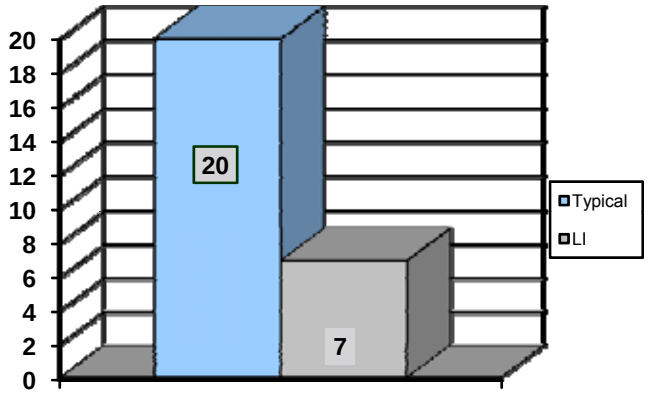


Figure 1. Structural model of literacy development from preschool through fourth grade. PPVT = Peabody Picture Vocabulary Test—Revised (Dunn & Dunn, 1981); One Word = One Word Picture Vocabulary Test (Gardner, 1990); BUS = The Renfrew Bus Story—American edition (Glasgow & Cowley, 1994); CELF = Clinical Evaluation of Language Fundamentals (Semel et al., 1987; Wiig et al., 1992); SAT = Stanford Achievement Test—Eighth Edition (The Psychological Corporation, 1989); WRAT = Wide Range Achievement Test—Revised (Jastak & Wilkinson, 1984). Gr. = Grade, Comprehen. = Comprehension.

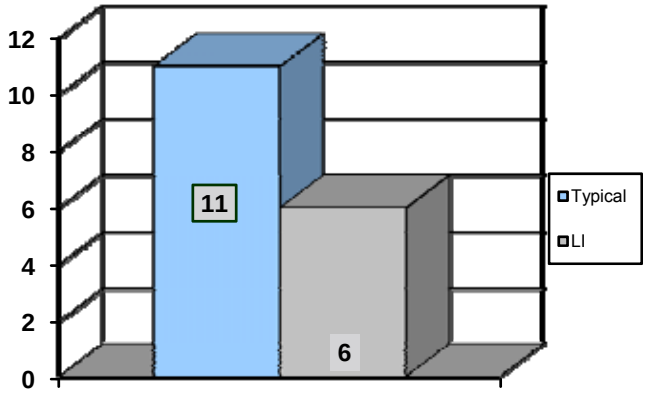
Storch & Whitehurst, 2002

Framework and Premises

Preschoolers with language impairment (LI) consistently exhibit lags in development of early literacy skills, particularly **print knowledge**



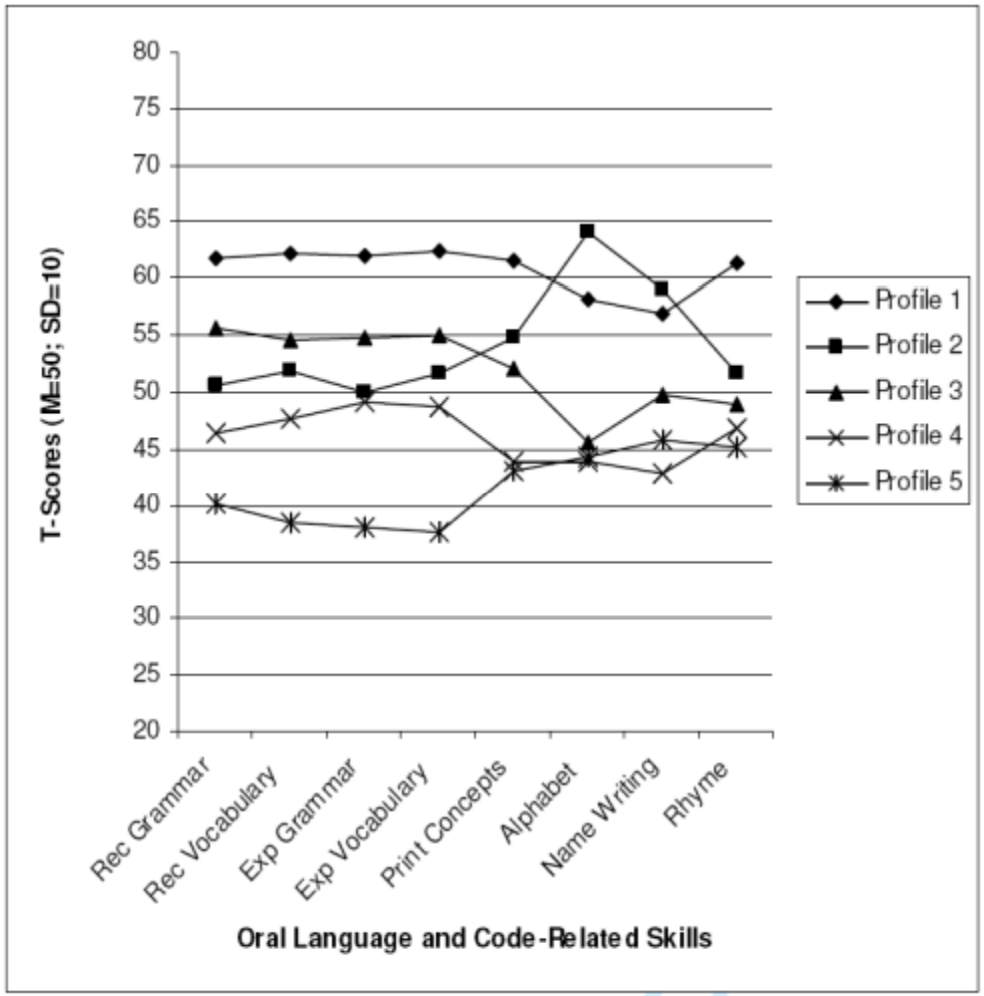
Left: Upper-case alphabet
Below: Name-writing



Cabell, Justice, Zucker, & McGinty, 2009

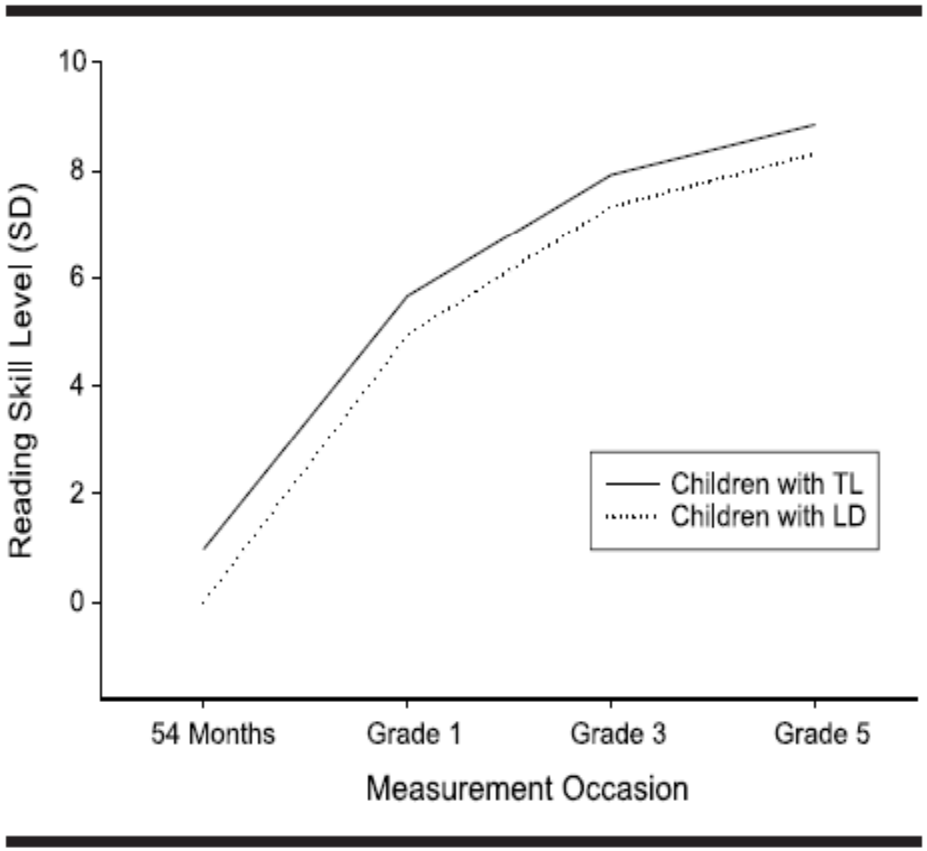
Framework and Premises

Language difficulties and lags in **print knowledge** often co-occur in larger population of young children considered "at-risk" (estimated profile at 16%)



Framework and Premises

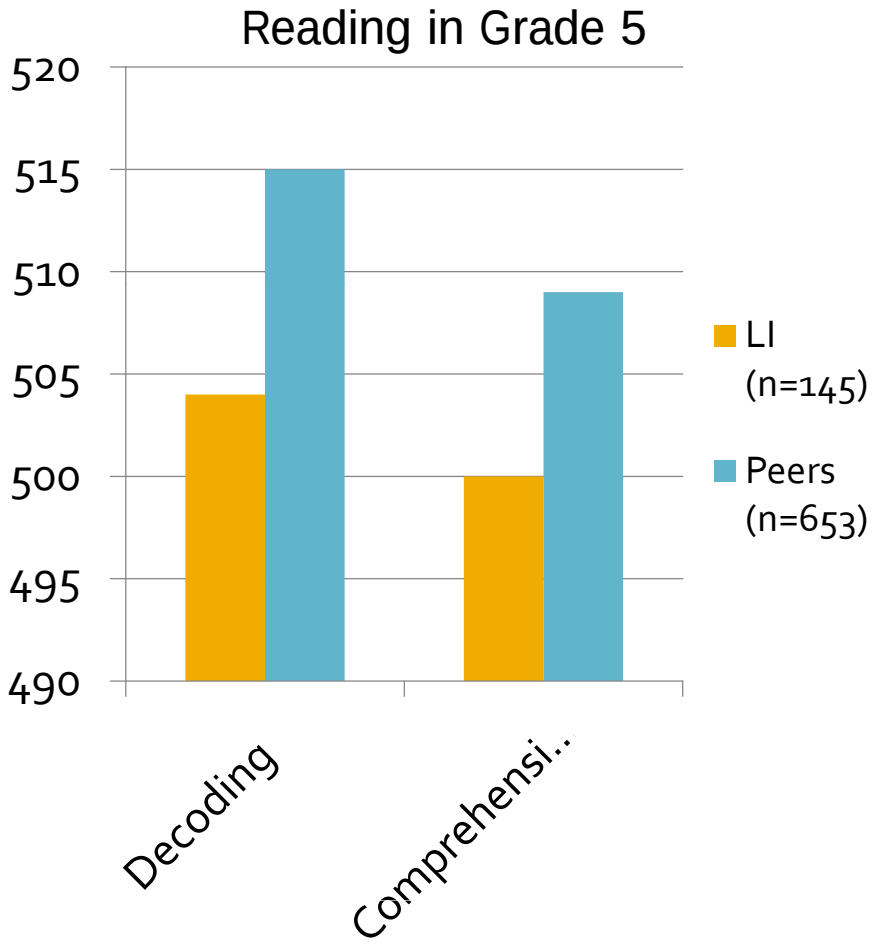
Early lags in early literacy skills for children with LI contribute to long-term risks in reading achievement



