

---

# Impact of Comparative Effectiveness on Practice

---

Marc S. Williams, MD, FAAP, FACMG  
Director, Intermountain Healthcare Clinical  
Genetics Institute  
June 12, 2009

---

# Comparative Effectiveness vs. Improvement

## ■ CER

- Definition evolving
- Methodologies diverse
  - Retrospective meta-analysis
  - Use of patient registries
  - 'Mining' health system databases
  - Head-to-head prospective trials
  - Others?

## ■ Quality Improvement

- Primarily management of processes
  - Also uses diverse methods
  - Not primarily a research tool
  - Does result in impressive improvement in care that can be disseminated
-

---

# Process

- A series of linked steps, often but not necessarily sequential, designed to...
    - ❑ Cause some set of outcomes to occur
    - ❑ Transform inputs into outputs
    - ❑ Generate useful information
    - ❑ Add value
-

---

# Process Management

- Start with knowledge of...
    - Processes
    - Systems (interacting processes)
    - Variation
    - System for ongoing learning
  - Build a rational system to *manage processes*
  - What you get is *quality improvement theory*
-

---

# Defining and Measuring Outcomes in Medicine

- Physical outcomes
    - Medical outcomes: complications and therapeutic goals
    - Patient outcomes
      - Functional status measures
      - Perceptions of medical outcome
  - Service outcomes
    - Satisfaction: patients and families, referring providers, other 'customers'
    - Includes access
  - Cost outcomes
    - Another outcome of the clinical process
    - Includes cost of burden of disease
    - Inextricably linked with Physical outcomes
-

