



# Engineering a Learning Healthcare System

VA's Experience in Embedding Randomization via a Point-of-Care  
Clinical Trial in the Healthcare System

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# Introduction

- MAVERIC
  - Intramural VA Research Program at the Boston VA
  - Funded largely by VA Cooperative Studies Program
  - **Multi-disciplinary** research & development program:
    - Large scale clinical trials
    - Informatics
    - Epidemiology
    - Biospecimen repository
- Our ***vision*** is to create a *Learning Healthcare System* within VA through application of research resources and methodologies to important clinical problems.



# The Healthcare Value Gap



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## Perspective

### Ranking 37th — Measuring the Performance of the U.S. Health Care System

Christopher J.L. Murray, M.D., D.Phil., and Julio Frenk, M.D., Ph.D., M.P.H.  
N Engl J Med 2010; 362:98-99 | January 14, 2010 | DOI: 10.1056/NEJMp0910064

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Article **References** Citing Articles (14) Letters

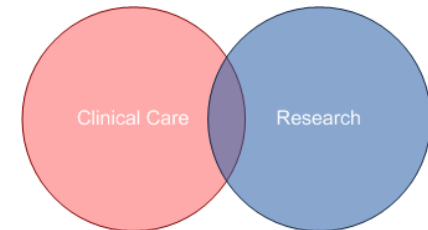
Evidence that other countries perform better than the United States in ensuring the health of their populations is a sure prod to the reformist impulse. The World Health Report 2000, *Health Systems: Improving Performance*, ranked the U.S. health care system 37th in the world<sup>1</sup> — a result that has been discussed frequently during the current debate on U.S. health care reform.

The conceptual framework underlying the rankings<sup>2</sup> proposed that health systems should be assessed by comparing the extent to which investments in public health and medical care were