Skibbe, Grimm, Stanton-Chapman, Justice, Pence, & Bowles, 2008

Framework and Premises

This cascade of effects results in functional disadvantages in reading outcomes for children with a history of LI



Skibbe, Grimm, Stanton-Chapman, Justice, Pence, & Bowles, 2008

Program of Research

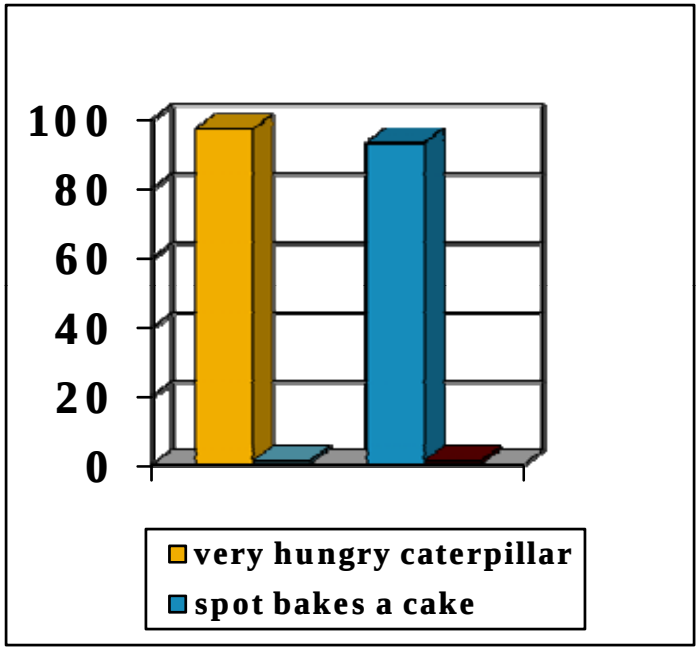
Increasing Children's Contact With Print

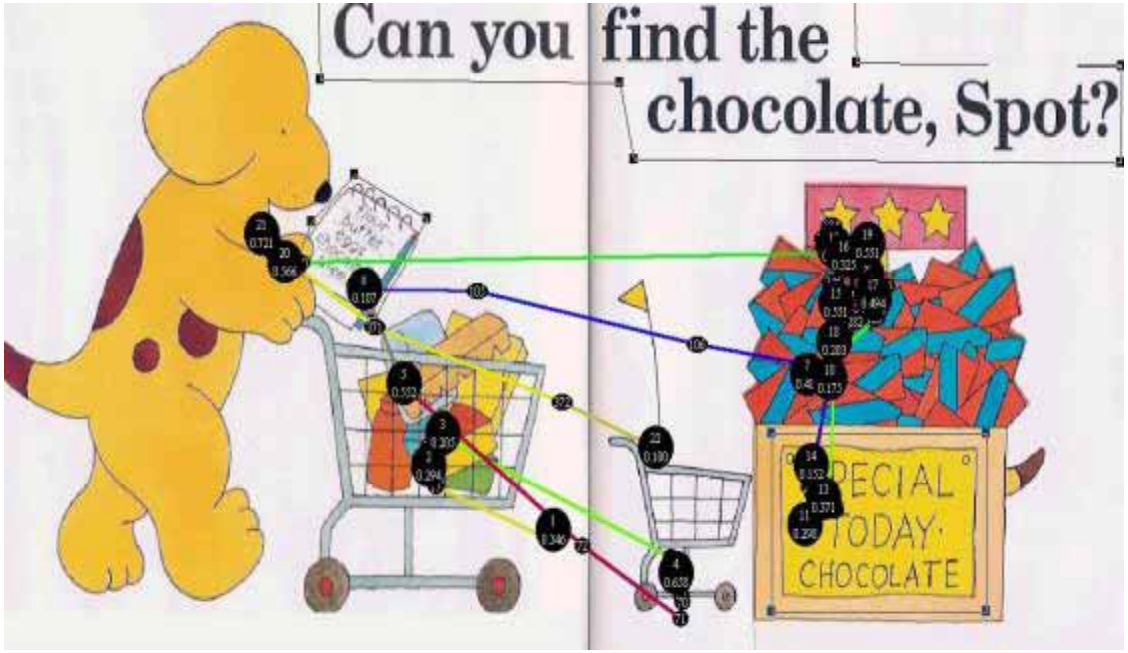
Clinical Outcomes Research

Identification Research	Feasibility Research	Efficacy Research	Meta-Analyses	Scale-Up Research
Identification of key mechanisms through which children develop early literacy skills during literacy events	Early tests of intervention potential	True tests of intervention potential (designed to make strong causal inferences)	Unbiased estimates of effects as aggregated across studies	Estimates of effects when implemented in variety of routine settings; tests of moderation

