Translational Research Methodology

Combining Scientific Rigor and Community Engagement to Improve Population Health

Susan Davies, PhD

April 30, 2019

UAB SCHOOL OF PUBLIC HEALTH
Knowledge that will change your world

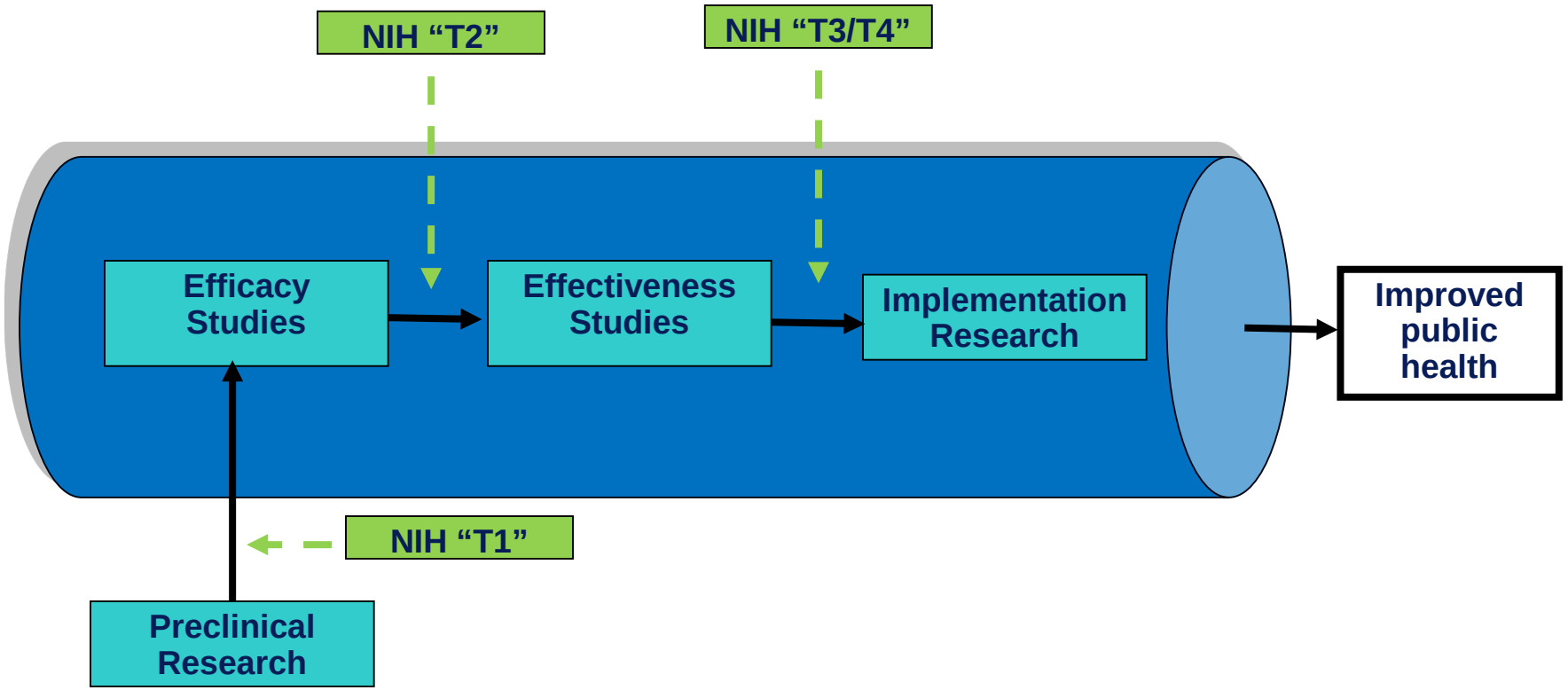
Translational Science

- A rapidly growing discipline in biomedical research which aims to expedite the discovery of new diagnostic tools and treatments by using a multi-disciplinary, highly collaborative approach; often described as the practice of transferring scientific knowledge "*from bench to bedside" (B2B)*

- Refers to translating research into practice; i.e., ensuring that new treatments and research knowledge reach the population for whom they are intended and are implemented correctly. Publishing a paper or producing a new drug, an end point for B2B translation, is only the starting point, or the first step in a complex set of processes needed to change behavior. Wolf, S.H. *The meaning of translational research and why it matters. JAMA 2008;299(2):211-213.*

- "Knowledge translation is defined as the exchange, synthesis and ethically sound application of knowledge—within a complex system of interactions among researchers and users—to accelerate the capture of the benefits of research... through improved health, more effective services and products, and a strengthened health care system."