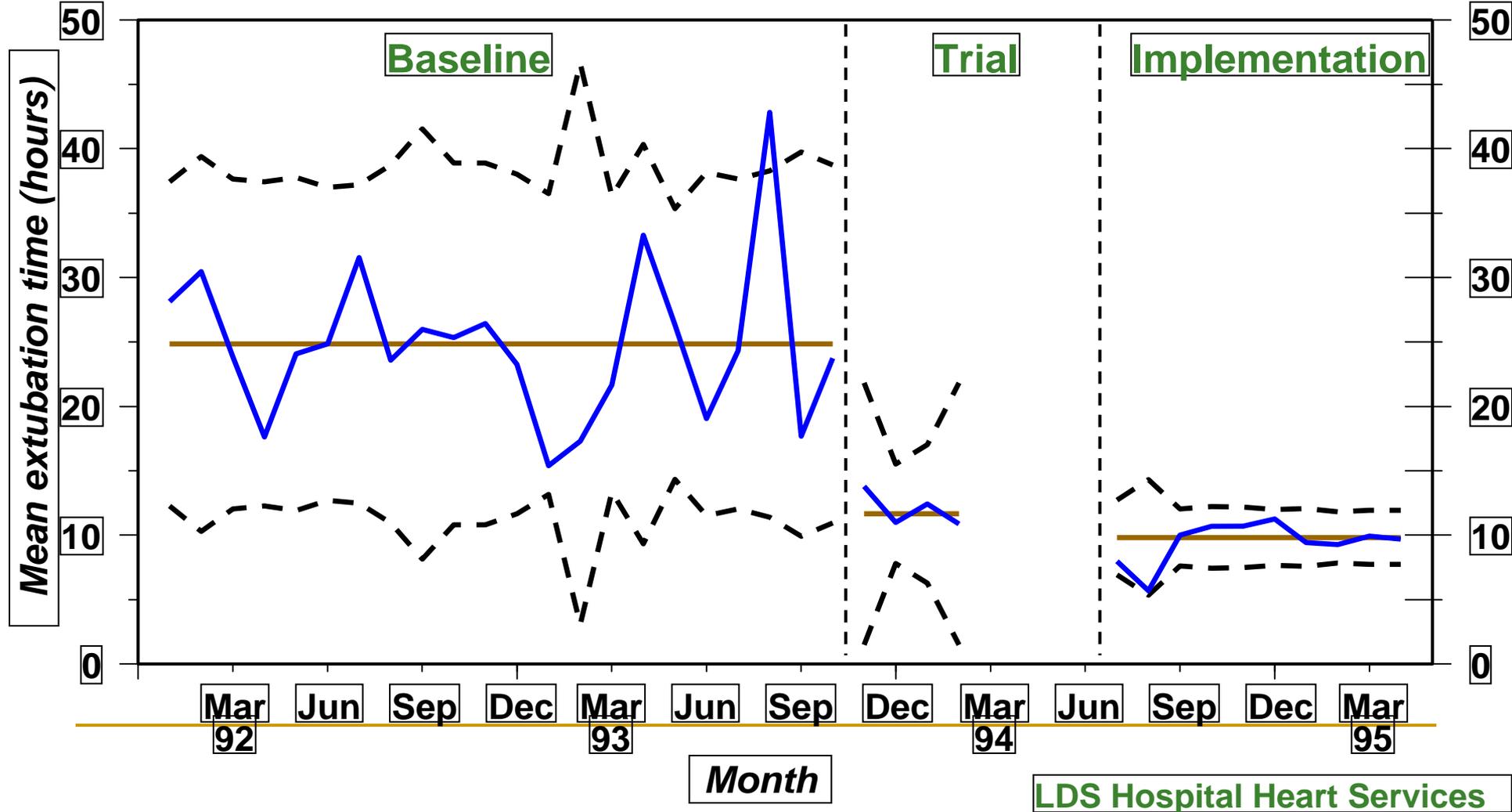
---

# Clinical Examples

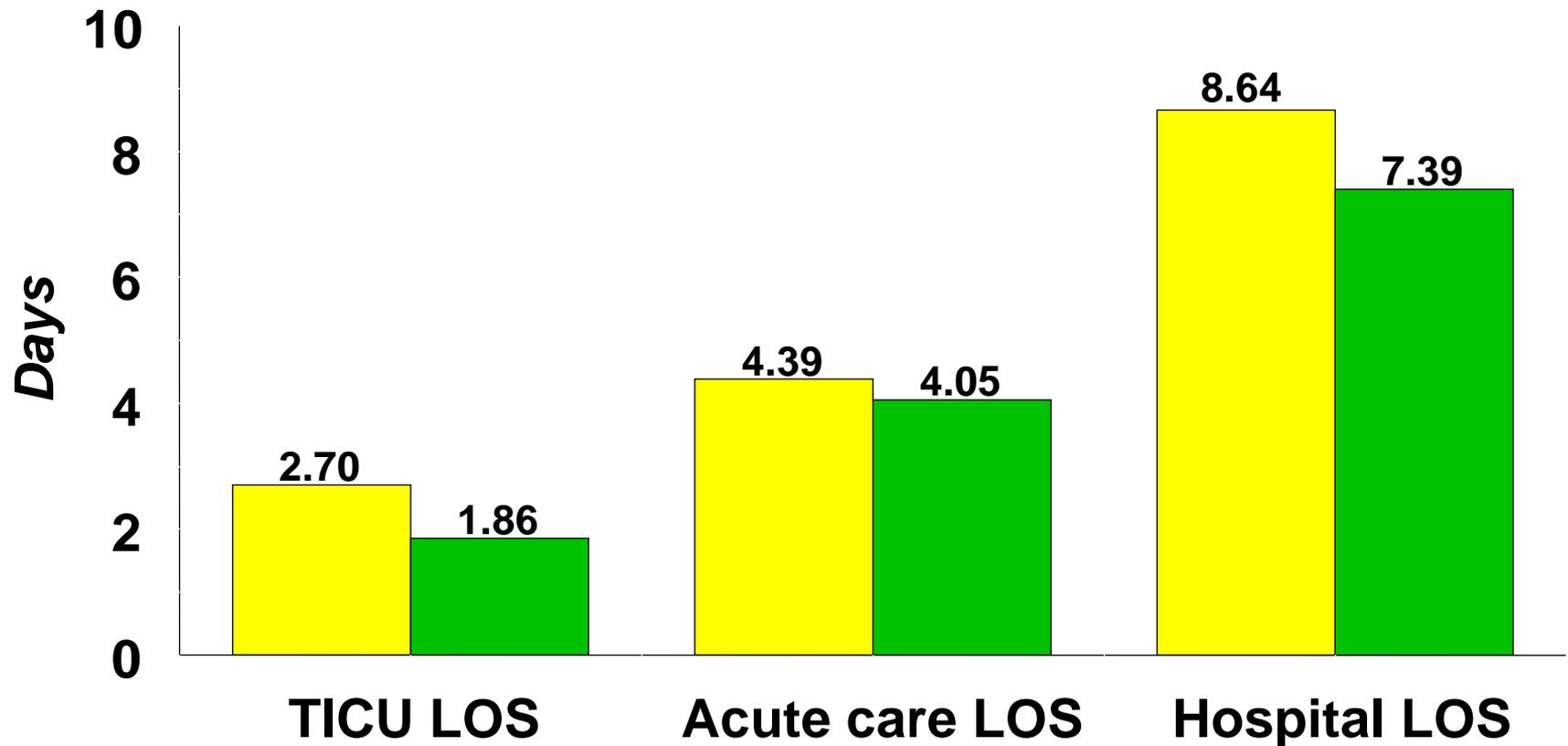
- Fast Track Extubation
  - Beta Blockers
  - Cardiac Discharge Medications
  - Impact on cost to system
-