Identification Research

Children have very little contact with print during literacy events

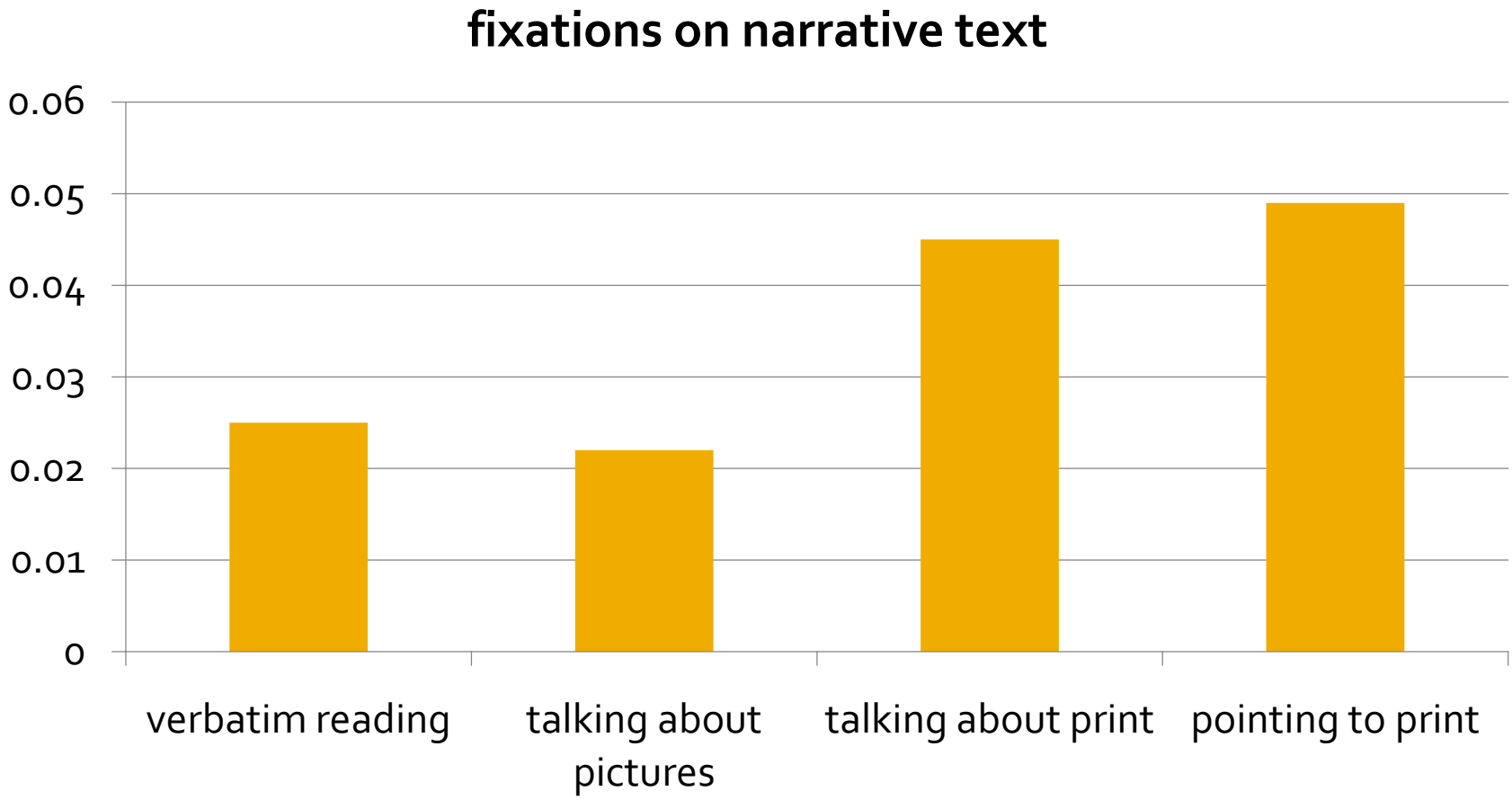




Justice, Skibbe, Canning, & Lankford, 2005

Feasibility Research

Adults can increase children's contact with print during literacy events

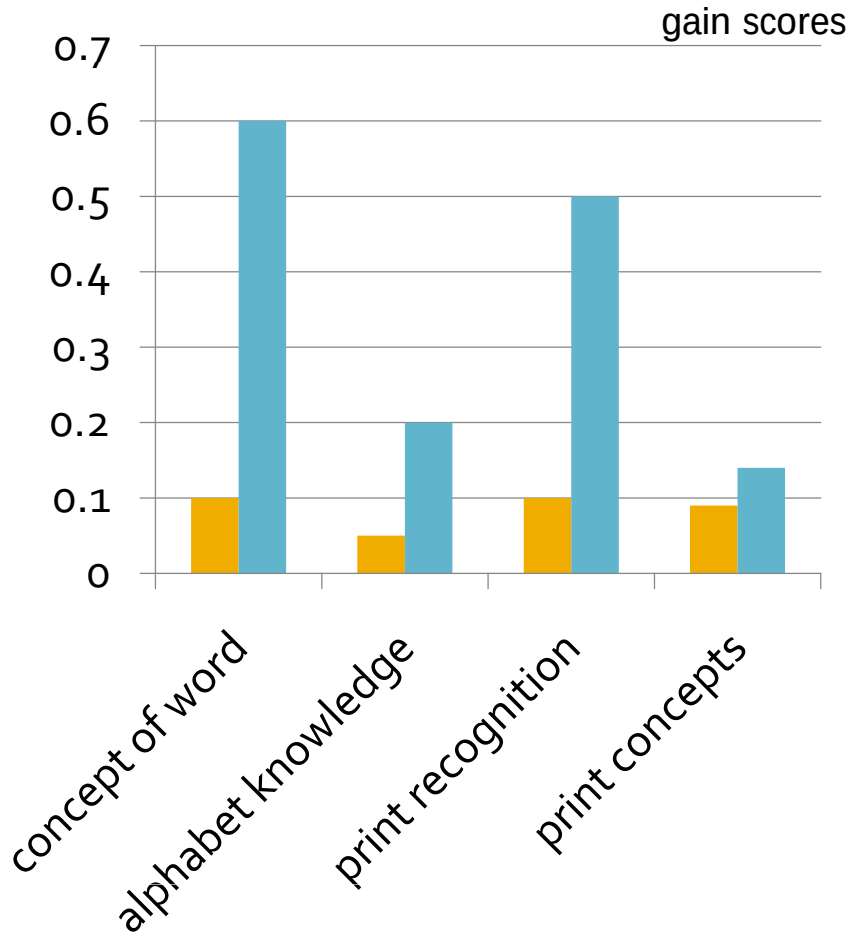


Justice, Pullen, & Pence, 2009

Efficacy Research

*Referencing print has **strong causal impacts** on children's early literacy skills*

- 38 preschoolers
- random assignment to reading conditions:
  print focus
  picture focus
- 24 small-group reading sessions in Head Start

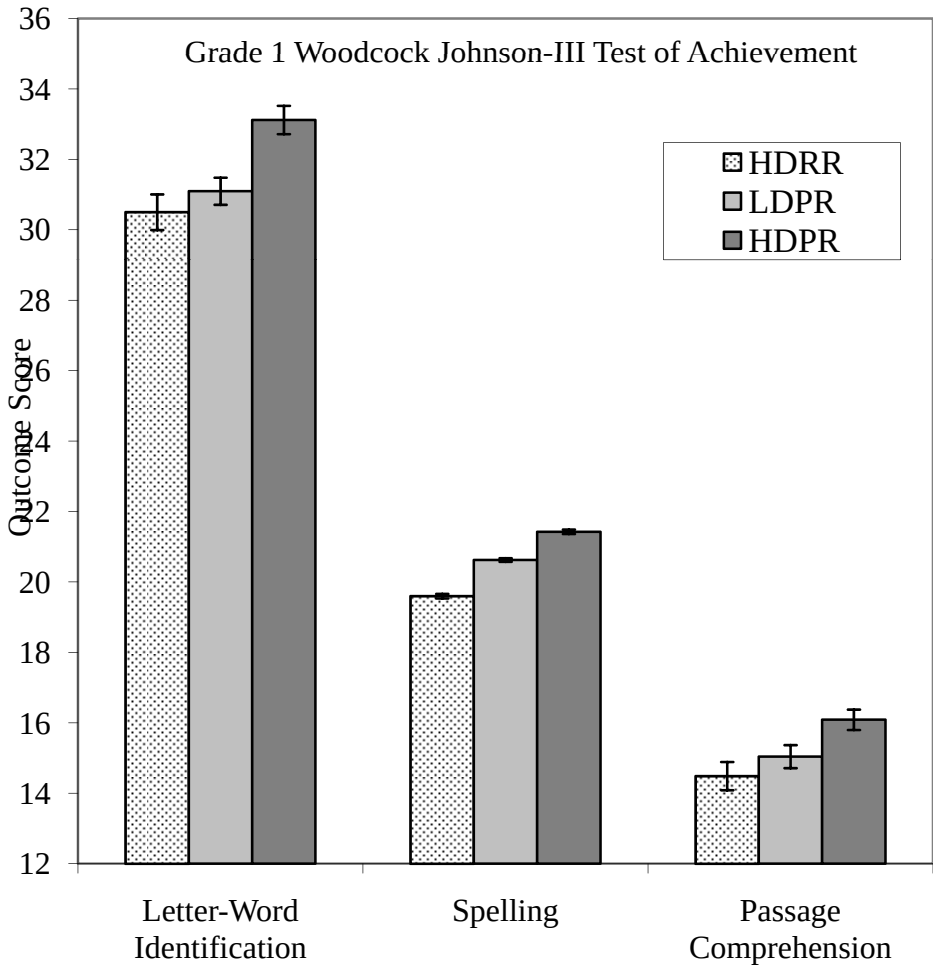


Justice & Ezell, 2002

Scale-Up (Effectiveness) Research

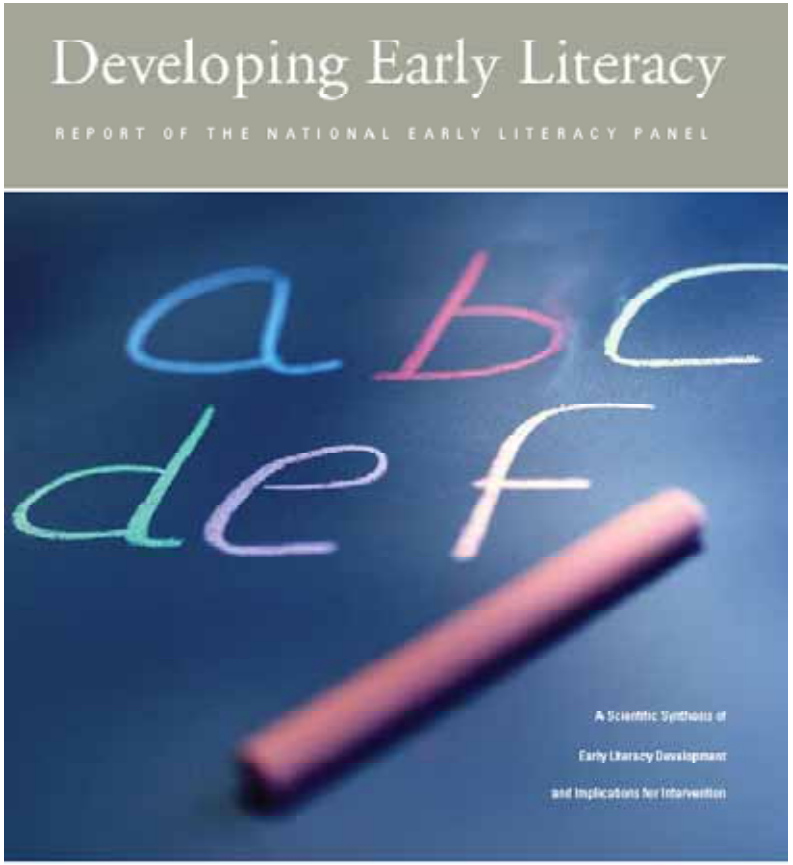
*Referencing print has **longitudinal impacts** on reading achievement when implemented in everyday circumstances*

- 84 preK teachers in high-risk classrooms
- random assignment to reading conditions:
  - **everyday regular reading (HDRR)**
  - **everyday print referencing (HDPR)**
  - **twice-weekly print referencing (LDPR)**
- 4-6 children randomly selected and tracked for 3 years (n =



Piasta, Justice, & Kaderavek, 2009

Meta-Analysis



ES Estimate = .51

95% CI 0.28 to 0.73
($p < .0001$)

(Based on 4 studies with print knowledge as DV)

The Final Frontier: Diffusion and Dissemination

From Librarians to Ladies (First Ladies of Ohio, that is)...

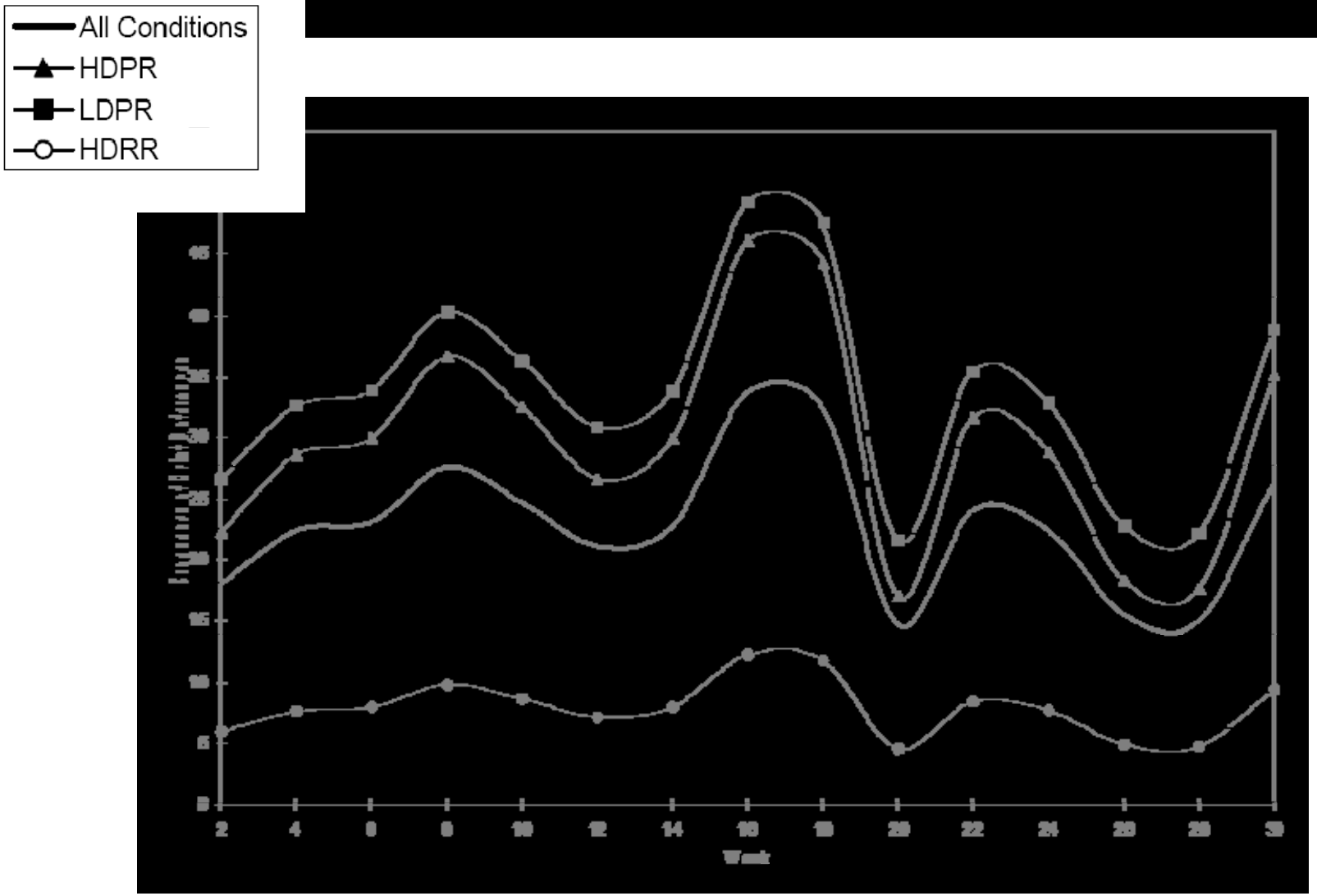
The Final Frontier: Diffusion and Dissemination