The Translational Research Pipeline



Source: Bauer M, Harvard School of Public Health

UAB SCHOOL OF PUBLIC HEALTH
Knowledge that will change your world

Translational Research Phases

- T1: initiates translation process; often case study research and Phase 1 & 2 clinical trials
- T2: expands discovery to larger patient population seen in Phase 3 and 4 clinical trials
- T3 relies on dissemination and implementation research to answer questions: Is treatment X now actually being used in the world-at-large, and if not, why not?

If T1-T3 have reached their goals and responded effectively to any new issues:

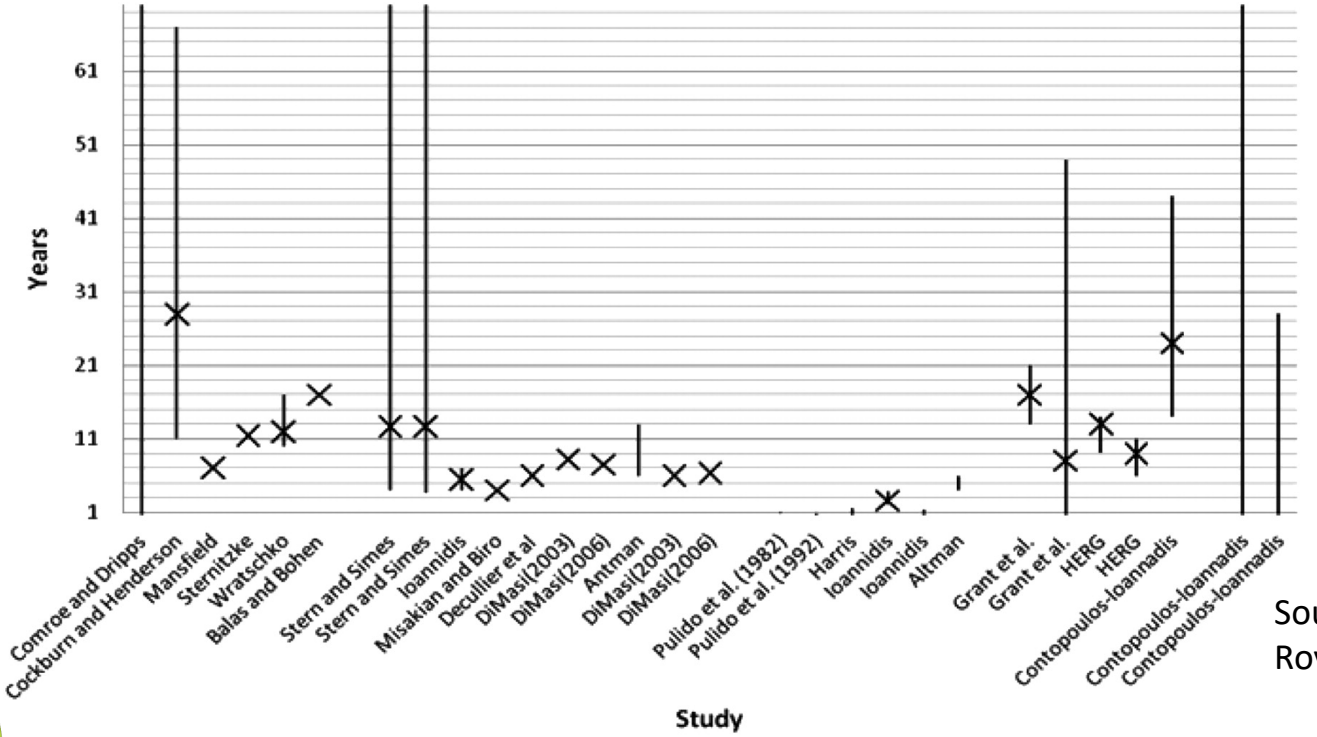
- T4: produces new policy research
- Effective translational science incorporates all aspects of the T1-T4 scale.
- Each stage brings to life important research – takes all 4 phases to bring scientific advancements to all segments of the general population.

