

Please read the following paragraphs adapted from the article "Practice-based research--Blue Highways" by Westfall JM, Mold J, Fagnan L. in JAMA 2007;297:403-6, and answer questions 1-4

The National Institutes of Health (NIH) spends billions of dollars annually on biomedical research. Most of this money is spent on basic research that aims to understand how living organisms work. A relatively smaller amount is spent on clinical studies involving people. A new initiative, the NIH Roadmap, has focused increased attention on the need to "translate" basic research more quickly into human studies and then, hopefully, into tests and treatments that can improve clinical practice for the benefit of patients.² The NIH Roadmap may benefit from "blue highway" research that connects the major academic science laboratories to the physicians and patients in primary care offices across the United States.

Inventing a new medicine or treatment is only the starting point for improving the health of an individual patient. The magnitude and nature of the work required to translate findings from human medical research into valid and effective clinical practice, as depicted in the current NIH research pipeline diagrams,³ have been underestimated. Frequently, years or even decades are required for laboratory discoveries to reach clinical practice. It takes an estimated average of 17 years for only 14% of new scientific discoveries to enter day-to-day clinical practice.⁴ McGlynn et al⁵ reported that Americans only receive 50% of the recommended preventive, acute, and long-term health care. For example, just over 50% of eligible Americans have received appropriate colorectal cancer screening.⁶ While the beneficial effect of β -blockers in acute myocardial infarction was established 25 years ago, β -blockers are widely underused and there is still wide variation in their use.⁷

Myriad detours, speed traps, roadblocks, and potholes limit the movement of treatments from bench to practice. They include the limited external validity of randomized controlled trials, the diverse nature of ambulatory primary care practice, the difference between efficacy and effectiveness, the paucity of successful collaborative efforts between academic researchers and community physicians and patients, and the failure of the academic research enterprise to address needs identified by the community.⁸

The vast majority of patients receive medical care in the ambulatory primary care setting, yet the majority of clinical research occurs in the academic clinical setting.⁹⁻¹⁰ Clinical research studies, with their tight inclusion and exclusion criteria, create an artificial sample of patients who are not representative of the majority of

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those who present to primary care offices across the United States. Because treatment recommendations and disease management guidelines are often based on evidence from a relatively small number of large tertiary care centers, their applicability to the everyday practice of medicine may be limited.

What is efficacious in randomized clinical trials is not always effective in the real world of day-to-day practice. The treatment effect and benefit-to-harm ratio reported in randomized trials are often not found in clinical practice. Graham et al¹¹ reported that patient-specific factors greatly affect physicians' treatment of heart failure and pointed out that imprecise definitions, reliance on single measures, and organizational factors limit the validity of heart failure treatment guidelines. O'Connor et al¹² reported that the evidence-based clinical practice guideline on upper respiratory tract infections was generally unhelpful because only 13% of patients with upper respiratory symptoms were actually eligible for adherence to guideline care. Katz¹³ found that guidelines for treating unstable angina likely do not decrease unnecessary hospitalizations and might actually increase admission to limited intensive care unit beds. After initial widespread use of tissue plasminogen activator for acute ischemic stroke, several studies reported significant deviation from national treatment recommendations leading to unacceptably high complication rates.¹⁴ Physicians and care teams involved in randomized trials are often the best in their discipline and the clinical skills they possess may not be available in all communities.

Frequently, the major questions that need to be answered to close the gaps between scientific discovery and widespread use in primary care are not prioritized by funders or undertaken by academic researchers. For example, many studies have involved hypertension, and hypertension treatment guidelines are routinely updated and distributed. Yet, fundamental questions about how to implement these recommendations in primary care remain unresolved. What is the incremental benefit to lowering blood pressure an additional 10 mm Hg by adding another medicine? What are the additional risks? Patients want to know if the benefit is worth the costs of taking yet another pill.

Just as "blue highway" has entered the American travel lexicon, "practice-based research" should enter the mainstream medical research vocabulary and become a strong component of the NIH Roadmap and the CTSA program. Practice-based research is a crucial scientific step, the blue highway, between the great medical advances of the next 25 years and the millions of Americans who want to live a long and healthy life.

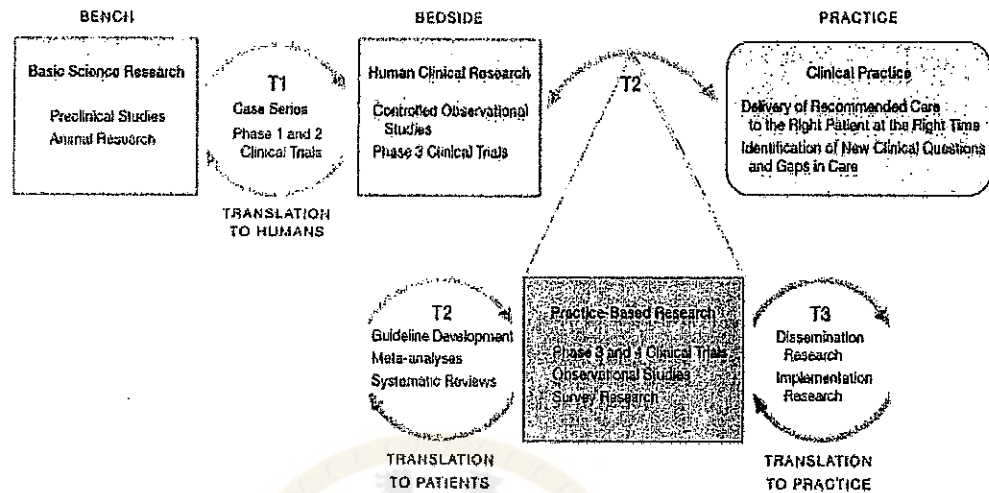


Figure. The current National Institutes of Health (NIH) Roadmap for Medical Research includes 2 major research laboratories (bench and bedside) and 2 translational steps (T1 and T2). Historically, moving new medical discoveries into clinical practice (T2) has been haphazard, occurring largely through 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.

1. 請以中文說明“blue highway”意義並說明“blue highway”主題背景原因
2. 請以中文說明“from bench to practice”意義並說明其限制因素
3. 請以中文敘述“randomized clinical trials”瓶頸和困難
4. 請以中文說明圖意義