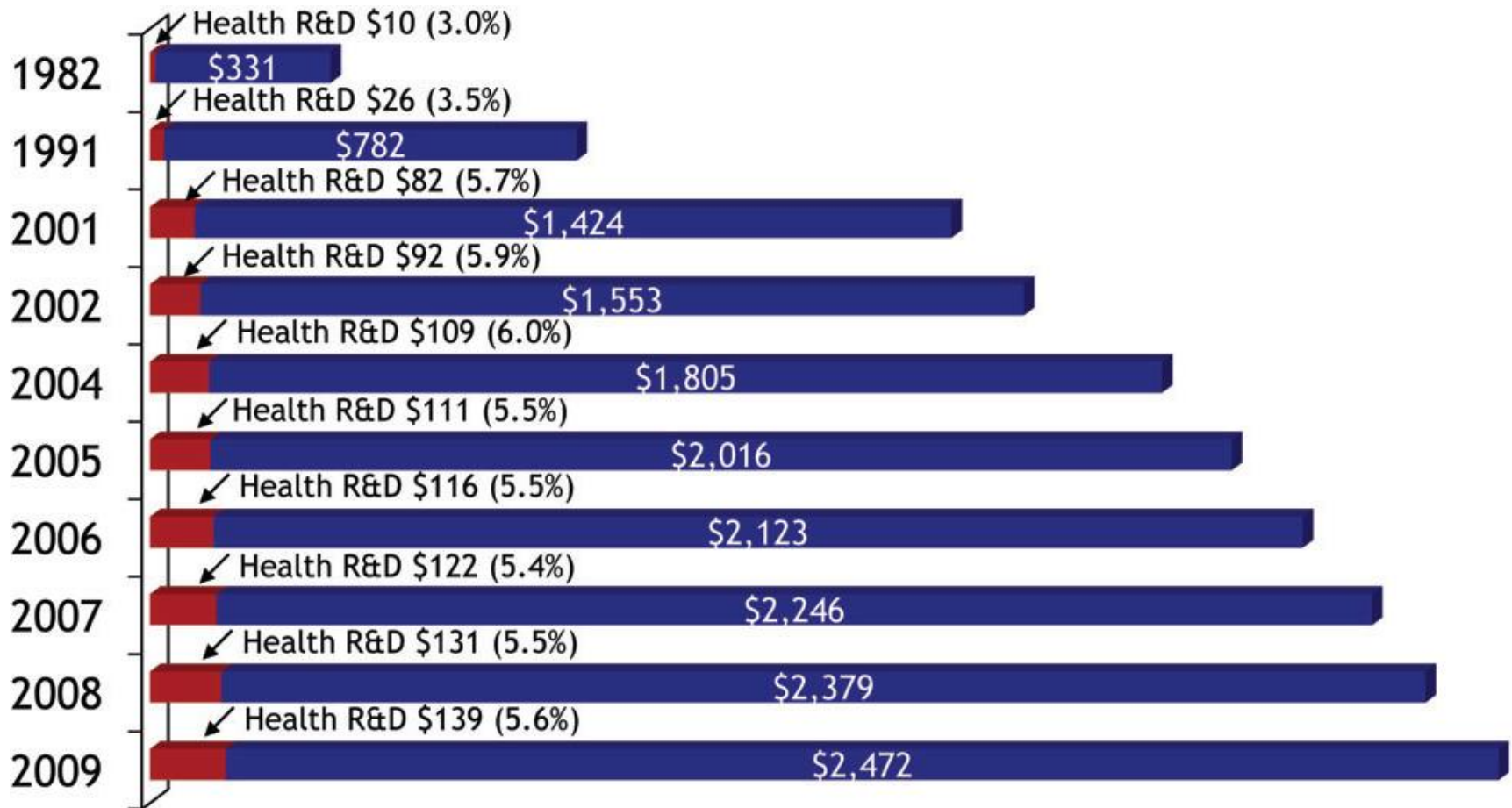


# Problem Statement

- Evidence creation is inefficient
- Healthcare system's **information** needs are not met by the current research enterprise
  - Designed for basic science inquiry and drug and biomarker discovery
  - Asynchronous worlds
  - Scalability



# Health R&D as a Percentage of Health Costs



Sources: NIH Data Book; Research!America, Investment in U.S. Health Research 2001, 2002, 2004-2009



# A Solution:

- Creation of a Learning Healthcare System that creates locally applicable knowledge
  - Identifies its' own needs
  - Uses its' own infrastructure
  - Uses available research methodologies and expertise
  - Directly implements research results into practice
- The knowledge gained is thus not generalizable (thus not 'research') but rather is 'locally selfish'.