Impetus for the CTSA Program

- Implementing biomedical discoveries made in the last 10 years demands an evolution of clinical science.
- New prevention strategies and treatments must be developed, tested, and brought into medical practice more rapidly.
- CTSA awards will lower barriers between disciplines, and encourage creative, innovative approaches to solve complex medical problems.
- These clinical and translational science awards will catalyze change -- breaking silos, breaking barriers, and breaking conventions.

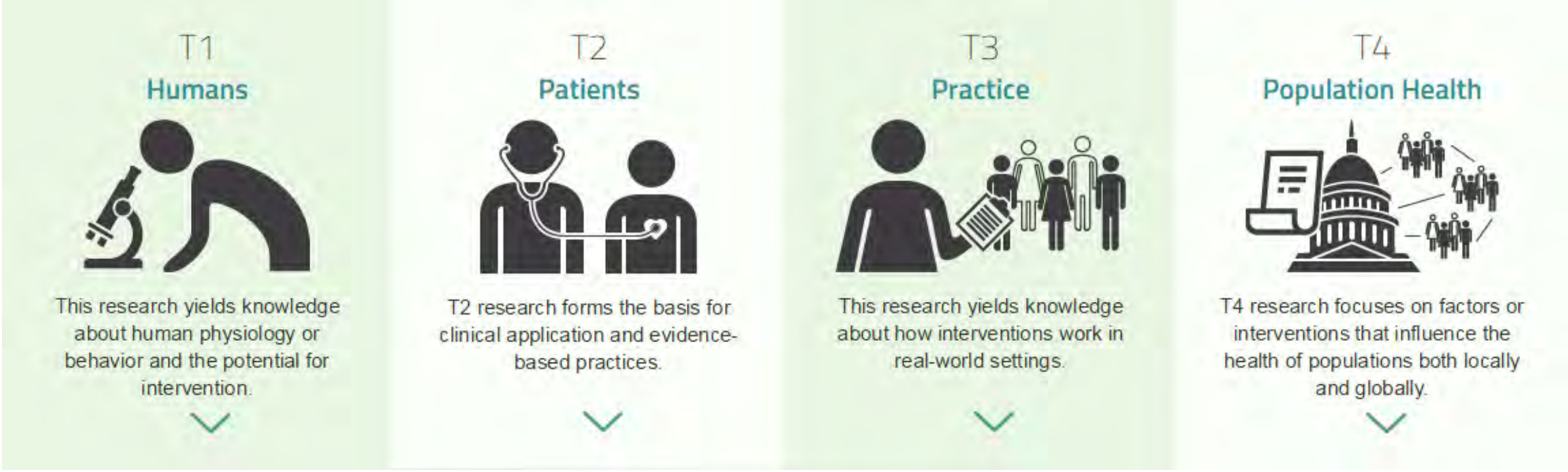
Well-established lags….

- Most of evidence-based treatments never make it into practice
- Among those that do, there is a 17 year timeline from discovery to practice



Source: Morris et al., Journal of the Royal Society of Medicine, 2011.