# Fast-track extubation protocol

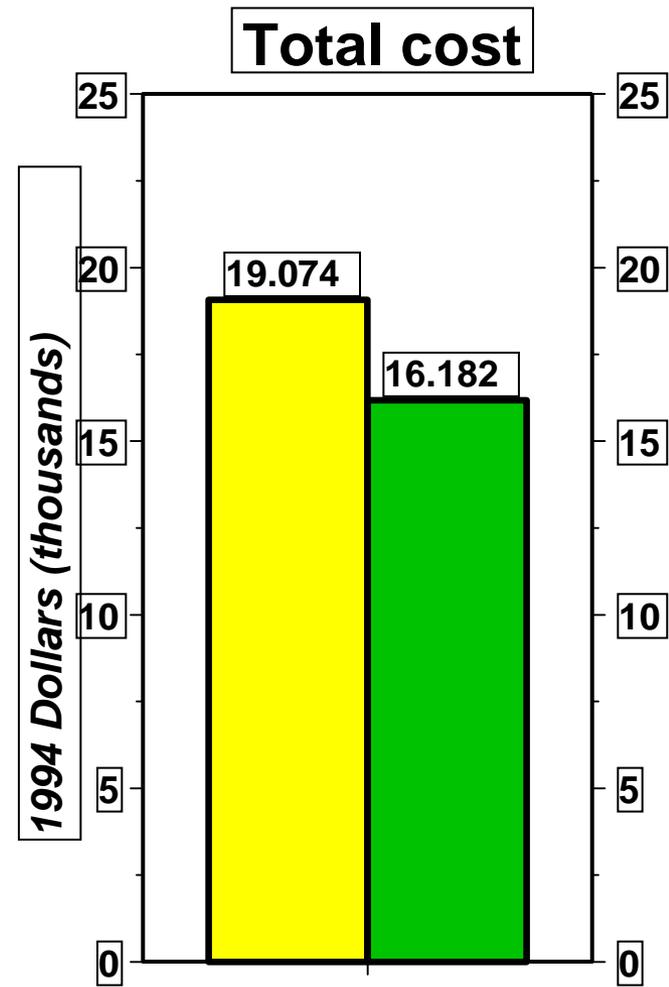
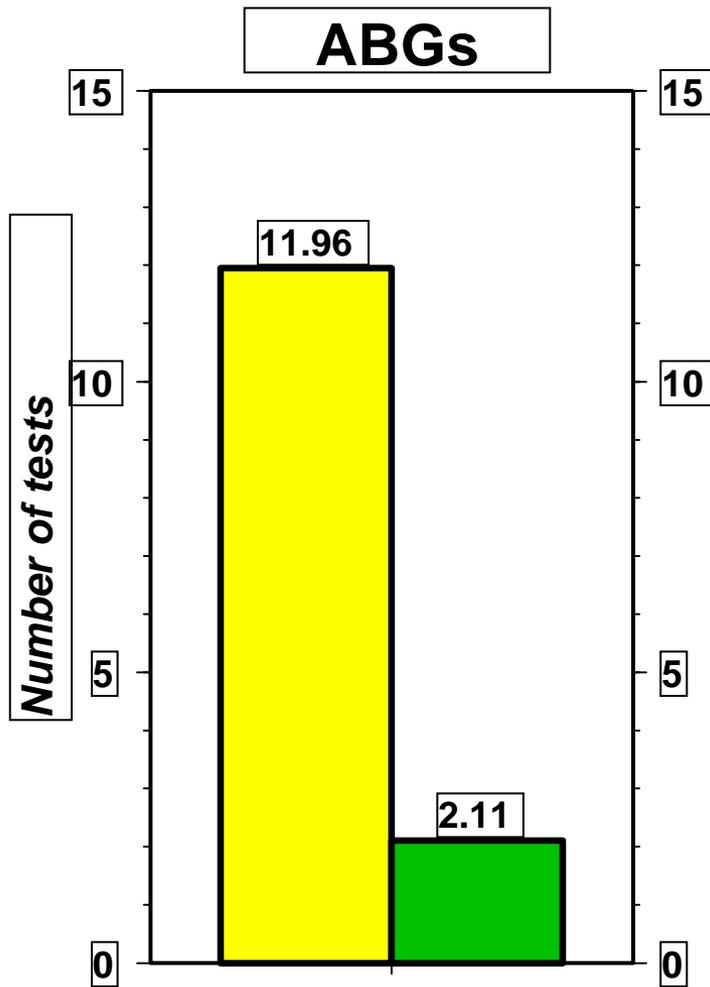
X-Bar Chart - 0.01 control limits