Some issues in translating research into practice:

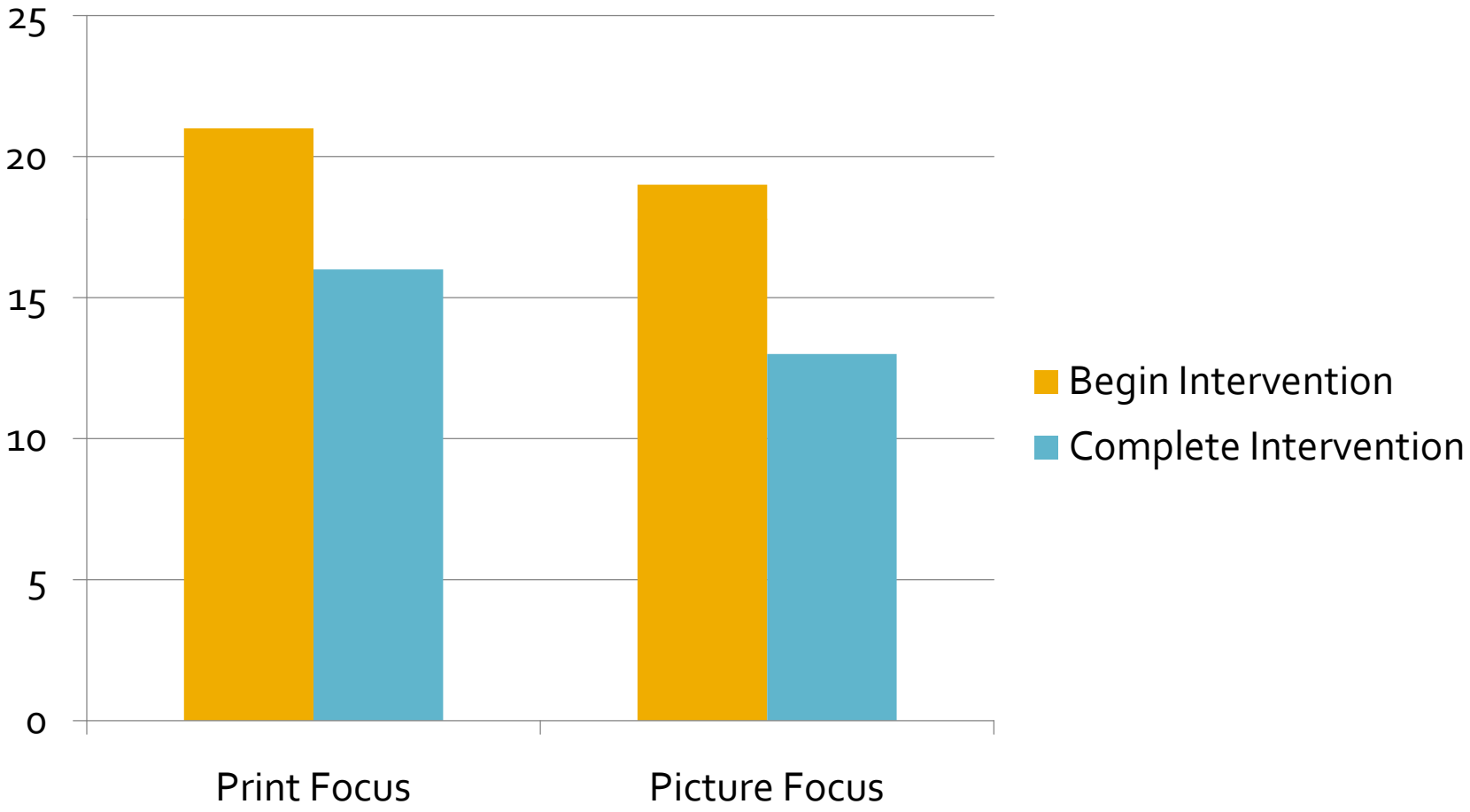
- **Storybook features** affect intervention implementation (session dose)
- **Session dose** affects child gains
- **Outcomes** attenuated or non-existent for some subgroups of children
- Some parents **cannot** complete this intervention (attrition estimates of 28%)

Attributes of Intervention Stimuli:

Association with Implementatoin Dose



Attrition Rates
Caregivers of Children with SLI



Justice, Skibbe, McGinty, Piasta, & Petrill, 2009

Clinical Practice Research in SLP

a subset of the larger domain of "clinical research" that investigates methods to:

(a) **prevent** disorders,
(b) **improve** the accuracy and precision of diagnostic and screening materials,
(c) **enhance** the effectiveness of therapeutic interventions, and
(d) **optimize** the cost-benefit ratio of services provided by audiologists and speech-language pathologists

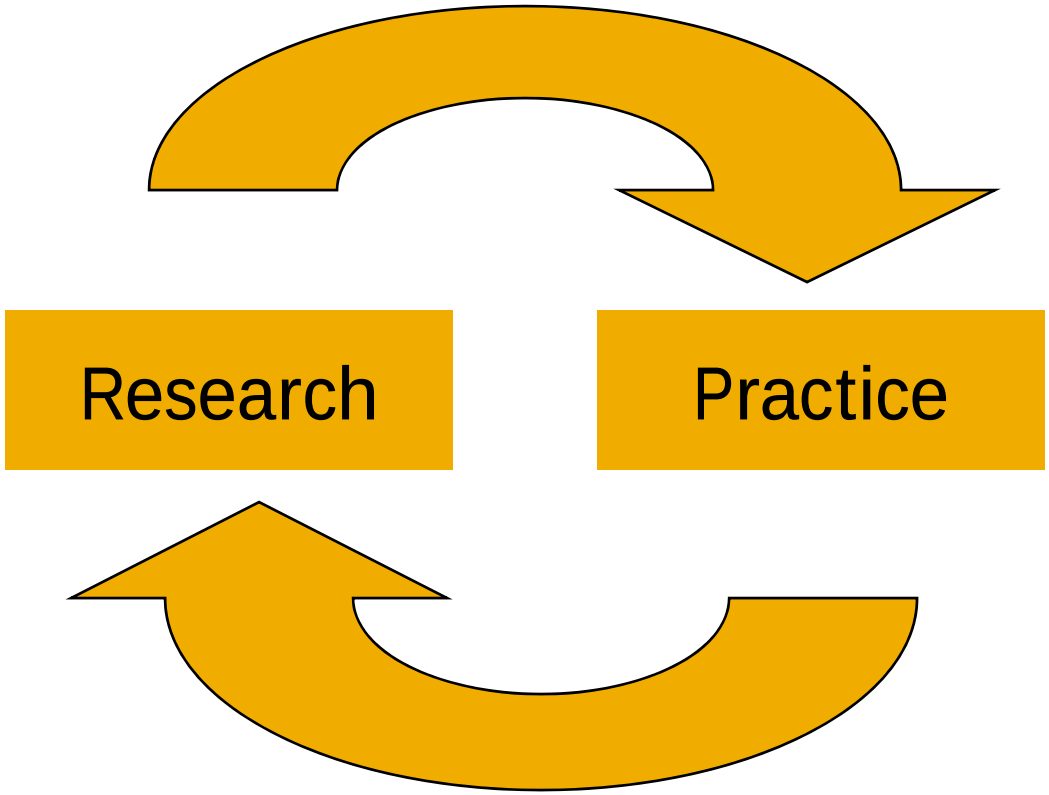
(ASHA, 2009)

