Learning Health System RCTs

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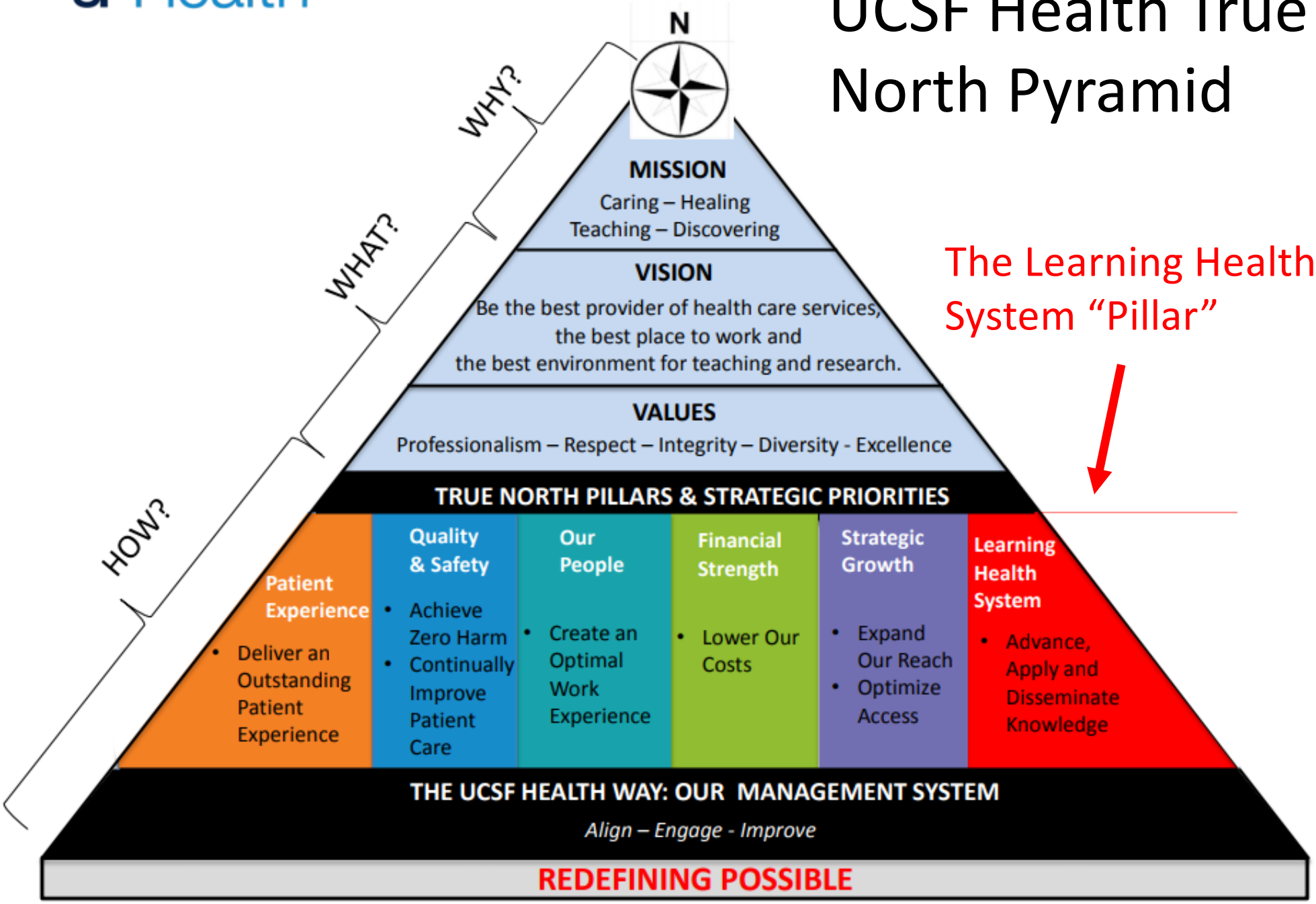
UCSF Health

UCSF Health True North Pyramid



The Learning Health System "Pillar"

What is a Learning Health System?

- "…a system that gains knowledge from every care delivery experience and is engineered to promote continuous improvement."

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  - A vision: every patient is randomized at least once during their encounter…

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- Can we "embed" RCTs in our healthcare system at UCSF?

