The Department of Veterans Affairs
Point of Care Clinical Trial and Precision Oncology Programs:
Using Electronic Medical Record Systems and Health System Data in Support of Learning Healthcare System Activities

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MAVERIC
The VA Cooperative Studies Program
VISN 1 Clinical Trail Network

10 May 2016
The Healthcare Value Gap
The Pharmaceutical Innovation Gap

Figure 1. Novel drugs approved by the FDA in 2009.
The VA VistA/CPRS National EHR
Kaleid - Healthcare System Business Intelligence
Point of Care Clinical Trials

1. Cohort Identification
2. Enroll & Consent
3. Randomize
4. Intervention
5. Data Capture
6. Clinical Decision Support
7. Study DB
8. Analysis

Study team using traditional scientific tools
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)
VA Activities in Support of LHS and Precision Medicine

‘OMICS
- Build a cohort
- Make data accessible
- Discover

Actionable Results
- Validate
- Implement

Million Veteran Program & GenISIS
Point of Care Research & Precision Oncology
U.S. Department of Veterans Affairs

Precision Oncology Program

*Precision cancer care as unique as your DNA*

The Crossroads of Clinical Care and Research
What is Precision Oncology?

- Perform genomic test on a cancer specimen
- Determine driver mutations in the cancer
- Deliver therapy based on identified target

But......
- Several targets in a given patient
- Different targets across patients
- Same targets in different cancer types
- Few patients with any given target at one site
Patient and Providers

Create POP Data Repository

Ongoing clinical care

Collection of Biomarkers from EHR

Usual care activities

Patient and/or provider asked to participate

Time

Patient match to clinical trial

Trial related activities
POP Clinical Care Component

- Molecular profiling for all NSCLC patients as routine care and ordered by their treating clinician
  - Provide opportunities for participation in traditional clinical trials
  - Provide local learning opportunities through analytics and randomization into point of care clinical trials
Traditional Clinical Trial Opportunities

- ASCO TAPUR Study
- NCI sponsored intergroup projects
  - SWOG VA Consortium – Storefront Mechanism
- Pharma sponsored trials
- VA sponsored trials
Local Learning Through Experiments

Prior N patients

N+1 cancer genome

Dx

Tx

Similar patients

Tx

Outcomes

A

B

If equipoise, offer randomization within routine care

Providers

randomized outcomes

N+1 patient

Time

MAVERIC
MASSACHUSETTS VETERANS EPIDEMIOLOGY
RESEARCH AND INFORMATION CENTER
Local Learning and Care Optimization

- Specific local actionable insights
- Predictions

Providers / Tumor board

Best care plan
- for specific patient and goals of care
- with best delivery mechanism
- with given providers

Patient
- Goals of care
- Functional status
- Obs daily living
- Cancer genomic alterations
- EHR clinical history
- Lab tests
- Imaging
POP Research Component

• Patients consented for broad data sharing, re-contact and reuse of tissue
• Research data and (virtual) tissue repositories created
  – Biomarker discovery and validation
• Shared resource with VA and non-VA stakeholders
POP Research Questions

• Clinical population-based knowledge generation
  • In combination with germ-line data from MVP
• Basic science research
  • Proteogenomics, other
Learning Healthcare System
1985

VA EHR national deployment

1985

VA CDW established

MVP created

2010

VA CDW for widespread use

CDW for widespread use

Murray & Frenk - "US Healthcare 37th in quality"

IOM - Envisioning transformed clinical trials enterprise

VA POC Insulin pilot launched (closed 2014)

2012

VISN 1 POP created

MVP created

2015

VA POC DCP funded

VA POC DCP funded

IOM - Transforming Clinical Research in US

VISN 1 POP created

2016

VA POP Clinical & Research program created

VA POP Clinical & Research program created