Clinical Practice Research in SLP: The Dissemination Frontier

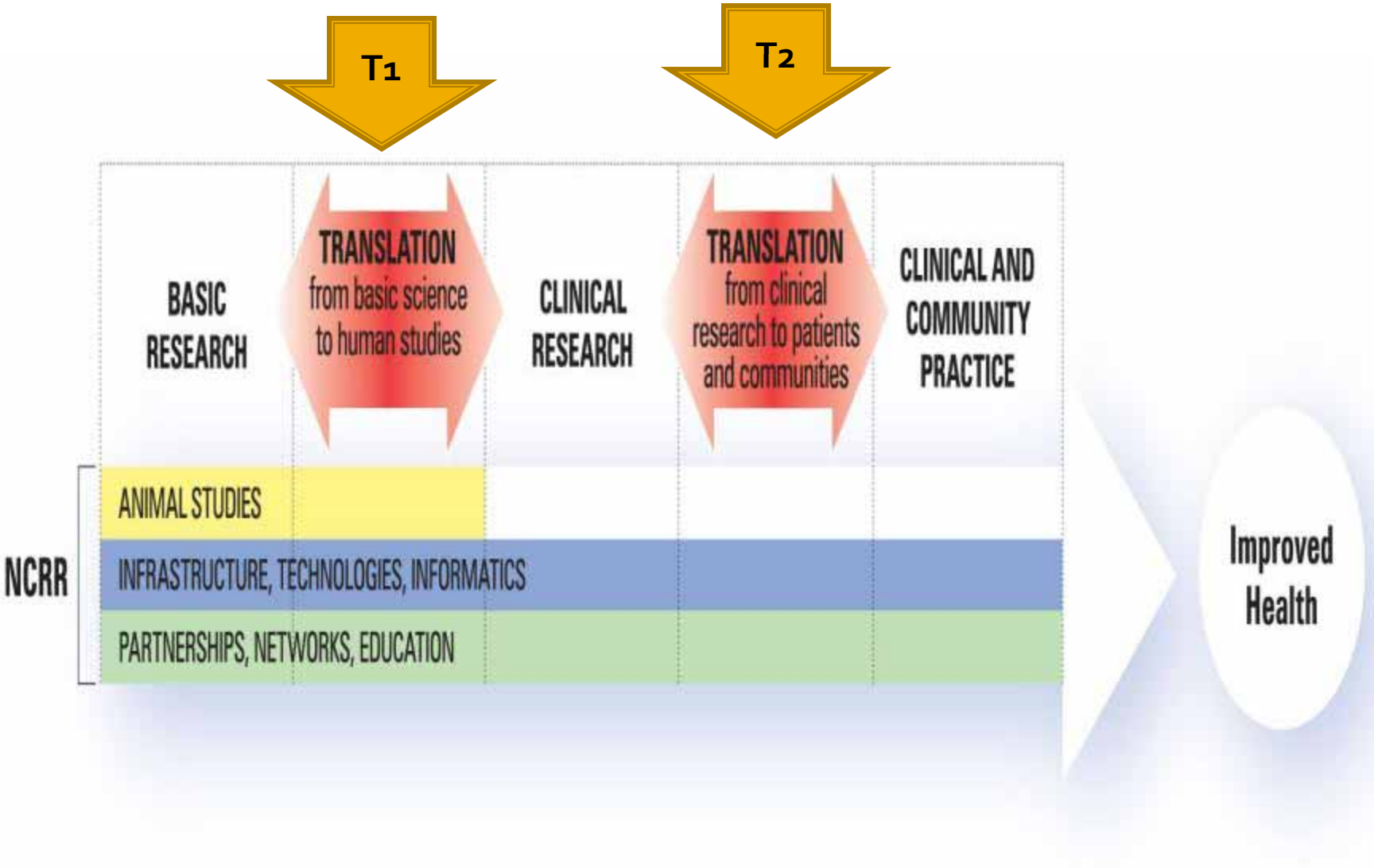
Research that is **directly relevant**
to the methods and outcomes
of clinical practice
and
Research that examines the **diffusion**, **dissemination**, and **implementation** of clinical practices

Clinical Practice Research

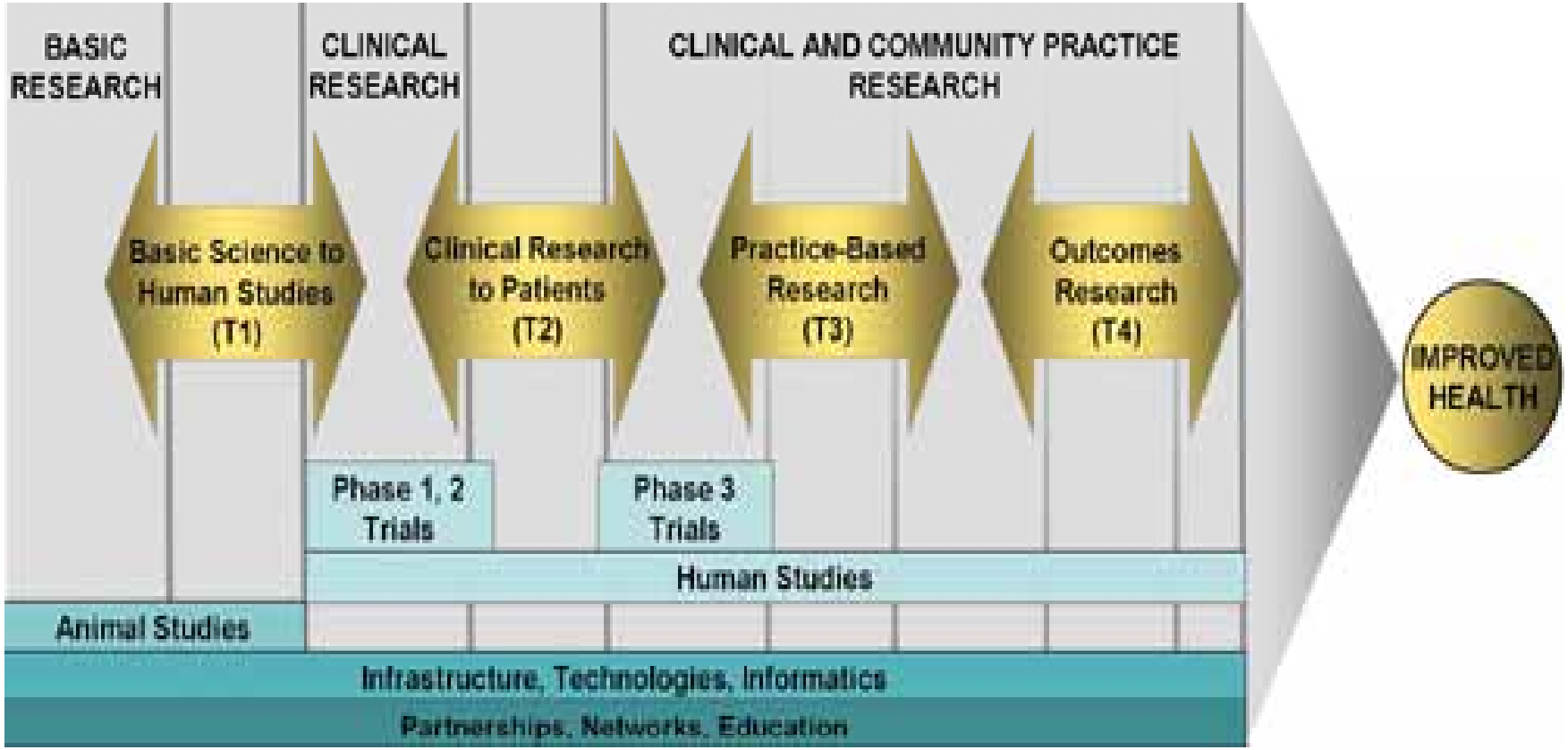
informs clinical practice and is informed by clinical practice



"T2" Research (NCRR, 2009)



"T3 and T4" Research (NCRR, 2009)

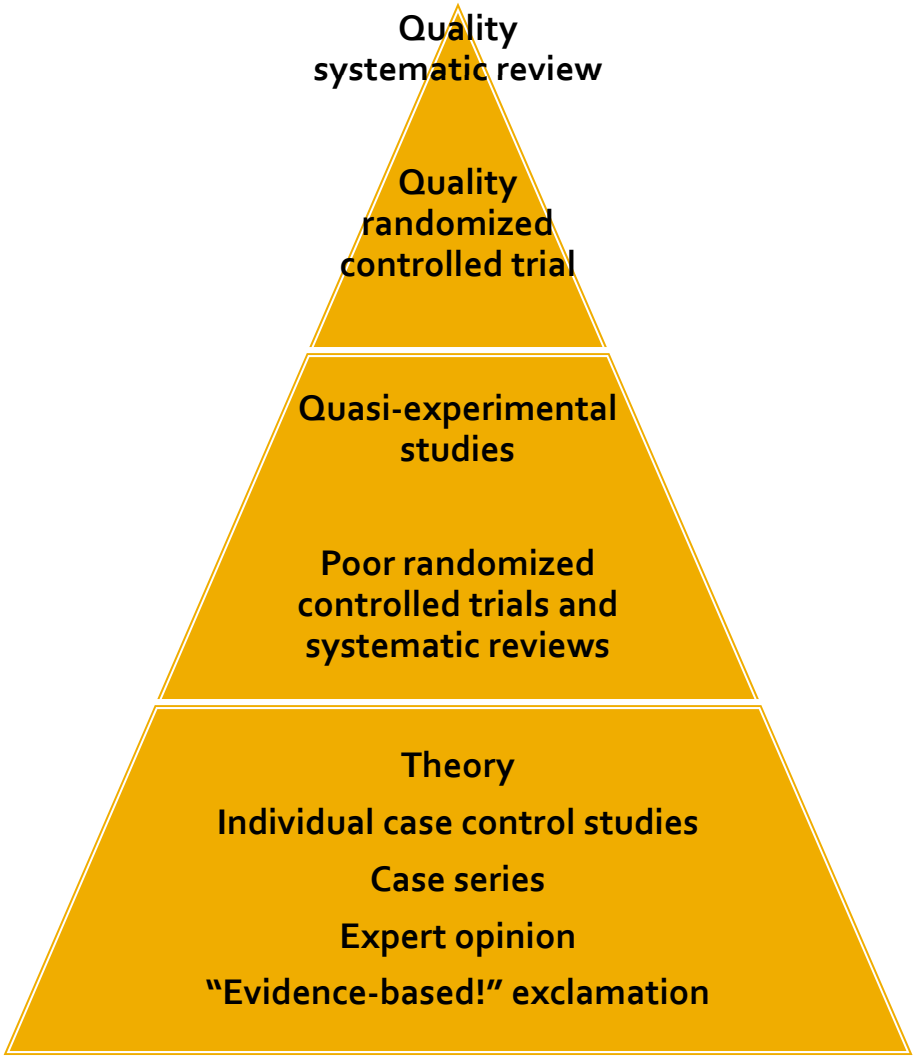


Translation Phases (from Genomics)

Translation Phase	Research Types	Sample Question
T1 **Translation to Humans**	**Basic Research:** Basic research of many types, Phase I and II trials	What are the mechanisms through which young children develop print knowledge?
T2 **Translation to Patients**	**Clinical Research:** Phase III and IV trials, validity studies, meta-analysis, systematic reviews	To what extent does use of a print-referencing reading style causally impact children's growth in print knowledge?
T3 & T4 **Translation to Practice**	**Clinical and Community Practice Research** Dissemination research, implementation research, diffusion research	What variables influence intervention implementation by various stakeholders? How is the intervention embedded within different organizational cultures?

