Let’s Get Pragmatic

Josephine P. Briggs, M.D.
Director, National Center for Complementary and Alternative Medicine
National Institutes of Health

May 30, 2013

What is a Pragmatic Trial?

Pragmatic trials address ‘real world effectiveness’, usually for interventions for which evidence already exists for ‘efficacy’.

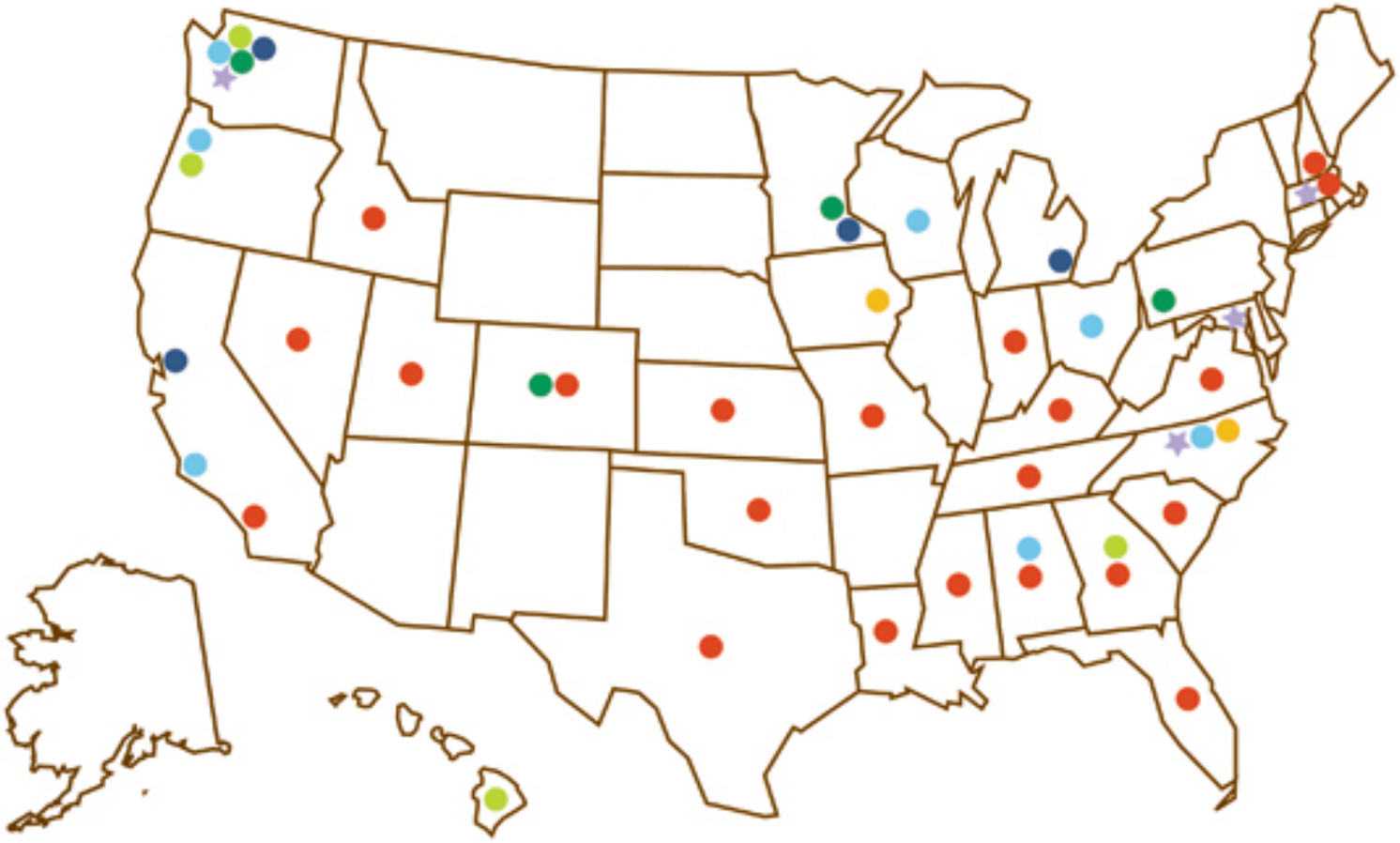
External validity is emphasized by utilizing:

- patient populations like those who would ordinarily be exposed to the treatment,
- interventions administered in standard clinical settings,
- representative practitioners.

Pragmatic trials should not sacrifice rigor. Strategies to achieve large representative patient populations are essential.

Randomization in pragmatic trials is often at the system rather than individual level.