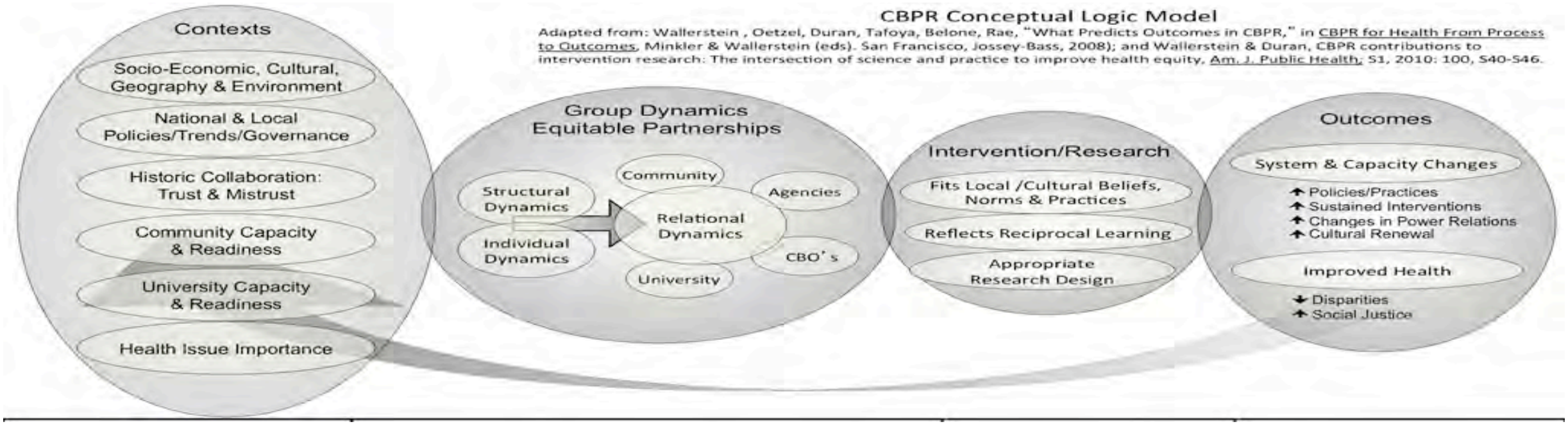
UAB SCHOOL OF PUBLIC HEALTH
Knowledge that will change your world



Community Engagement and Outreach

1. Establish a new infrastructure that actively involves the community in setting clinical and translational research priorities.
2. Develop new community-institution partnerships in clinical and translational science.
3. Identify, educate and prepare community leaders, healthcare providers and institutional trainees, researchers and scholars in the principles and practices of community-engaged and community-based participatory research.

CBPR Conceptual LOGIC MODEL



CBPR addresses intervention challenges:

- partnering with community members to contextualize an intervention for specific settings
- fosters the needed trust within partnerships to enable effective translation of research within diverse settings &
- integrating cultural values and practices to enhance and support policies and sustainability.

Implementation Science Defined

- "…the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practice into routine practice, and, hence, to improve the quality and effectiveness of health services" Source: Eccles & Mittman, Implementation Science, 2006

- A body of knowledge on methods to promote the systematic uptake of new or underused scientific findings into the usual activities of regional and national health care and community organizations, including individual practice sites Source: Rubenstein & Pugh, Journal of General Internal Medicine, 2006

Implementation Research Seeks to…

- Identify barriers and facilitators to evidence-based practice
- Develop strategies to increase the use of evidence-based practice
- Facilitate the widespread adoption of those strategies
- Further understand of implementation processes
- Iteratively develop and test theories, hypotheses, concepts, methods, and measures
- Support real improvement within participating sites/organizations

Source: Rubenstein, L.V. & Pugh, J., Journal of General Internal Medicine, 2006.