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Embedded RCTs

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

Embedded RCTs

- 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 RCTs

- 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

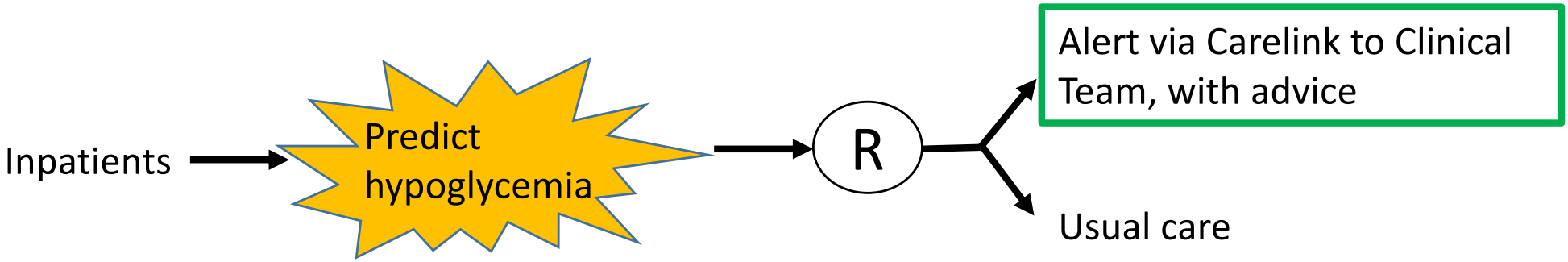
- Calls for proposals
  - Identify a health outcome measurable by APEX query
  - Propose a scalable intervention to improve the outcome
  - Design an RCT to evaluate impact

- 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



= predictive analytics

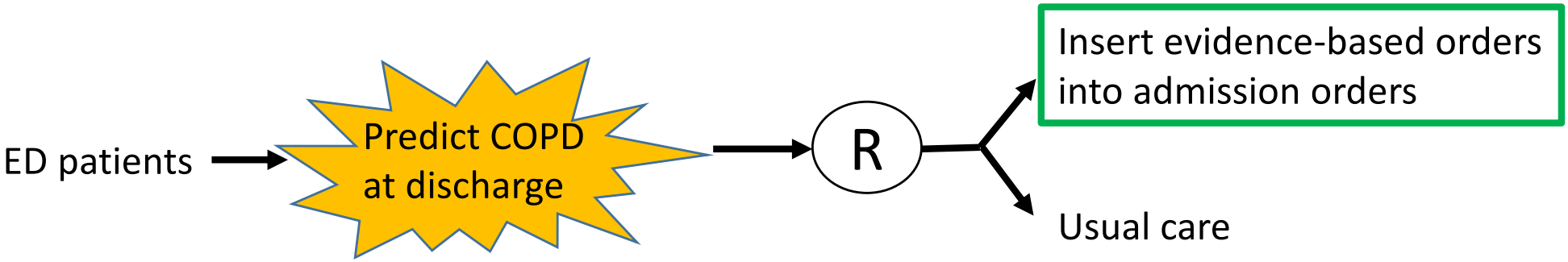
= modification of workflow

R = randomization

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



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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

