REALLY dangerous ideas

- Associations are effects.
- Models don’t need testing.
- Guideline developers never make mistakes.
- Clinicians should always follow guidelines.

Guidelines are dangerous beasts requiring proof of value before being released

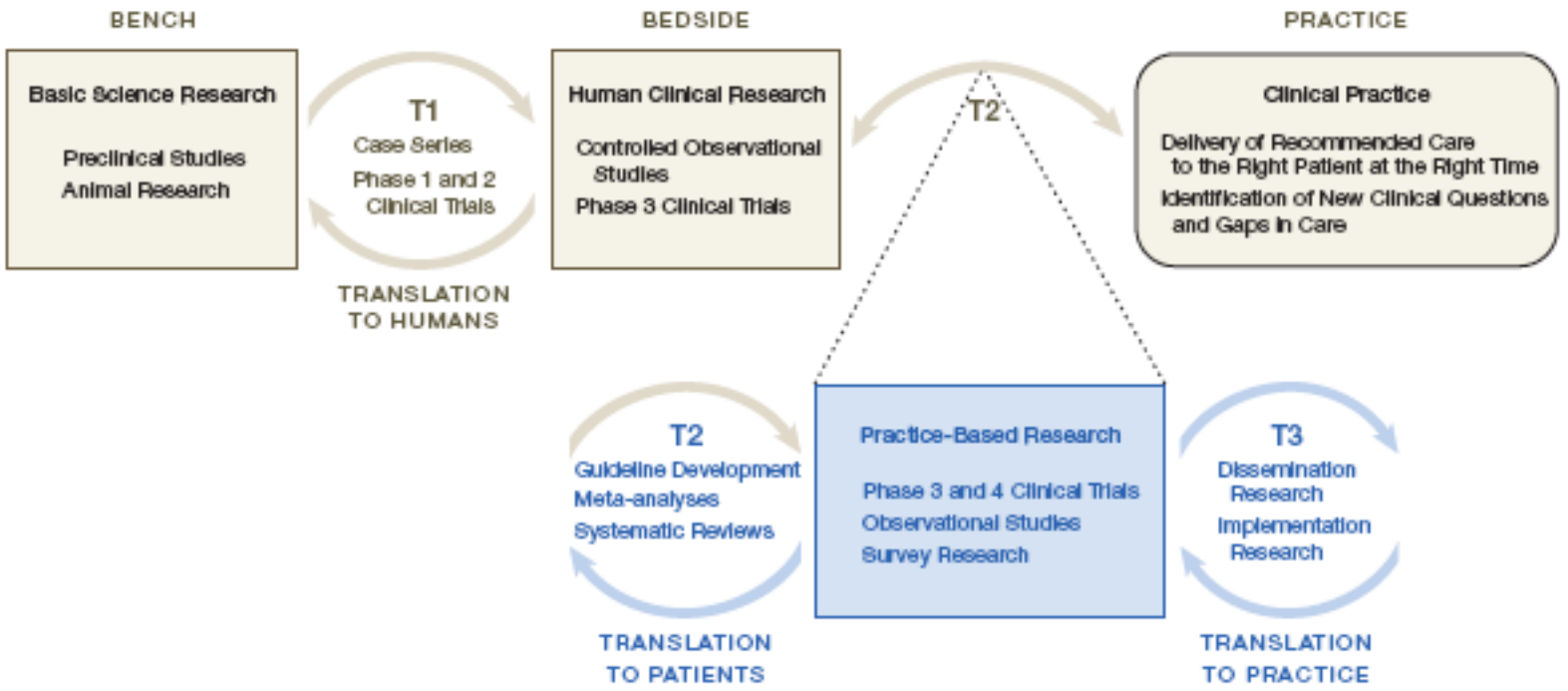
David Hahn MD MS

NAPCRG PBRN 2015

Daring Ideas

Background and Why Needed

Figure. "Blue Highways" on the NIH Roadmap



The current National Institutes of Health (NIH) Roadmap for Medical Research includes 2 major research laboratories (bench and bedside) and 2 translational steps (T1 and T2). Historically, moving new medical discoveries into clinical practice (T2) has been haphazard, occurring largely through continuing medical education programs, pharmaceutical detailing, and guideline development. Proposed expansion of the NIH Roadmap (blue) includes an additional research laboratory (Practice-based Research) and translational step (T3) to improve incorporation of research discoveries into day-to-day clinical care. The research roadmap is a continuum, with overlap between sites of research and translational steps. The figure includes examples of the types of research common in each research laboratory and translational step. This map is not exhaustive; other important types of research that might be included are community-based participatory research, public health research, and health policy analysis.