Implementation Science: Emphasis on External Validity

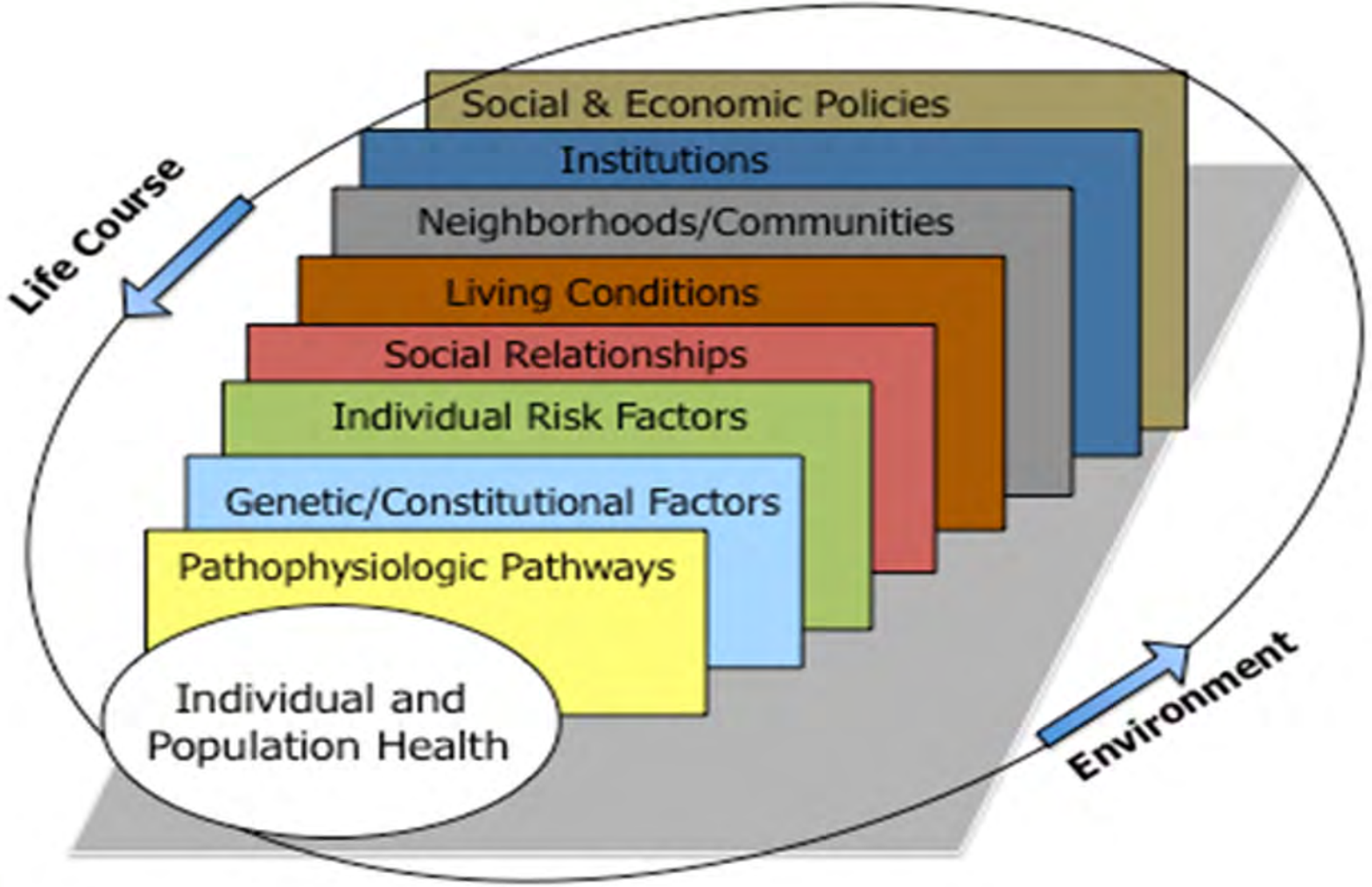
- Focused on processes and strategies for increasing adoption, use of innovative, effective practices and research findings

- What about other implementation areas…….
  - Interventions focusing on prevention?
  - Policies?
  - Community settings?
  - Other non-clinical settings?

Implementation Science
Removes Roadblocks

- Aims to reduce roadblocks to ***promote evidence-based practice***
- Is ***interdisciplinary*** and has evolved from several research traditions
- Involves ***partnerships with implementation stakeholders***
- Has ***evolving theoretical underpinnings and methodologies***

Socioecological Model that fits with Team Science:



UAB SCHOOL OF PUBLIC HEALTH
Knowledge that will change your world

Implementation Intervention Examples

- EHR: Clinical reminders, templates
- Technology-assisted interventions
- Incentives
- Technical assistance