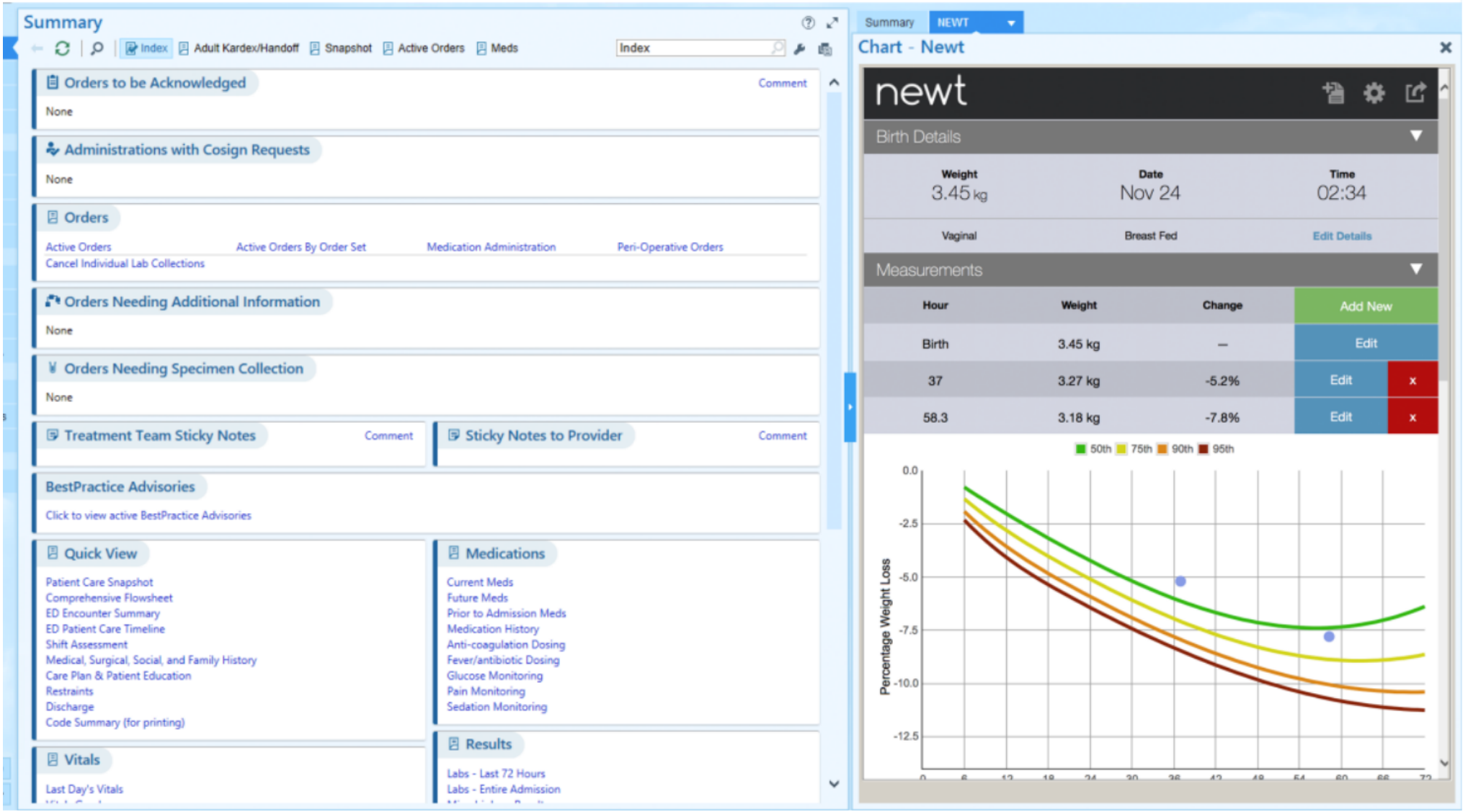
= predictive analytics

= modification of workflow

R = randomization

RQI Example #3: Healthy Start

Screenshot

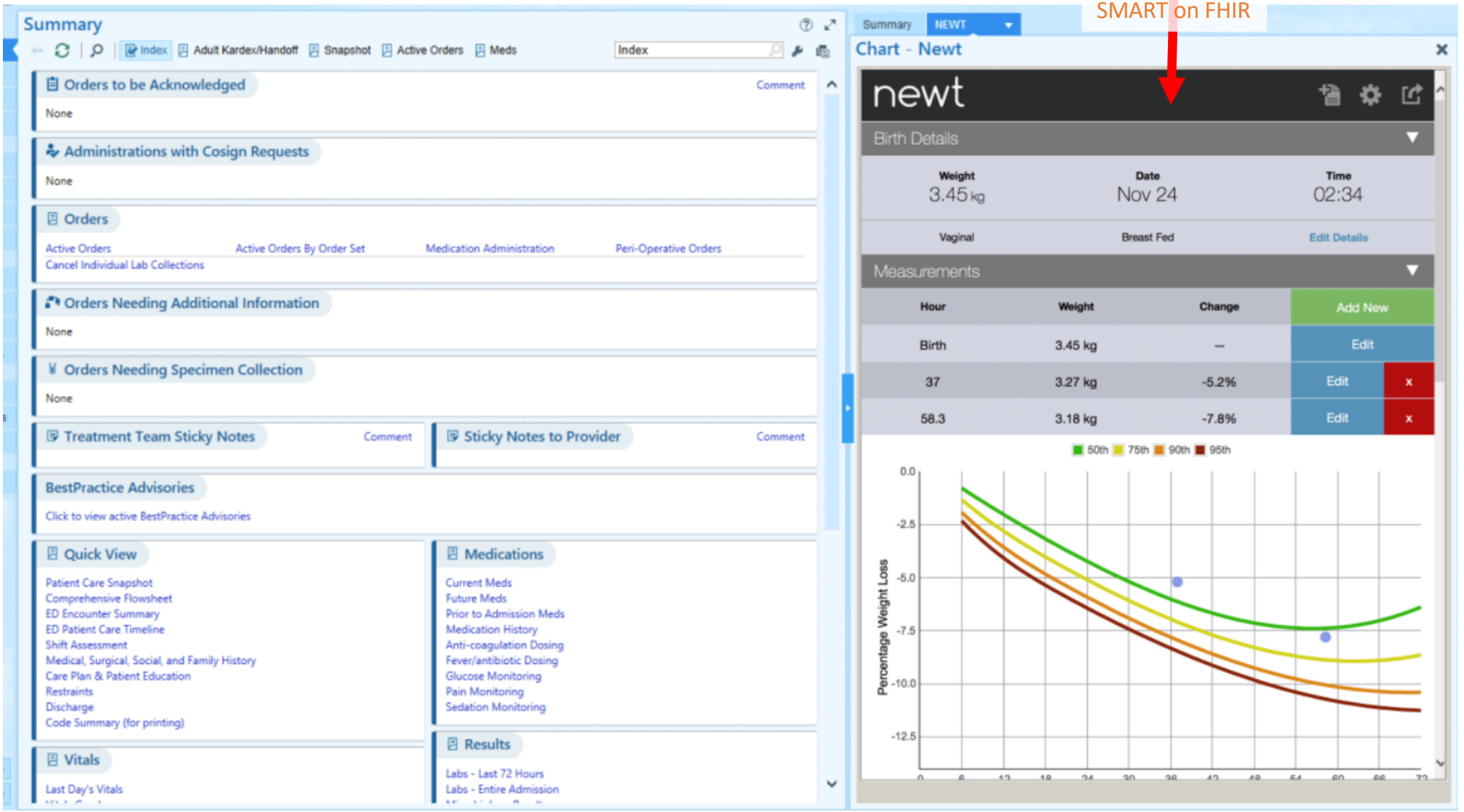


RQI Example #3: Healthy Start

Screenshot

External website

SMART on FHIR



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