



# An Overview of the VA Point of Care Program

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# The VA Point of Care Program

- Goal: large inexpensive RCTs
- Optimize use of EMRs
- Avoid the cost of “the clinical trial apparatus”
- Recruitment/randomization “at the point of care”
- DCP is the first full scale RCT in this program

# Chlorthalidone Versus Hydrochlorothiazide: A New Kind of Veterans Affairs Cooperative Study

Frank A. Lederle, MD; William C. Cushman, MD; Ryan E. Ferguson, ScD, MPH; Mary T. Brophy, MD, MPH; and Louis D. Fiore, MD, MPH

*Ann Intern Med.* 2016;165:663-664.

## Investigators:

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# Diuretic Comparison Project

## Study Question

Does treatment with chlorthalidone (CTD) reduce major adverse cardiovascular events (MACE) compared with hydrochlorothiazide (HCTZ) in older veterans with hypertension?

# DCP Study Design

- Prospective randomized open-label blinded-endpoint (PROBE) trial.
- Very broad inclusion criteria.
- Centralized informatics-based clinically integrated structure.
- N=13500
- HCTZ users randomized to stay on current therapy or to initiate CTD

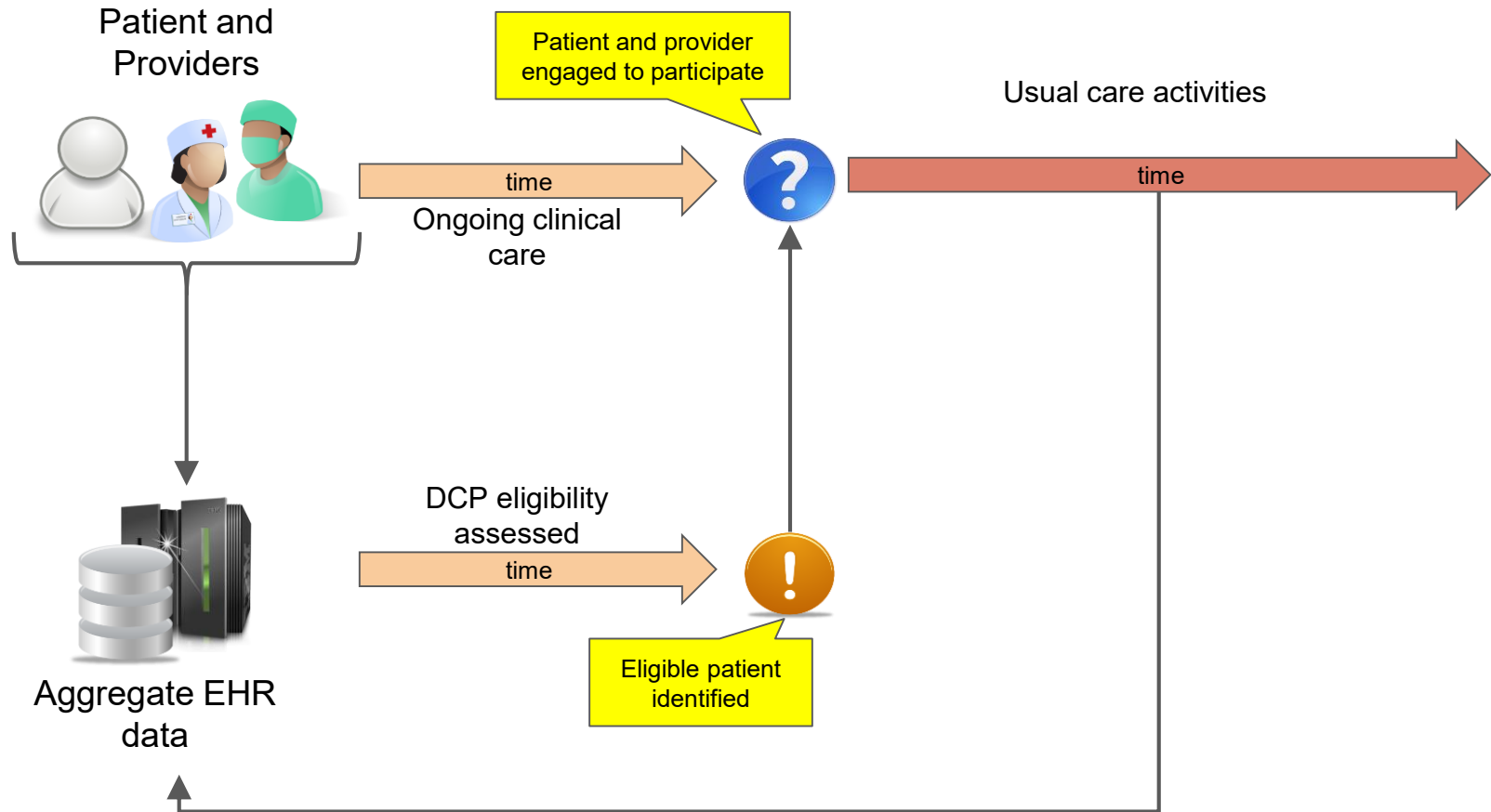
# Pragmatic Features:

- 1) Design with technology as a force multiplier
- 2) Embedded within VA Information Systems & EMR
  - find eligible patients using VA EMR
  - centralized recruitment and enrollment
  - centralized placement of notes & orders
  - PCPs: permission & pt care (including study drug)
  - centralized collection of outcomes from EMR database

# Pragmatic Features:

- 3) Clinical sites not “engaged in research” - no local personnel (10% cost)
- 4) Telephone base informed consent for participants with a clinical assent to maintain clinical autonomy
- 5) Minimal perturbation of the clinical workflow. Study designed to “fold into” PCP processes

# Simplified DCP Workflow





# Next Generation of Pragmatic Trials

- VA SOLID – Stenosis Outcomes in Lumbar Instrumentation or Decompression
  - Spinal Stenosis and Low back pain in veterans
  - Randomization to Laminectomy or Laminectomy plus Instrumentation (hardware)
  - Outcomes: Functional, surgical, medical
  - Disruptive features: Clinically integrated, embedded completely within surgical workflow, central PRO collection, observational arm

# Next Generation of Pragmatic Trials

- Alcohol withdrawal syndrome (AWS)
  - 17 admissions for AWS weekly in VA Boston alone.
  - Randomization to phenobarbital or to benzos when admitted to critical care unit
  - Outcomes: LOS, re-use within 30days.
  - Disruptive features: Clinically integrated, embedded within critical care and medical floor workflows, immediate decision support.

# Closing

- Reduction in barriers to participation has a real world impact.
- Engagement is a vital.
- Generalizability may be limited beyond the VA System -- “Locally selfish” learning.
- Use of Real World Data is challenging reality for the clinical trials enterprise – drives implementation.