From Causality to Dissemination

- This hierarchy does not include issues of **diffusion, dissemination**, and **implementation**



From Causality to Dissemination T3 and T4 Research Varieties

- **Diffusion Research**
  - Focuses on the **conditions** that increase or decrease the likelihood that a new practice will be adopted by various stakeholders
- **Dissemination Research**
  - Focuses on the **processes and variables** that influence adoptions of new practices by various stakeholders
- **Implementation Research**
  - Focuses on the **movement** of new practices into actual delivery contexts, including how these are integrated into existing organizations

National Cancer Institute, 2009

Examples of Questions

- What specific family-level conditions moderate the impacts of Intervention A on child gains?
- How can Intervention A be tailored to meet the needs of families experiencing these conditions?
- What barriers impact the diffusion of Intervention A into a community? Into a school? Into a home?
- Can alternative means be used to get Intervention A to children? Do effects hold?

The Causality Continua

Case Study Research	Feasibility Research	Efficacy Research	Meta-Analyses	Scale-Up Research
The Use of Conversation Analysis to Guide Individualized Advice to Carers and Evaluate Change in Aphasia: A Case Study (Booth & Perkins, 1999)	Self-Administered Cued Naming Therapy: A Single-Participant Investigation of a Computer-Based Therapy Program Replicated in Four Cases (Ramsberger & Marie, 2007)	The Efficacy of a Semantic Cueing Procedure on Naming Performance of Adults With Aphasia (Lowell et al., 1995)	A Meta-Analysis of Studies Carried Out between 1946 and 1988 Concerned with the Efficacy of Speech and Language Therapy for Aphasic Patients (Whurr et al., 1992)	Aphasia in Acute Stroke: Incidence, Determinants, and Recovery (Pederson et al., 2004)

The Translational Continua

Case Study Research	Feasibility Research	Efficacy Research	Meta-Analyses	Scale-Up Research	Diffusion-Dissemination-Implementation Research
The Use of Conversation Analysis to Guide Individualized Advice to Carers and Evaluate Change in Aphasia: A Case Study (Booth & Perkins, 1999)	Self-Administered Cued Naming Therapy: A Single-Participant Investigation of a Computer-Based Therapy Program Replicated in Four Cases (Ramsberger & Marie,	The Efficacy of a Semantic Cueing Procedure on Naming Performance of Adults With Aphasia (Lowell et al., 1995)	A Meta-Analysis of Studies Carried Out between 1946 and 1988 Concerned with the Efficacy of Speech and Language Therapy for Aphasic Patients (Whurr et al., 1992	Aphasia in Acute Stroke: Incidence, Determinants, and Recovery (Pederson et al., 2004)	

Four Phases in Genomic Research

Table 1

The continuum of translation research in human genetics: types of research and examples

Translation research phase	Notation	Types of research	Examples
TI	Discovery to candidate health application	Phases I and II clinical trials; observational studies	Is there an association between *BRCA* mutations and breast cancer?
T2	Health application to evidence-based practice guidelines	Phase III clinical trials; observational studies; evidence synthesis and guidelines development	What is the positive predictive value of *BRCA* mutations in at-risk women?
T3	Practice guidelines to health practice	Dissemination research; implementation research; diffusion research Phase IV clinical trials	What proportion of women who meet the family history criteria are tested for *BRCA* and what are the barriers to testing?
T4	Practice to population health impact	Outcomes research (includes many disciplines); population monitoring of morbidity, mortality, benefits, and risks	Does *BRCA* testing in asymptomatic women reduce breast cancer incidence or improve outcomes?

Barriers to Engaging in Clinical Practice Research

- A solid body of T2-T4 work is required to
  - Ensure that persons get the best care possible (focus on implementation of existing treatments rather than developing new ones)
  - To ensure that investments in T1 (basic) work is realized

Why We Need to Increase Amount (and Quality) of Clinical Practice Research

Translational Difficulties of Extant Literature:

1. Majority of participants in our studies are idealized versions of service recipients (artificial samples)
2. Majority of efficacy trials have inflated effects
3. Majority of efficacy trials (academic clinical settings) have limited validity for the "blue highways" (practitioners and clients across the United States)

Westfall, Mold, &

Dissemination Research: Rationale

Identifying a new treatment or assessment option is only the very first step

- The end point in 'bench-to-bedside' research is the **starting point** in dissemination research
- Very few scientific discoveries actually move into clinical practice (5% of highly promising genomic findings)

Amount and type of work needed to translate basic findings into clinical practice has been sorely under-estimated

Khoury et al., 2007; Westfall, Mold, & Fagnan, 2007; Woolf, 2008

Dissemination Research: Rationale

Ensures that persons get the best care possible

- focus on implementation of existing treatments rather than developing new ones

Ensures that investments in T1 (basic) work are realized

Limitations to Current Body of Clinical Practice Research

- **under-powered** (can only detect large effects, lots of measurement error)
- involve **exploratory work** when unnecessary (strong theory, prior evidence)
- little attention to **moderators** and **mediators** of intervention impacts (for whom and under what conditions interventions "work")
- few **replication** studies by **independent** researchers
- few **longitudinal studies** of intervention impacts
- few studies of **movement** of validated treatments into real delivery contexts
- participants and settings don't resemble who/where SLPs serve (**artificial sample**)
- limited attention to **multi-level influences** on interventions

In Turn…

The clinical applicability of a **specific body of work (including basic research)** is very limited because we don't know how to translate (diffuse and disseminate) findings:

"There is science in what we do, yes, but also habit, intuition, and sometimes plain old guessing… The gap between what we know and what we aim for persists. And this gap complicates everything we do."

-Atul Gawande, Complications (2002)

Problems and Challenges

Money

Skill

Tradition

T2 Studies

Money

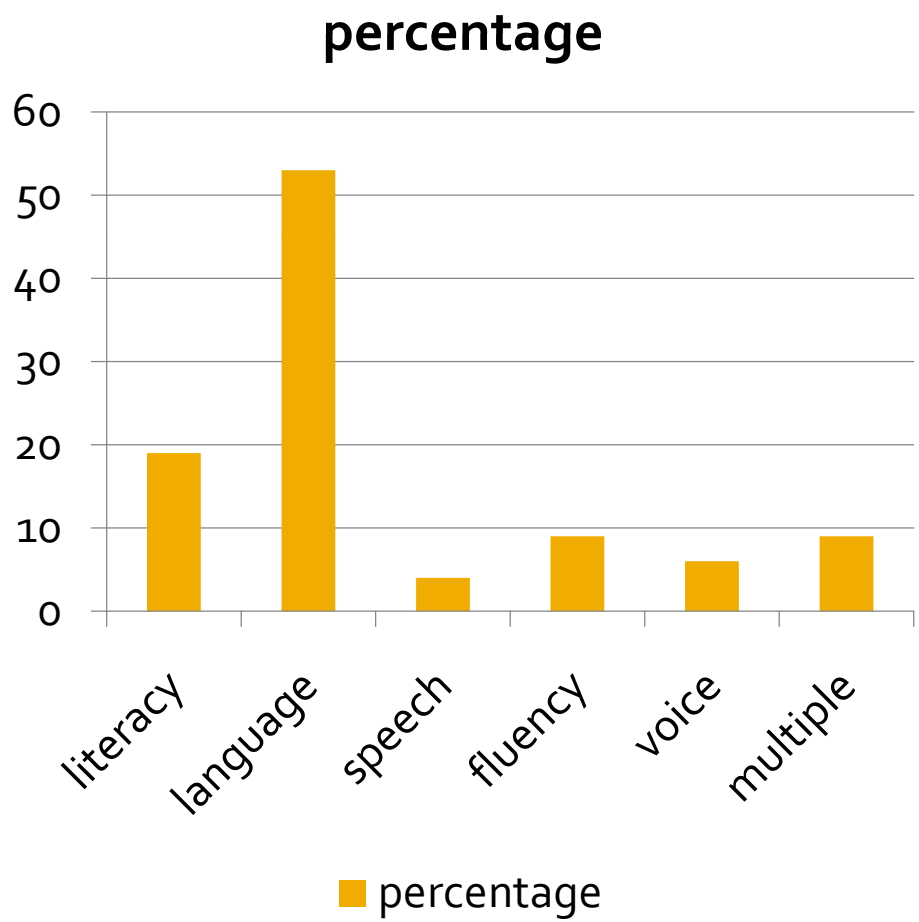
- Vast majority of research money is invested in basic research
  - 1.5% of NIH biomedical research funding is for dissemination research (Woolf, 2008)
    - Clinical and Translational Science Awards (2% of budget)
  - Federal AHRQ allocation = 1% of NIH budget
    - Translating Research into Practice (TRIP I and II; 1-2% of budget)

Skill (Woolf, 2008)

- **Specialized research skills**
  - recruiting and maintaining very large samples
  - involving field partners and organizations
  - multiple methods
- **Multiple disciplines/collaborations**
  - Epidemiology
  - Public policy
  - Financing
  - Organizational theory
  - Educational leadership
  - Systems redesign
  - Sociology, anthropology
- **Messiness**
  - Infrastructure constraints
  - Organizational inertia
  - Moving targets

Tradition

- Our research community has largely pursued basic research and applied basic research
  - 53 group-design efficacy/effectiveness trials between 1997 and 2007 published in ASHA journals (140 issues)



Justice, Nye, Schwarz, McGinty, & Rivera, 2008

T2 Studies

- We cannot move from the bench to the bedside… *and beyond*… until we have a solid corpus of T2 work to build upon

Concluding Comments

In the interest of the persons we serve, clinical practice research needs to "come out from under the shadow of T1" (basic research) (Woolf, 2007)

Clinical practice research offers great promise for closing the gap between *habit, intuition, and guessing* and providing the most effective treatments for communication disorders.