Education & training

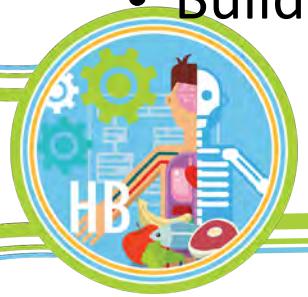
Audit-feedback

Toolkits

Community health workers

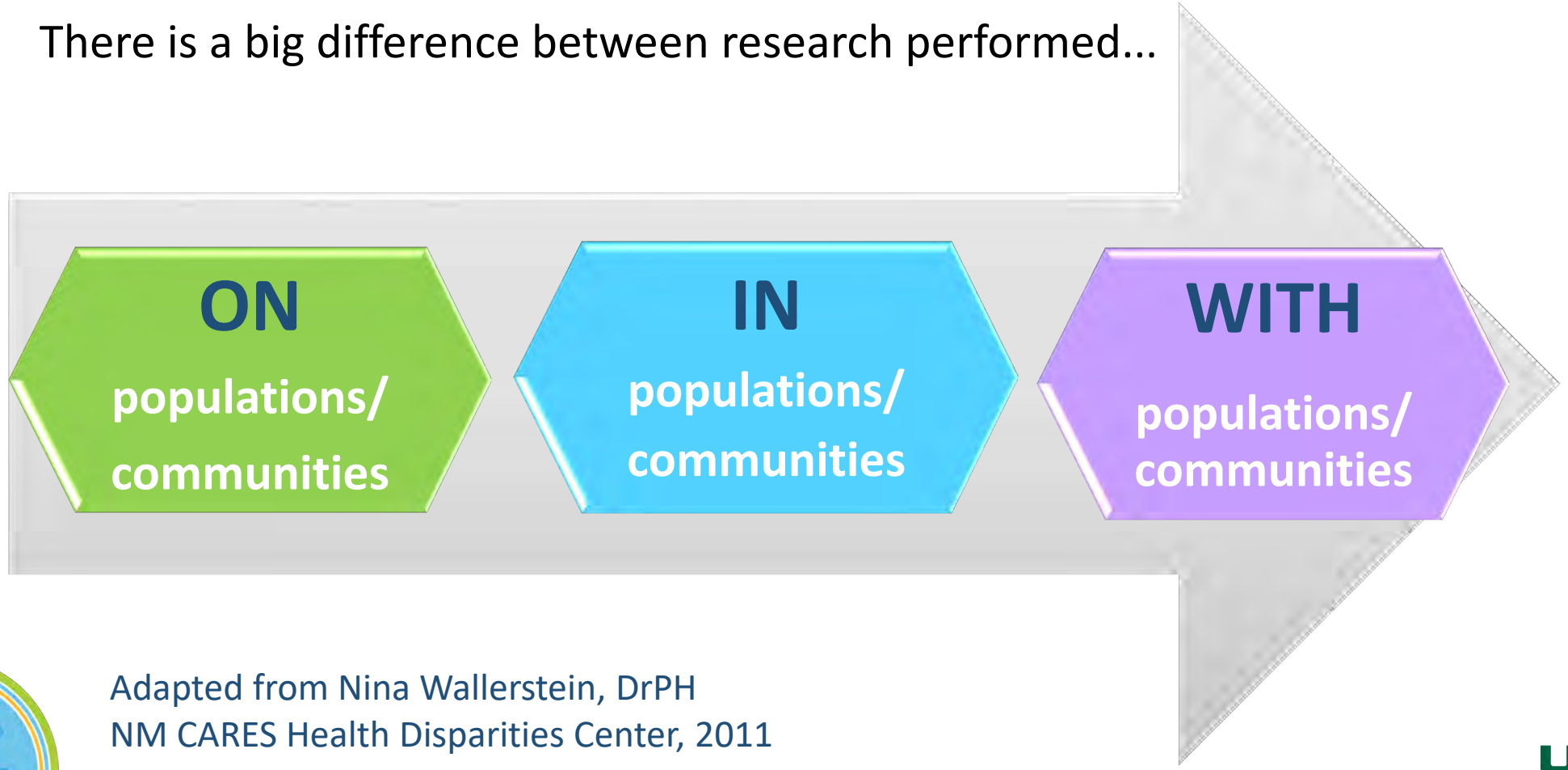
Theory basics supporting Implementation Science

- Addresses factors that impede or facilitate efforts to translate evidence into practice improvements at all levels (patient, provider, system, external context
- Supports the replication of successful implementations
- Helps us navigate complex implementation efforts
  - Planning, guiding, monitoring
    - Structural inputs, needs
    - Implementation as a complex process
- Ideally, helps chances of adoption, sustainability
  - Identify and understand the many factors that can determine implementation success
- Furthers generalizable knowledge about implementing interventions
  - Build on knowledge across studies; settings



Community-engaged research continuum

There is a big difference between research performed...