# Fast-track extubation protocol



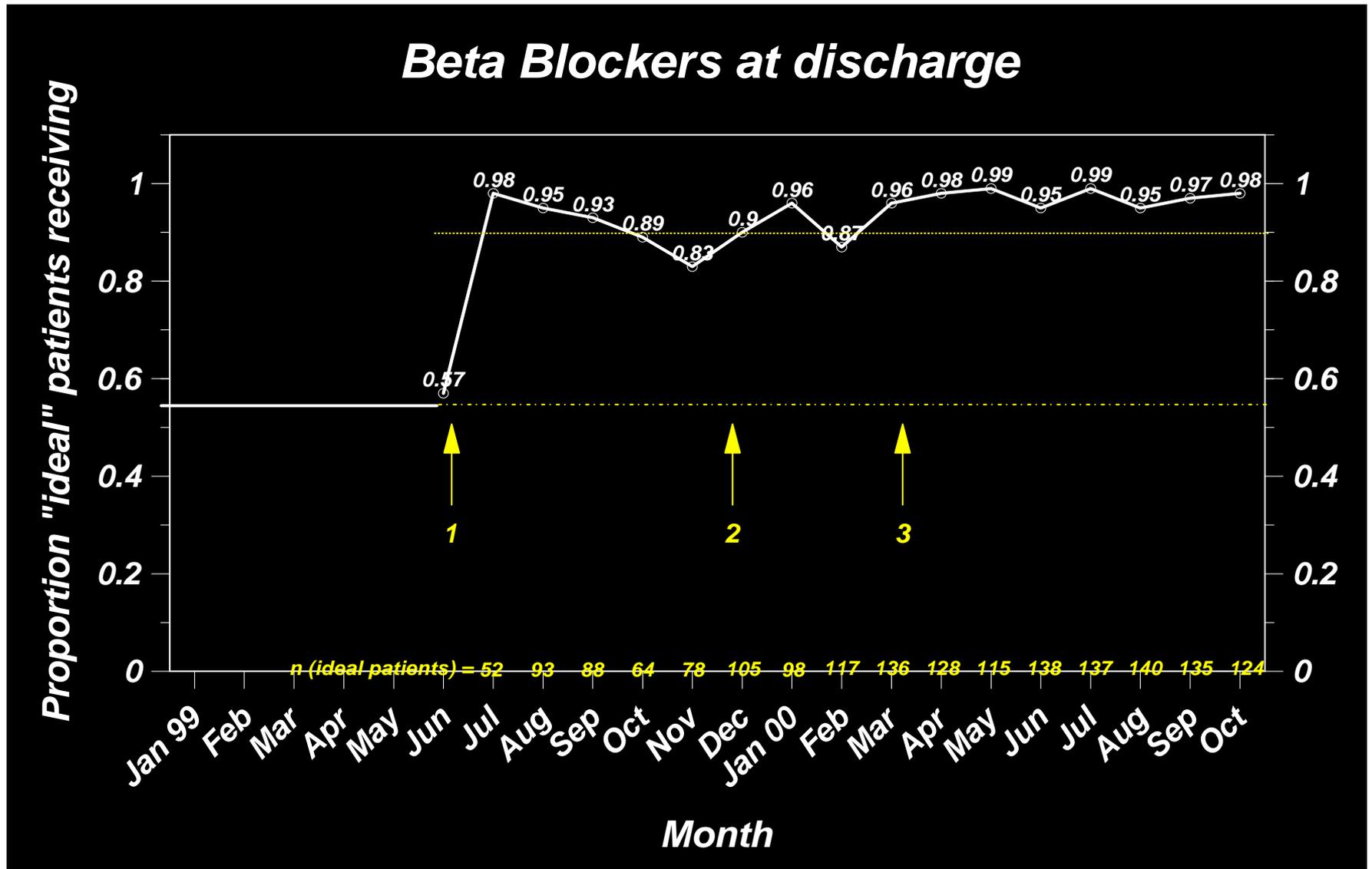
# Fast-track extubation protocol



**Baseline** (Jan 93--Aug 93)

**Fast-Track** (Nov 93--Feb 94, Aug 94--Nov 94)

# Beta blockers at discharge



# Cardiac discharge meds

	<u>Before</u>		<u>National 2000</u>
<b>Beta blockers</b>	57%		41%
<b>ACE / ARB inhibitors</b>	63%		62%
<b>Statins</b>	75%		37%
<b>Antiplatelet</b>	42%		70%
<b>Wafarin (chronic AFib)</b>	10%		<10%

# Clinical QI at Intermountain- Cost Outcome

<u>Clinical Project</u>	<u>Cost structure improvement (\$MM)</u>
1. Fast-track extubation in TICU	\$ 5.5
2. Long-term ventilator management *	4.7
3. HFOV (RDS in premature newborns) *	3.7
4. Shock Trauma Respiratory ICU *(12 protocols)	2.5
5. Antibiotic Assistant *	1.2
6. Pediatric ICU *(8+ protocols)	.7
7. Infection prophylaxis in surgery *	.6
8. Adverse drug event prevention *	.5
9. Community-acquired pneumonia *	.5
10. Ventilator support for hypoxemia *	.5
11. Group B strep sepsis of newborn *	.3
<b>Subtotal:</b>	<b>\$20.7</b>
-- 30+ additional successful clinical projects --	?

---

Will this work with Genomics?

---

---

# CoumaGen Trial

- Prospective randomized study of 200 patients
- Genotype turnaround median 48 minutes
  - Information used for initial dosing using developed algorithm
- Follow-up one month

---

# CoumaGen Trial

- Differences in genotyped patients
    - Initial dose closer to stable maintenance dose
    - Fewer and smaller dose adjustments
    - Fewer INR measurements (cost savings)
    - Larger doses required for wild-type patients (~6 mg/d)
  - No differences
    - Time in range for group as a whole
      - PG guidance better for wild-type or multiple variant
    - Unable to measure differences in bleeding/clotting
  - Economic analysis presented at ISPOR
-

---

# CoumaGen Trial

- Why no difference?
    - All patients managed by anticoagulation clinic
      - Clinical process management results in superior time in range compared to benchmarks
      - Harder to detect differences
  - Points to consider
    - Should system invest in anticoagulation clinic rather than genotyping? (alternative approach)
    - Would genotyping be appropriate in rural setting?
    - Could INR monitoring be optimized? (alternative approach)
      - Home monitoring
      - Clinical process to standardize dose adjustments
-

---

# Cookbook Medicine?

---

---

# Protocol $\neq$ Cookbook

- Multidisciplinary team
    - Select a high priority care process
    - Generate evidence-based best practice
    - Implement guideline into clinical workflow
    - Guideline = shared baseline
      - Clinicians free to vary based on individual patient
      - Capture outcome from each decision
    - Measure, **learn** and eliminate professional variation while retaining responsiveness to patient variability
-

---

# Why Learn?

- Experience shows that when guidelines hit patient care with few exceptions
    - No protocol fits every patient
    - More importantly, no protocol perfectly fits **any** patient
  - Mass customize
    - A shared baseline focusing on small subset of factors that are unique for individual patients (typically 10-15%)
    - Concentrates most important resource-the human mind- where it can have the greatest impact
-

---

# Protocol = Tool

- Manage complexity
  - Mass customization
    - Retaining the “art of medicine”
  - Improving productivity
  - Do—
    - All the right things
    - Only the right things
    - Every time
    - With grace and elegance
    - Under the patient’s knowledge and control
-

---

# CER, QI and Personalized Medicine

- Is this CER?
  - These approaches will work for personalized medicine
    - We believe they will be necessary to realize benefit from personalized medicine
    - Basis of internal strategy to promote translation and study impact
  - Recommend article by Garber and Tunis (NEJM) (Tab 6)
-