Thank You

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CLINICAL PRACTICE RESEARCH IN AUDIOLOGY

- Nancy Tye-Murray, Ph.D.
- Washington University School of Medicine

GOALS

- Raise awareness about what faculty might do to encourage and nurture student's interest in applied research
- Consider a model for developing a career in clinical practice research
- Affirm that careers in clinical practice research are viable

GETTING THERE:

- No undergraduate student starts out wanting to be a clinical researcher in audiology

MY ROUTE: A TEACHER OF THE DEAF WHO NEVER MADE IT PAST STUDENT TEACHING

- Frustration with teaching methods that didn't seem to be working
- Observation that many veteran teachers seemed to have lost their vim and vigor for teaching

HELLO IOWA!

- Audiology/AR practica
- Instrumentation class
- Julia and Jerry
  * Text book research
  * A flaky idea
- Research assistantships
  * Cadavers & cats, grants & graphs
- Independent readings seminar
- Cognitive psychology

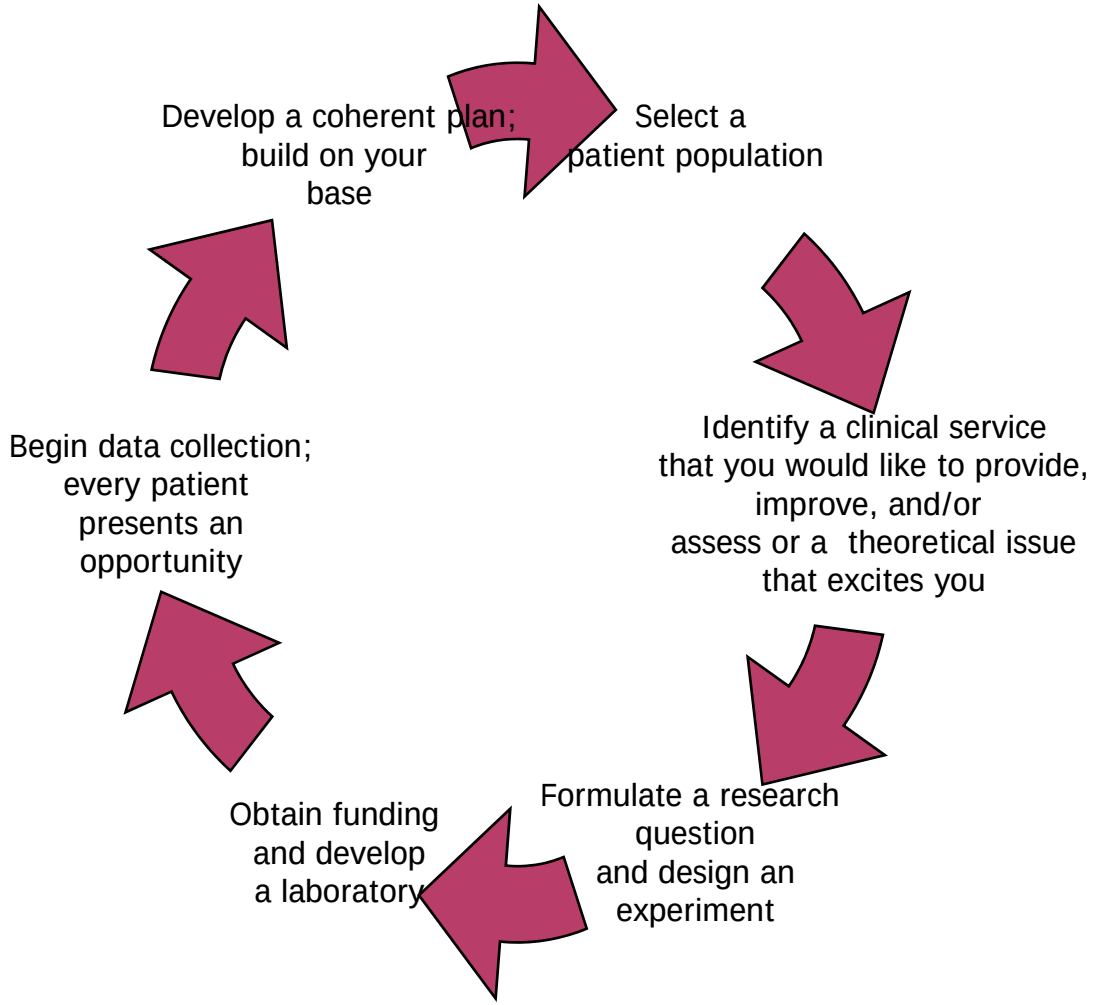
HOW THESE KINDS OF EXPERIENCES MIGHT AFFECT STUDENTS

- **Practica**: Exposure early on to clinical practice, opportunity to learn what excites you
- **Classes**: "I can do this" and "I want to do this"
- **One-on-one interactions with professors**: Learn what they do and how they do it; Importantly, learn that they value your contributions and your abilities to perform
- **Research assistantships:** Living the day-to-day life of a scientist
- **Readings:** Gaining exposure to the scientific method; nurturing interests
- **Psychology (and other disciplines):** Exposure to top-notch behavioral research; information about the perceptual systems; the importance of cross-pollination

OVERT INSTRUCTION

- A blueprint for developing a career
- Teaching them before they leave our tutelage

A MODEL FOR DEVELOPING A CAREER IN CLINICAL PRACTICE RESEARCH



SELECT A PATIENT POPULATION

- Assess your current job.
- Assess patient availability; look for niche topics.
- Assess challenges and opportunities.

IDENTIFY A CLINICAL SERVICE AND A THEORETICAL ISSUE

- Is there a service that you want to include but don't have the resources to do so?
- Is there a service or intervention that you want to create or alter?
- Has your experience led you to hypothesize about mechanisms or processes? Translational research means moving from basic science to clinical practice *AND* moving from clinical practice to basic science.

FORMULATE RESEARCH QUESTIONS AND DESIGN AN EXPERIMENT

- Do your homework—Read, read, and then read some more; attend conferences; trawl outside of your field.
- Network, especially within your academic setting; e.g., clinical psychologist, cognitive psychologist; psychometrician; statistician; second language learning expert; speech-language pathologist; psychosocial therapist; otolaryngologist; anesthesiologist; neuroscientist; fellow audiologist.

OBTAIN FUNDING (YOU DON'T HAVE TO BE HEMMINGWAY)

- Read successful grant applications and develop an eye for what works.
- Hang out with people who know how to write grant applications. Grant writing is a craft that can be learned, not a talent that you have or don't have.
- Consider first fishing at a small pond and moving into larger waters later. Pilot data lead to larger projects.
- Follow the instructions! And if they tell you to jump through a hoop, jump through the hoop.
- Pay attention to the details.

BUILD YOUR LABORATORY

- Procure space.
- Get the best equipment you can afford.
- Hire great people and let them do what they do best.
- Expect excellence.
- Create safeguards.

BEGIN DATA COLLECTION

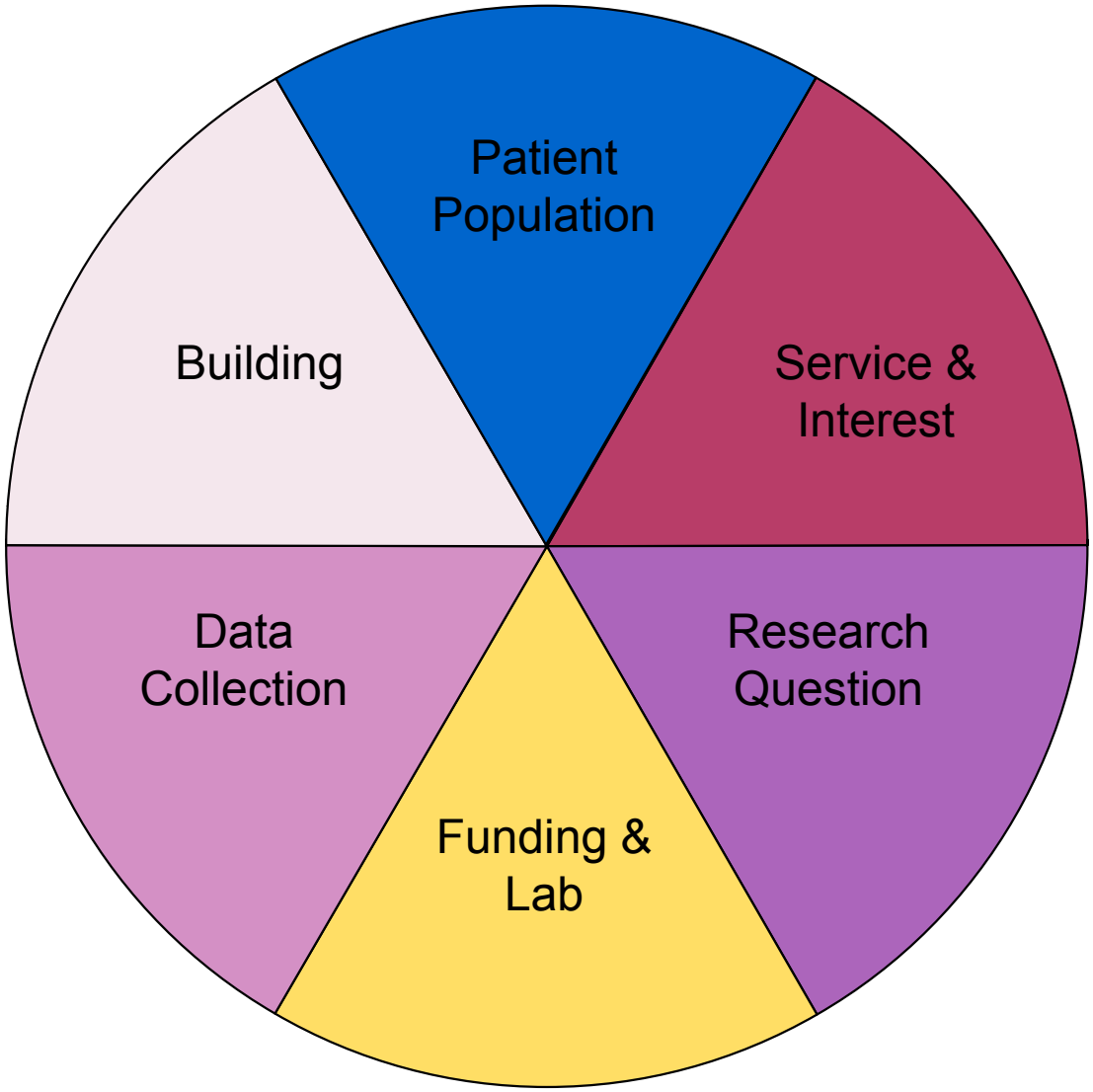
- Every patient can provide a data point.
- Resources are available for recruiting participants.
- Community outreach can be effective and can also be cost-free.

