



Engineering a Learning Healthcare System

The Department of Veterans Affairs' Point of Care Research Program

Ryan E. Ferguson, ScD, MPH

Acting Center Director, VA CSP Coordinating
Center

Deputy Director, MAVERIC

BU School of Public Health



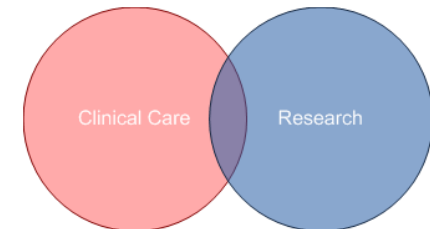
Introduction

- MAVERIC
 - Intramural VA Research Program at the Boston VA
 - 140+ FTE **multi-disciplinary** research & development
 - Large scale clinical trials
 - ISO 9001Registered
 - 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.



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





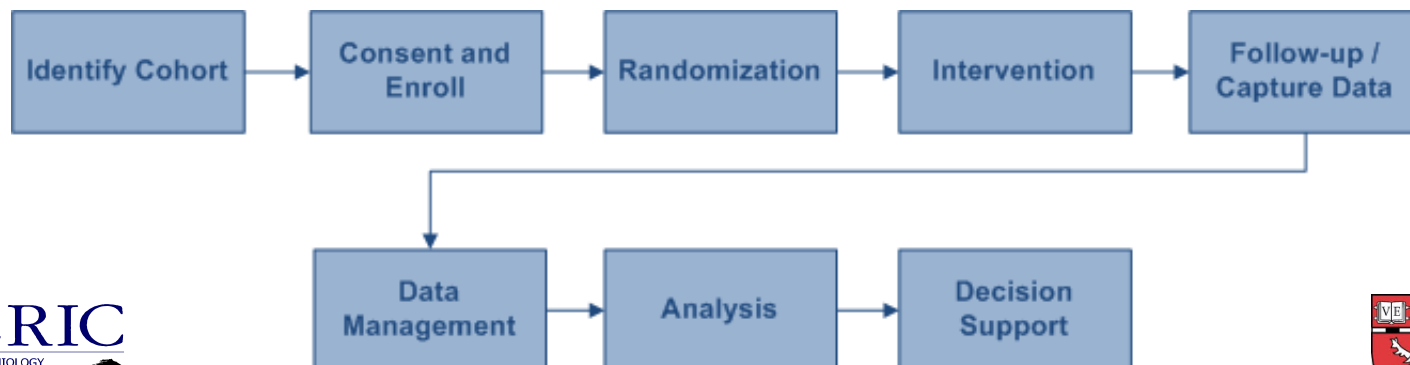
A Solution:

- 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 Example

- 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 VA's homegrown EMR:





Closing the Implementation Gap

- Hybrid Bayesian/frequentist approach “adaptive learning”
 - Use of Bayesian posterior probability to reset the randomization (adaptive randomization)
 - Use of conventional (frequentist) error rate calculations to evaluate the evidence
- “Learning” promotes automated **implementation** of the winning strategy



POCR Advantages

- *Pragmatic* qualities address issues of Clinical Effectiveness
 - Ability to assess long-term clinically relevant outcomes (lower cost)
- Faster (immediate) Integration of results into practice thereby lowering the T2 translation barrier
 - Enhanced acceptance by providers
 - Adaptive randomization
 - Conversion to a decision support node
- Improved logistics – speedy answer and speedy use



POCR Pilot Study goals

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



POCR – 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
- Inclusion: inpatients not in the ICU
- Exclusion: stay on home regimen; inability to give informed consent
- Endpoints:
 - Primary - LOS
 - Secondary - inpatient glycemic control and readmission within 30 days for glycemic control



POCR – Insulin Protocol

- Methods:
 - No modification of the current sliding scale or weight based regimens as they exist in the VA VistA system
 - Interface with clinicians entirely through the VA EMR (VistA) packages
 - Data collection and follow-up is done passively through the VistA system

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)

Study Information and Instructions

(select **Yes** or **No**)

Study Information

Done

STUDY INFORMATION

Purpose
To compare effectiveness of Sliding Scale vs. Weight Based insulin protocols for diabetic inpatients.

Entry Criteria
Patients who are not in the ICU for whom you have no preference for insulin protocol. Patient must be able to provide signed informed consent.

Study Procedures

1) Routine initial insulin orders as needed prior to randomization.

2) Consent by research team and randomization to the Sliding Scale or the Weight Based insulin protocols.

3) Usual medical care. Enrollment does not restrict new or added insulin orders.

4) Medical record reviewed by research team up to one month post discharge.

Choose one of the options below to indicate whether or not you agree to allow your patient to be considered for enrollment into the study. Note that whether you recommend your patient for the study or not you will be fully responsible for their medical care.

YES The research team may approach this patient for consideration of enrollment.
Click [HERE] Yes

NO The patient may not be approached. Proceed with usual care.
Click [HERE] No

Dialog template for note (decision to enroll)

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.