Background and Why Needed

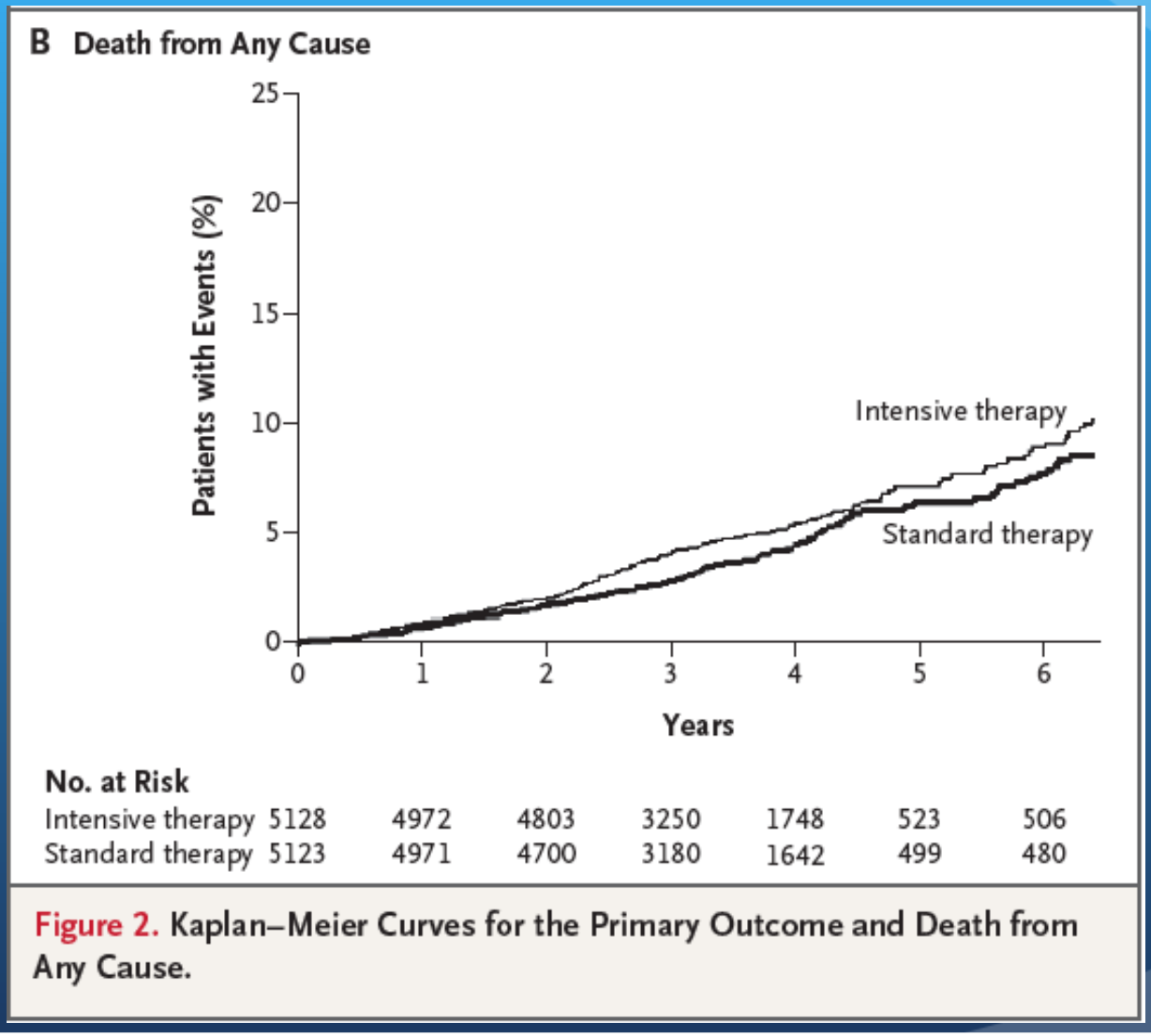


Figure 2. Kaplan–Meier Curves for the Primary Outcome and Death from Any Cause.

Proposed idea

- Current “evidence-based” guidelines are made up of strings of efficacy results of unexamined effectiveness.
- All guidelines should be subjected to RANDOMIZED comparative effectiveness research (CER) in practice-based research networks (PBRNs) prior to being released into the wilds of primary care.
- This critique applies equally to current “quality” metrics.

Ethical Oversight in Quality Improvement and Quality Improvement Research:

New Approaches to Promoting a Learning Healthcare System

Kevin Fiscella, MD, MPH
University of Rochester

Jonathan N. Tobin, PhD
Clinical Directors Network (CDN)
The Rockefeller University
Center for Clinical and Translational Science

Jennifer Carroll MD, MPH
University of Colorado
AAFP National Research Network

Short background of the idea

- Previously held distinctions between research and treatment and quality improvement are no longer tenable
- The failure to use information gathered routinely from the point of care for research and learning is unethical and should be considered suitable for research use from the standpoint of “discarded specimens”
- How do we/should we begin such reform?

What is the daring idea and why is it needed?

- Idea: Create a New Review Process to re-balance oversight, appropriate to risk
  - Two-step review
  - Integrate IRBs with Clinical Ethics Committees
  - MUCH shorter turnaround time
  - Level of auditing and standardization built in
- Why we need this…
  - Level of scrutiny should balance risk to participants with need to expedite care improvement, learn quickly and implement results directly into practices
  - Quality and timeliness of reviews vary
  - QI may under-protect, and QIR may over-protect
  - New standards of review need to balance individual privacy considerations with the overall needs and benefits of a learning healthcare system