BUILD ON YOUR BASE

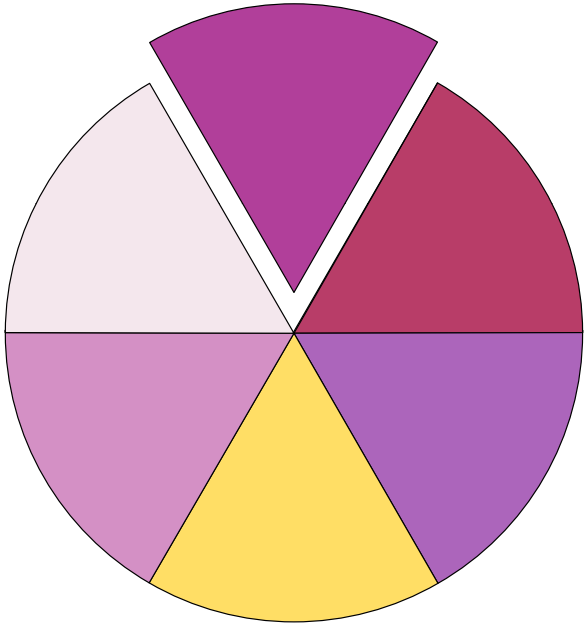
- Where have you come from, where are you going?
- What's your 1-year plan, 3-year plan, and even 5-year plan?

Example:

FROM UNIVERSITY OF IOWA HOSPITAL TO WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

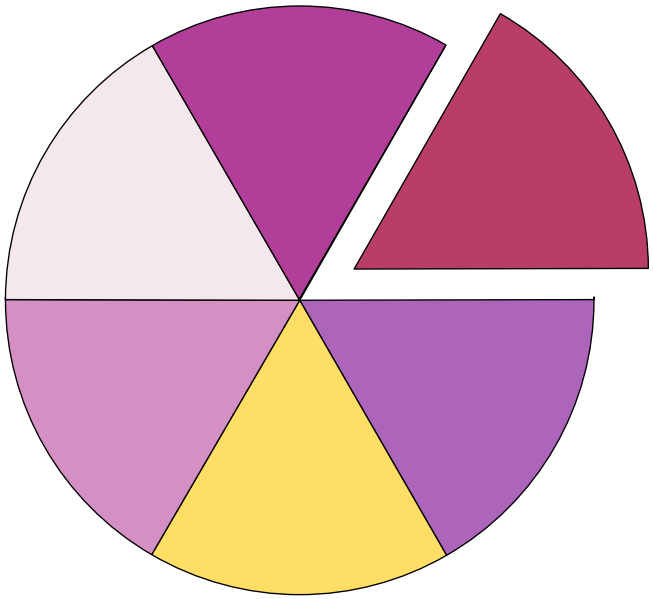

Patient Population
Service & Interest
Research Question
Funding & Lab
Data Collection
Building

PATIENT POPULATION



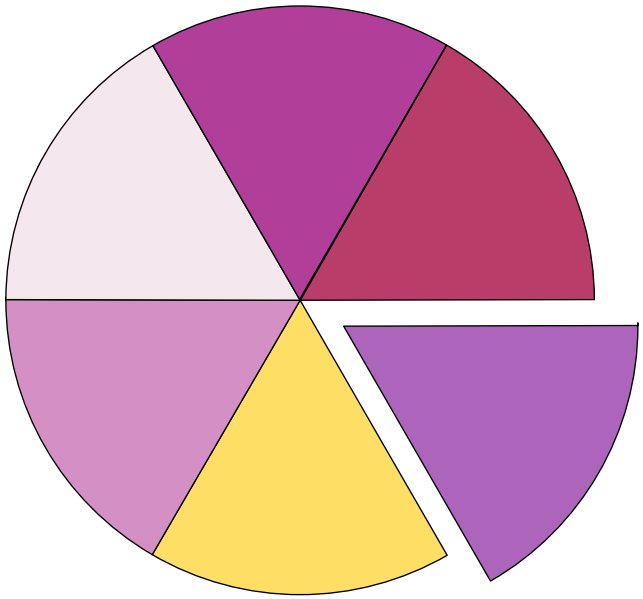
- Adults with profound hearing loss who receive cochlear implants

SERVICE AND INTEREST



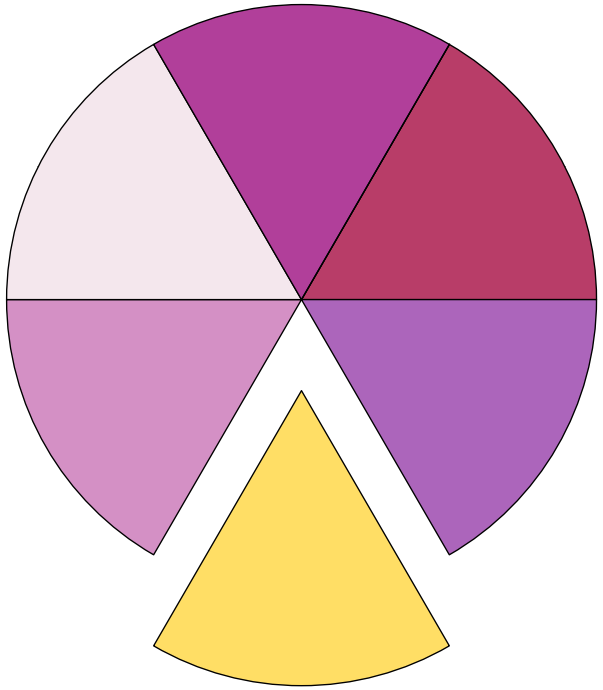
- Service: Provide aural rehabilitation to new implant recipients
- Research interests:
  - AV speech perception
  - Conversational fluency
  - Perceptual learning

RESEARCH QUESTION



- Does computerized speechreading/ communication strategies training work?

FUNDING AND ESTABLISHING A LABORATORY: IT'S OKAY TO THINK SMALL

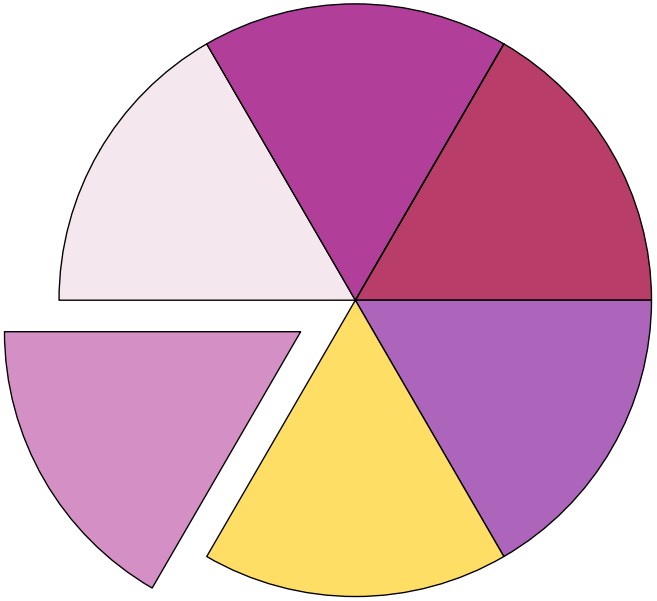


- Funding
  - DRF
  - Easter Seals Society
  - University of Iowa Video studio
- First lab: You got to start somewhere….

MY FIRST LAB

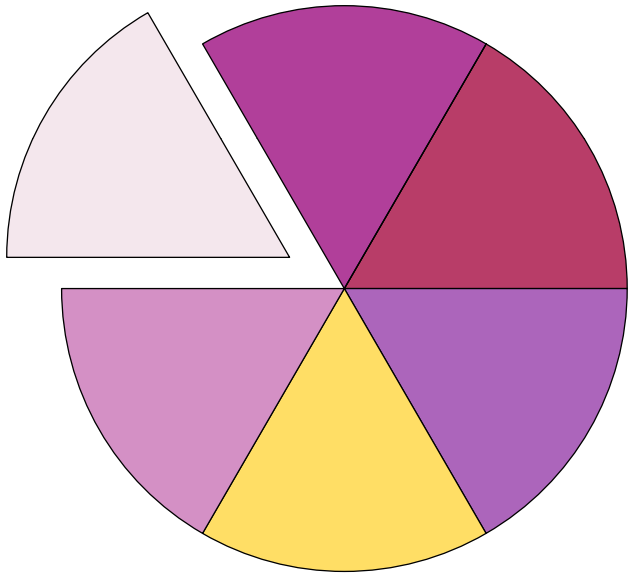
Hung a sign on an under-used closet and voila!

DATA COLLECTION



- Cochlear implant recipients across Iowa

BUILDING: FLASH FORWARD, 4 NIH GRANTS @ WUSM



Grants

- Computerized auditory training (stemming from interests in perceptual learning)
- Auditory discourse comprehension (stemming from interest in conversational fluency)
- Children's audiovisual speech perception and lexicon development (stemming from interest in audiovisual perception)
- Audiovisual speech perception and aging (Stemming from interest in audiovisual perception and perceptual learning)

SOME CLINICALLY-RELEVANT OUTCOMES

- Speechreading tests for both adults and children
- "Conversation Made Easy"; "Communication Training" manuals
- Discourse comprehension tests for adults, auditory and audiovisual
- Computerized auditory training programs based on 2nd language learning principles
- Indices to gauge integration
- Methods to assess conversational fluency
- Psychosocial workshops

IN THE WORKS: ONE-, THREE-, FIVE-YEARS FROM NOW

- **Auditory discourse comprehension.** Next step: to assess the effects of training working memory and of auditory training on discourse comprehension and to finalize standardized test lists of auditory discourse comprehension.
- **Auditory training.** Next step: to compare the effects of multiple versus single talkers for persons with hearing loss and to determine benefits for patients who have aphasia.
- **Audiovisual integration and aging.** Next step: to develop an index of integration that can be used for clinical and research purposes.
- **Children's speech perception.** Next step: to standardized tests of speechreading and to study performance as a function of maturation and hearing loss and to continue to study audiovisual lexicon development.

QUESTIONS OR COMMENTS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