NIH Health Care System Research Collaboratory



- Collaboratory Coordinating Center
- Nighttime Dose of Anti-Hypertensive Medications
- Prevent Suicide Attempt
- Reduce Mortality in End Stage Renal Disease (sites to be selected from units across all 50 states)
- Stop Colon Cancer in Priority Populations
- Chronic Pain in Primary Care
- Reduce Infections and Readmissions
- Lumbar Image Reporting and Epidemiology

Additional sites to be determined

Seven Questions: Pragmatic Trials from the Current NIH HCS Collaboratory

1. **Nocturnal blood pressure control:** Does taking anti-hypertensive medications at night reduce CV events?
2. **Longer dialysis duration:** Does a system-wide approach to increase dialysis duration reduce mortality?
3. **Preventing hospital acquired infections:** Do intensified antibacterial bathing measures reduce infections?
4. **Suicide prevention:** Does a intervention for patients who acknowledge suicidal thoughts reduce attempts?
5. **Colorectal cancer screening:** Does a simple intervention implemented through Federally Qualified Health Centers improve colorectal cancer screening?

A Pragmatic Trial of Lumbar Image Reporting with Epidemiology (LIRE)

Principal Investigator: Jeffrey Jarvik, MD

Institution: University of Washington

- Kaiser Permanente of Northern California
- Group Health Cooperative, Seattle, WA
- Mayo Clinic, Rochester, MN
- Henry Ford Health System, Detroit, MI

NIH Institute/Center Providing Oversight: NIAMS & NCCAM

Program Officer: Jim Panagis (NIAMS)

Project Scientist: Partap Khalsa (NCCAM)

Description: Low back pain, an Institute of Medicine priority condition for comparative effectiveness research, is of major public health importance. It is one of the most common reasons for physician visits and an important cause of functional limitation and disability. Imaging is frequently performed as part of the diagnostic evaluation and is an important contributor to the cost of back pain care, which totaled more than $86 billion in 2005. It is well known that, even without back pain, magnetic resonance (MR) imaging of the lumbar spine frequently reveals...(read more)

Collaborative Care for Chronic Pain in Primary Care

Principal Investigator: Lynn DeBar

Institution: Kaiser Foundation Hospitals

- Kaiser Permanente – Georgia
- Kaiser Permanente – Northwest
- Kaiser Permanente - Hawaii

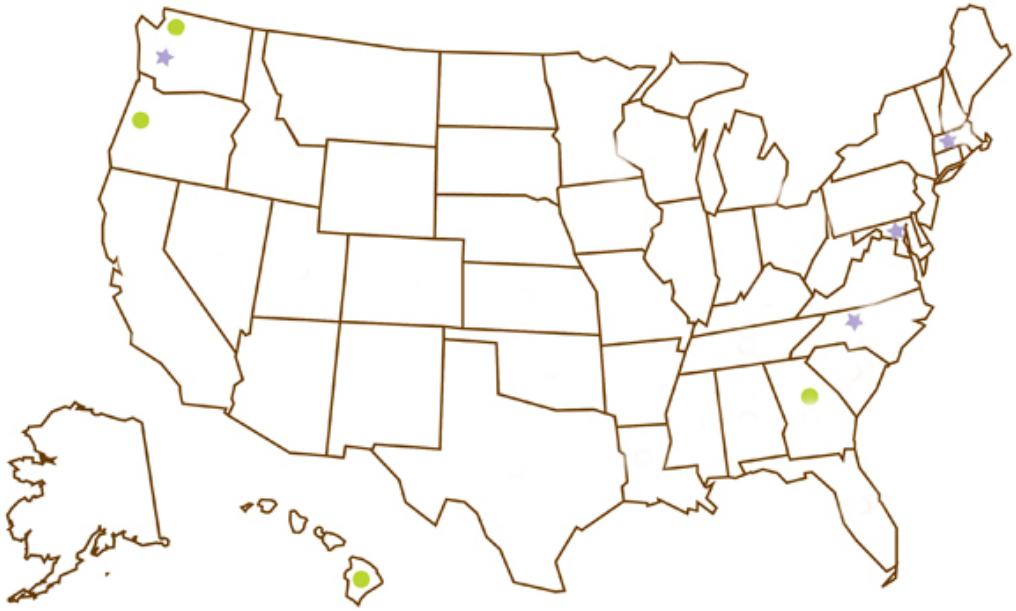
NIH Institutes Providing Oversight: NINDS & NIDA

Program Official: Linda Porter (NINDS)

Project Scientist: Sarah Duffy (NIDA)

Description: Chronic pain affects at least 116 million adults in the United States and exacts a tremendous cost in suffering and lost productivity. While health systems offer specialized pain services, it is in the primary care setting where most patients seek and receive care for pain. However, primary care providers often lack the specific training, not to mention the time, to deliver effective pain-management care. To address this problem...(read more)

NIH Health Care System Research Collaboratory



★ Collaboratory Coordinating Center
● Chronic Pain in Primary Care

Additional sites to be determined

National Center for Complementary and Alternative Medicine

Clearinghouse: 1-888-644-6226

Web site: nccam.nih.gov

Twitter: @NCCAM