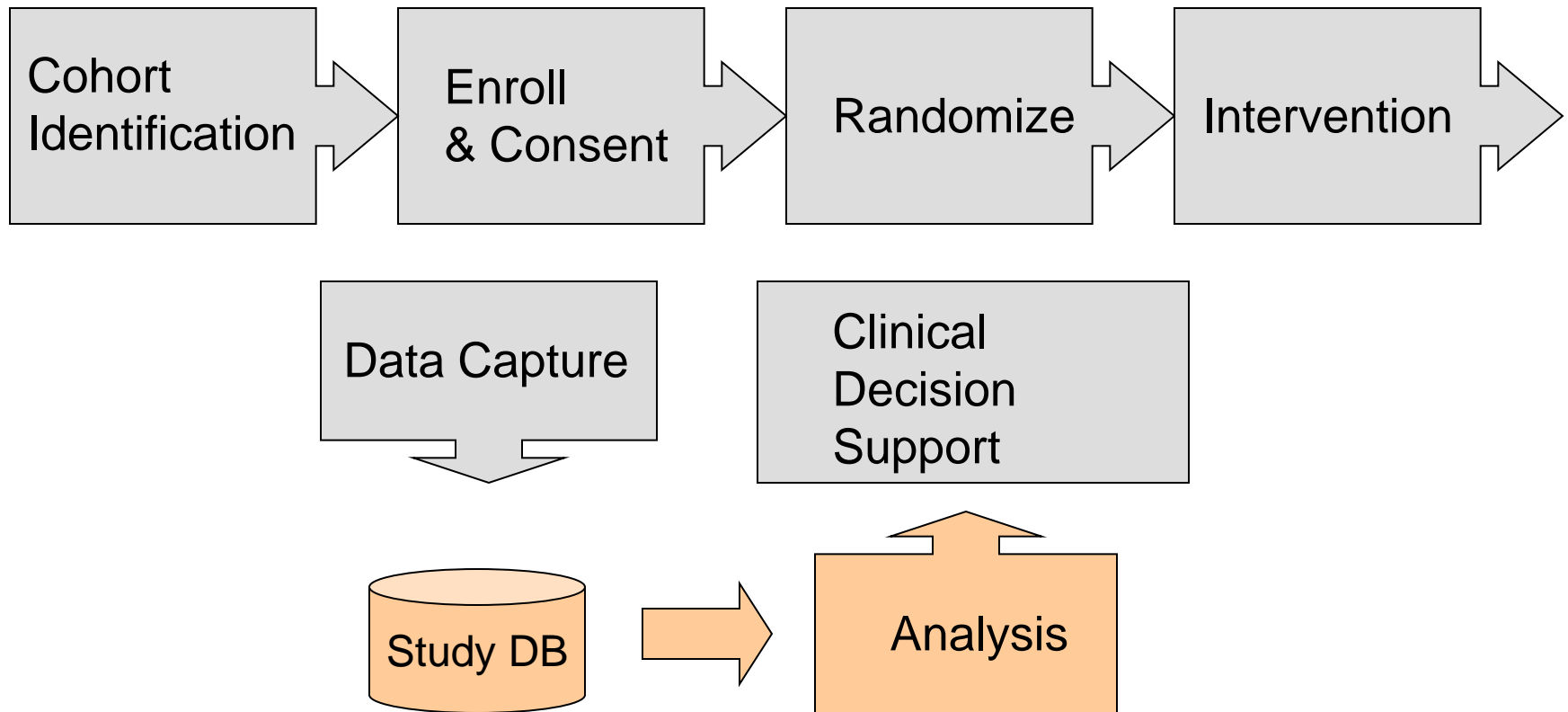


# Point of Care Research - Clinical Trial

- A clinical trial with a substantial portion of its operations conducted by clinical staff in the course of providing patient/subject's routine clinical care and where the choice of treatment is between two “equivalent” options
- RCT workflow done entirely within the EMR



## Care providers using EMR



## Study team using traditional scientific tools



# POCR Pilot Study goals

- Establish feasibility of POCR
  - Physician and patient acceptance
  - EMR
    - Ability to modify the EMR screens
    - Data quality
    - Ability to use NLP, etc
  - IRB and regulatory acceptance
- Settle a substantive clinical issue to the system/institution
- Demonstrate closing the implementation gap



# POC Pilot Study – Insulin Protocol

- Little evidence supports the use of sliding scale over weight based administration of insulin and vice versa.
- Open label RCT comparing the regimens @ 3 VAMCs
- Broad eligibility criteria.
- Primary endpoint = LOS
  - In-patient glycemic control and readmission within 30 days for glycemic control were secondary outcomes.

**Option 1** for  
consideration  
of study

**Endocrine Medication Menu** Done

**Diabetes Medications**

**Insulin Options:**

- 1. No preference for insulin regimen. Consider enrollment in an inpatient study of Weight Based vs. Sliding Scale protocols.**  
To choose option 1 **\*\*Click HERE\*\***
- 2. Weight Based insulin protocol.**  
Weight Based Insulin protocol **\*\*Click HERE\*\***
- 3. Sliding Scale or other inpatient insulin regimen.**  
Other Inpatient Insulin Orders **\*\*Click HERE\*\***

**Portland Protocol (ICU Patients)**  
Portland Protocol **\*\*Click HERE\*\***

**Oral Hypoglycemics**  
Oral Diabetes Medications Menu **\*\*Click HERE\*\***

**Thyroid Medications**  
Thyroid Medications Menu **\*\*Click HERE\*\***

**Steroids (under construction)**

**Reminder Dialog Template: RESEARCH STUDY RANDOMIZED INSULIN PROTOCOL**

You have started the process to enter the patient in a randomized trial of insulin protocols. If you continue this process, the patient will be automatically placed (randomly) on either the Sliding Scale insulin protocol, or a Weight Based insulin protocol.

<-- Click here if the patient has consented for all study procedures. Note that a signed consent form is needed to proceed.

