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 Clinical Trials and Learning Healthcare System Activities

Louis Fiore
Mary Brophy
Ryan Ferguson

The VA Cooperative Studies Program
VISN 1 Clinical Trial Network

30 March 2016
The VA VistA/CPRS National EHR
Exemplars

• Insulin Study
  – Randomization to sliding scale or weight based insulin regimens
  – Recruitment from EHR without a registry or data warehouse

• Diuretic Comparison Study
  – Randomization to hydrochlorothiazide or chlorthalidone
  – Recruitment from Corporate Data Warehouse

• Precision Oncology Program
  – DNA targeted sequence with subsequent enrollment into matched clinical trial
  – Recruitment from the Precision Oncology Clinical Data Repository
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)
Workflow of the POC DCP

- Present to coordinating center staff
- Present to provider and capture provider consent via EHR order

Recruitment

- Patients identified by data repository
- Supported by EHR workflow
- New EHR orderable item
- Application to support study

Data sources

- CDW aggregate (needs validation, cleaning, curation for study usage)
- Lessons from FDA mini-sentinel, PCORNet, EDM

Clinical Care
Workflow of the POP (and rLHS)

- Patient
- Providers
- CDW aggregate
- Vista EHR

Clinical Care

- Identify patients
- Present to study staff
- Engage clinical flow
- Manual check eligibility
- Consent patient for research arm of POP

- Offer CT match
- Present insights
- Offer randomization in routine care

- Special data repository
- Automated processes
- Study workflow application
- All patients participate in learning

Knowledge Repository

Clinical Care

- Imaging
- Research
- Patient entered observations

Subsequent data
Major Barriers and Solutions

• Technical
  – Phenotype identification compromised by data
    • Unstructured
    • Not administrative data
    • Drives enrollment criteria and outcome selection
  – Corporate Data Warehouse
    • Not validated
      – Data Wiki (Mini Sentinel)
    • Data interpretation issues
    • Missing data elements
    • Missing data fields
  • Macro data use
  • Micro data use
Major Barriers and Solutions

• Research versus Learning
  – Ownership by clinical care providers and administration
  – Types of questions that are asked
• Cultural
  – Researcher mentality (Silo)
  – Clinical autonomy
  – Patient preference
  – Perception of patient preference
• Site support
  – Alternative provider incentive
• Regulatory
  – Engagement in Research
Major Barriers and Solutions

• Informed consent
  – Data repository requires waiver if not operational
  – Obtained centrally by phone
  – Equates to risk mitigation
  – HIPAA authorization through mail

• Implementation of Intervention
  – Workflow in EHR (vs parallel ecosystem)
  – Conversion to decision support (T2 translation gap)

• SAE monitoring
  – Surveillance through data review (vs parallel ecosystem)
  – Detected late
  – Risk based
  – Drives intervention possibilities
Generalizability

• Reduction of barriers to patient participation = better enrollment
• Locally selfish