Learning Health System RCTs

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- "...a system that gains knowledge from every care delivery experience and is engineered to promote continuous improvement."
- Randomized controlled trials (RCTs) are the best way to gain knowledge...
 - A vision: every patient is randomized at least once during their encounter...
- Can we "embed" RCTs in our healthcare system at UCSF?

- What does it mean to embed an RCT?
 - Embedded in EHR technology
 - Embedded in clinical workflow

- Embedded in EHR technology
 - Eligible patients automatically identified by APEX
 - Randomization implemented by APEX (our Epic EHR)
 - Interventions (in each arm) are delivered by APEX
 - APEX is designed to support clinical decision-making and "nudge" clinicians to deliver better care
 - Outcomes are measured using APEX data

- Embedded in clinical workflow
 - "Unsuspecting" clinicians will encounter the intervention
 - Whether they know it or not
 - No prior knowledge of the research required
 - Must not perturb clinical workflows too much
 - Extra time, unbillable services, etc
 - Patient consent? Extra data collection?
 - Allow clinicians (and patients) to make clinical decisions
 - Pragmatic, non-protocolized interventions

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LHS Demonstration Projects

- CTSI-supported embedded RCTs at UCSF
- Calls for proposals
 - Identify a health outcome measurable by APEX query
 - Propose a scalable intervention to improve the outcome
 - Design an RCT to evaluate impact
- CTSI supports investigator time + in-kind support
 - APEX programming, study design, data work, etc
 - 8 projects total, 6 launched so far

RQI Example #1: Hypoglycemia

- Hypoglycemia events in the hospital
 - Lead Rob Rushakoff
- Background
 - Uncommon, but should be predictable and preventable
 - Risk score exists
- Plan
 - Implement risk score, alert clinicians with advice

RQI Example #1: Hypoglycemia





= modification of workflow



RQI Example #2: COPD orders

- Standardizing COPD orders
 - Lead Ari Hoffman
- Background
 - Lots of standard COPD treatments that are not getting done at UCSF; and readmission rates are high
- Plan
 - Develop evidence-based orders, and insert into admission order sets for persons at high risk

RQI Example #2: COPD orders





= modification of workflow



RQI Example #3: Healthy Start

- Nomogram for expected weight loss in neonates
 - Lead Valerie Flaherman
- Background
 - Well babies are expected to lose weight in first weeks
 - But losing too much weight is dangerous
 - Nomogram and web tool exists
- Plan
 - Autopopulate web-based nomogram and show to clinicians as guide to supplementation

RQI Example #3: Healthy Start





= modification of workflow



RQI Example #3: Healthy Start

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RQI Example #3: Healthy Start Screenshot

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Lessons learned

- Embedded RCTs are feasible and useful
 - Allowed us to see unintended consequences
- Hard to design good decision support!
- Technology evolving
 - More shareable (SMART on FHIR)
 - Machine learning, etc