Adapted from Nina Wallerstein, DrPH
NM CARES Health Disparities Center, 2011

UAB SCHOOL OF PUBLIC HEALTH
Knowledge that will change your world

What is community-engaged research?

- **Community-based research** takes place outside the walls of the researcher's clinical or academic home.
- **Community-engaged research** "begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities."*
- **Community-based participatory research** is a "collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings." *

*WK Kellogg Community Health Scholars Program

Why is CEnR relevant for clinical and translational research?

- Widening socioeconomic & health disparities, importance of local/cultural context
- Greater demand by communities for equity and research relevance – history of abuse/mistrust
- Difficulty in moving from efficacy to effectiveness
- Limitations of current research approaches to address 'translational blocks' (i.e., is researcher asking the wrong questions or looking in the wrong place?)
- Growing appreciation of the value of partnerships, community-engaged research movement: Partnering with community can help with translation of data gathered into concrete changes in treatment, policy and practice (= improved public health!)

Benefits of Community-Engaged Research (CEnR)

- Generates research questions and answers that have important practice/ translation implications
- Practitioners are invested early on, creating greater potential for translation and sustainability of practice change
- Enhances community benefits from research
- Can improve the research product – more culturally appropriate research instruments, greater understanding of the role of context, improved recruitment
- Allows you to move “up-stream” on the social determinants of health
- Is like a muscle that gets stronger with use; increased trust and increased experience working together create new opportunities for collaboration and new funding opportunities

NIH/CDC/ATSDR Principles of Community Engagement*

- Be clear about the purposes of engagement and the populations you wish to engage.
- Become knowledgeable about the community.
- Establish relationships.
- Collective self-determination is the responsibility and right of the community.
- Partnering is necessary to create change and improve health.
- Recognize and respect the diversity of the community.
- Mobilize community assets and develop community capacity to take action.
- Release control of actions and be flexible to meet changing needs.
- Collaboration requires long-term commitment.

*CTSA Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. *Principles of Community Engagement,* 2nd edition. Bethesda, MD: National Institutes of Health, 2011 (#11-7782).

Increasing National Emphasis on Sexual Health

- National Prevention Strategy and Healthy People 2020 recognized “reproductive and sexual health” as a key area for improving the lives of Americans
- Opportunity to refocus the efforts of U.S. health-care professionals by adding sexual health to reproductive health as a U.S. public health priority, with important implications for clinicians and patients
- Addressing sexual health in health-care settings has the potential to
  - reduce redundancy in care and to minimize the stigma associated with adverse outcomes
  - increase clinical efficiency and the proportion of the population receiving sexual health services

Fostering Sexual Health

- National Prevention Strategy and Healthy People 2020 recommend:
  - increasing access to sexual health services
  - emphasizing sexual health education and
  - encouraging screening for STIs including HIV
- Activities should involve both health care providers and patient audiences
- New national emphasis = opportunity and a challenge
  - Patient care approach WRT sexual behavior needs to be reframed
  - Educational efforts for both HCPs and patients need to support a more comprehensive approach to understanding and promoting sexual health throughout the life span

Critical Questions

What can we do, individually and collectively, to improve translation of sexual health programs, products and services? How can we use data to illuminate disparities in sexual health in Alabama? What will it take to make it a primary tool?

How can we support policymakers, community level service providers, and schools in recognizing the importance of accurate sexual health education?

Take-home Messages

- Ultimate goal of translational research is to improve health of the US population; this will require us to do things very differently than we've been doing them
- Engaging the public in clinical research is an NIH priority, not an option
- Implementation science may be out best hope of achieving HP 2020 goals
- Communities are fundamental to all phases of prevention research *(epi studies, formative research on risk/protective factors, intervention development and pilot testing, large-scale prevention trials, and disseminating results in communities)*
- Community-engaged research is an approach to the research enterprise that takes into account the needs and assets of the community, bringing benefits for communities *and* researchers