<-- Click here if the patient has not agreed to randomization, but has agreed to the review of his/her medical record. Note that a signed consent form is needed to proceed.

<-- Click here if the patient has refused consent.

**Point of Care Randomization Progress Note**


This patient is a subject in the Point of Care Randomization study comparing the efficacy of two accepted methods of subcutaneous insulin administration - the sliding scale regimen and the weight based regimen. Each of these methods of insulin treatment has a standard order menu in CPRS. With the patient's permission, the ordering clinician has agreed to participate in this study, allowing the software to randomly select one of the insulin protocols. Participation in the study allows the software to randomly select one of the insulin protocols. Once this action was taken the provider was instructed to assure that consent was obtained from the patient and then to select this template progress note to serve as notification that the patient has been enrolled in the study and is now a study subject. Beyond these actions there are no other study-defined interventions that are to be followed. At some time point in the future the subject's medical record will be accessed and reviewed to determine blood sugar values during this hospital stay, the length of this hospital stay in days and whether the patient is readmitted for blood sugar control within 30 days of discharge. Other medical data that describes why the patient was admitted and what other medical conditions they have will also be gathered.

By comparing the results in the two groups of study subjects (those randomly assigned to sliding scale versus weight based regimens)

Dialog template for note  
(decision to enroll)



# Recruitment Summary

Recruitment	Total N (%)	Boston N	Providence N
Number of Eligible Patients	168	149	19
	119	108	11
Patients enrolled 	111(93.2%)	103	8



# Interesting Qualitative Data from Focus Groups and Surveys:

- **Providers:**
  - Resist (or do not notice) minimal changes to the EMR.
  - Accept the method and scientific methodology.
  - Question R&D role in clinical care.
  - Concerned about autonomy, compliance, time.
- **Patients:**
  - Worry a lot less about the things that we think they worry about.



# Interesting Quantitative Data from Pilot:

- Data quality is hyper-variable (structured vs not)
- High acceptance rates
  - Regulators, providers, and patients
- High participation rates
  - Zero losses to follow-up
  - Decline rate is 3x lower than traditional trials!
- **No safety events and no deaths!**



# From the Specific to the General





# POCR Advantages

- *Pragmatic* qualities address issues of Clinical Effectiveness
  - Results directly relevant to healthcare system
- Faster (immediate) Integration of results into practice thereby lowering the T2 translation barrier
  - Enhanced acceptance by providers and patients
  - Bayesian approach allows conversion to a decision support node
- Improved logistics – speedy answer and speedy use



# Use of the EMR to implement a clinical trial is possible!

- Good (i.e., usable and interpretable) data from the EMR is NOT an illusion.
- Few technical problems with adaptation of screens and order sets.
- But there are issues with:
  - Governance
  - Structure of data and ability to use informatics tools like NLP



# Cultural Barriers to Implementation

- Patients do not believe that doctors do not know what is best for them
- Doctors do not believe that they do not know what is best for their patients
- IRBs do not believe that patients want to enter a research study without completing a 25 page consent form
- Statisticians do not believe...



# The Free Rider Dilemma





# POCR Requirements and Priorities for Implementation

- Rethink relationship between clinical care and research
- Buy-in by patients, providers and clinical operations
- Next Generation EMR
- Rational approach to oversight of research



# Next Steps in the VA

- More Focus Groups and Surveys
- More Studies
  - HCTZ vs Clorthalidone (n=12,000)
  - Case Management in PTSD (n=7,800)
- Reframing POC Activities
  - Not Research – normal course of clinical care.
- Participation in design of the next EMR

...and beyond the VA...



# Why now?

- Digitization of medical care information
- Reimbursement for quality not volume
- Accountable care organization needs
  - Development of healthcare intelligence tools
  - Need for comparative effectiveness research
- Increasing costs of clinical trials



# The Healthcare System is:

*The Bad News*

- *inhospitable to*
- *intolerant of*
- *and unmoved by experimental research*

*The Good News*

- *unaffordable*
- *unsuccessful*
- *and on the verge of collapse*



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# VA POCR Team

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- Statisticians: Robert Lew, Gheorghe Doros