[Visit Info](#) [Finish](#) [Cancel](#)

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)

(please see next slide for complete text)



Interesting Data from Pilot:

- Qualitative:
 - Providers
 - Resist change (to EMR, workload, workflow).
 - Accept the method if engaged.
 - Patients
 - Accept the method if engaged and informed
- Quantitative:
 - Data quality is hyper-variable (structured vs not)
 - High acceptance rates
 - Regulators, providers
 - High participation rates
 - Zero losses to follow-up
 - No deaths
 - No safety events



From the Specific to the General



Asking the right questions for the healthcare system

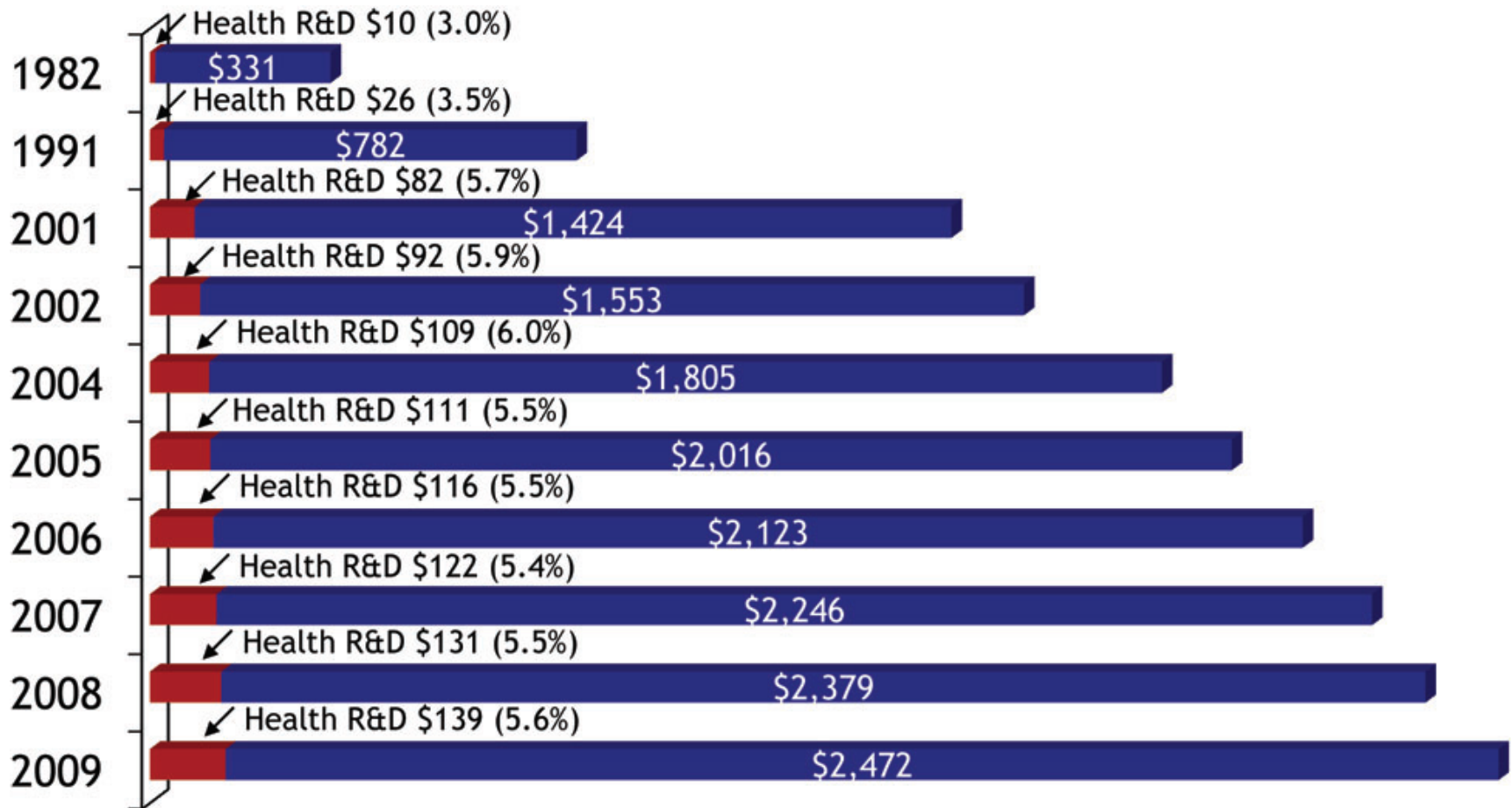
- Driven by clinical ‘side of the house’
- Optimal Characteristics:
 - Limited to questions of the type: *which “approved” treatment works better?*
 - Interventions with well described toxicity
 - Broad inclusion criteria; limited exclusion criteria
 - Objectively identifiable endpoints
 - Minimal need for study specific visits



Use of the EMR is possible!

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

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



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 R&D
- Buy-in by providers and clinical operations
- Next Generation EMR for more sophistication
 - App-Driven approach
- Rational approach to regulatory oversight:
 - Informed consent
 - Engaged in research
 - SAE reporting



Next Steps in the VA

- Focus Groups and Surveys
- Additional use cases using CSP infrastructure
 - Hep C
 - Cardiology
 - Mental Health
- Pre-consented population
- Redefinition as quality improvement activity
- Participation in design of the next EMR

...and beyond the VA...



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

- Principal Investigators: Louis Fiore and Philip Lavori
- Program Director: Ryan Ferguson
- Co-Investigators: Ryan Ferguson, Mary Brophy, James Kaufman, Mike Gaziano
- Informatics: Leonard D'Avolio and Chester Conrad
- Trial Managers: Patricia Woods and Katherine Riley
- CPRS Engineers: Gus O'Neil and Tom Sabin
- Ethics and Informed Consent: John Hermos
- Content Expert: Stephen Swartz
- Data Management: Maria Androsenko, Galena Sokolovskaya
- Statisticians: Robert Lew, Gheorghe Doros