
Impact of Comparative Effectiveness on Practice

Marc S. Williams, MD, FAAP, FACMG
Director, Intermountain Healthcare Clinical
Genetics Institute
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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
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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
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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*
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Defining and Measuring Outcomes in Medicine

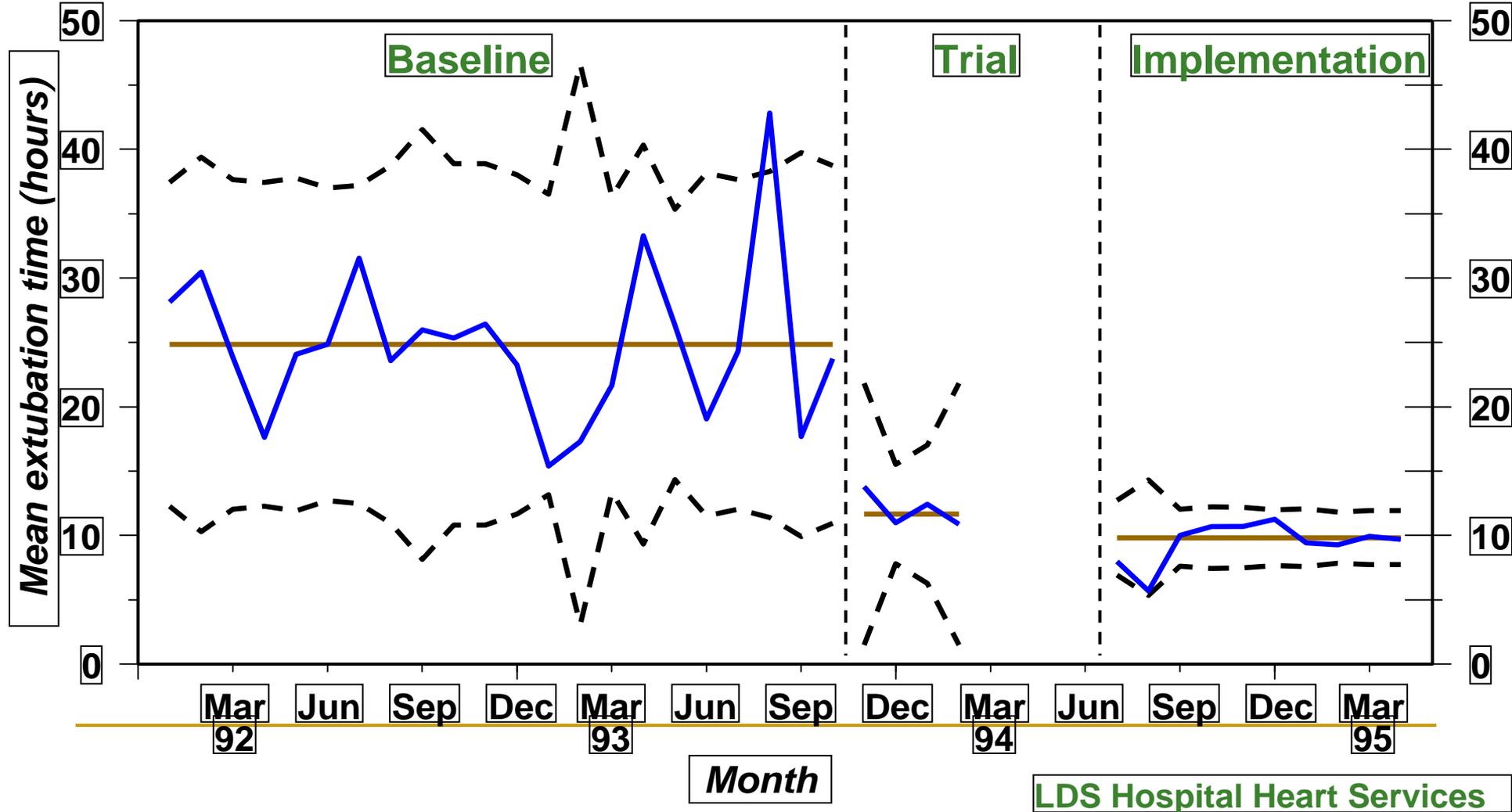
- Physical outcomes
 - Medical outcomes: complications and therapeutic goals
 - Patient outcomes
 - Functional status measures
 - Perceptions of medical outcome
 - Service outcomes
 - Satisfaction: patients and families, referring providers, other 'customers'
 - Includes access
 - Cost outcomes
 - Another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

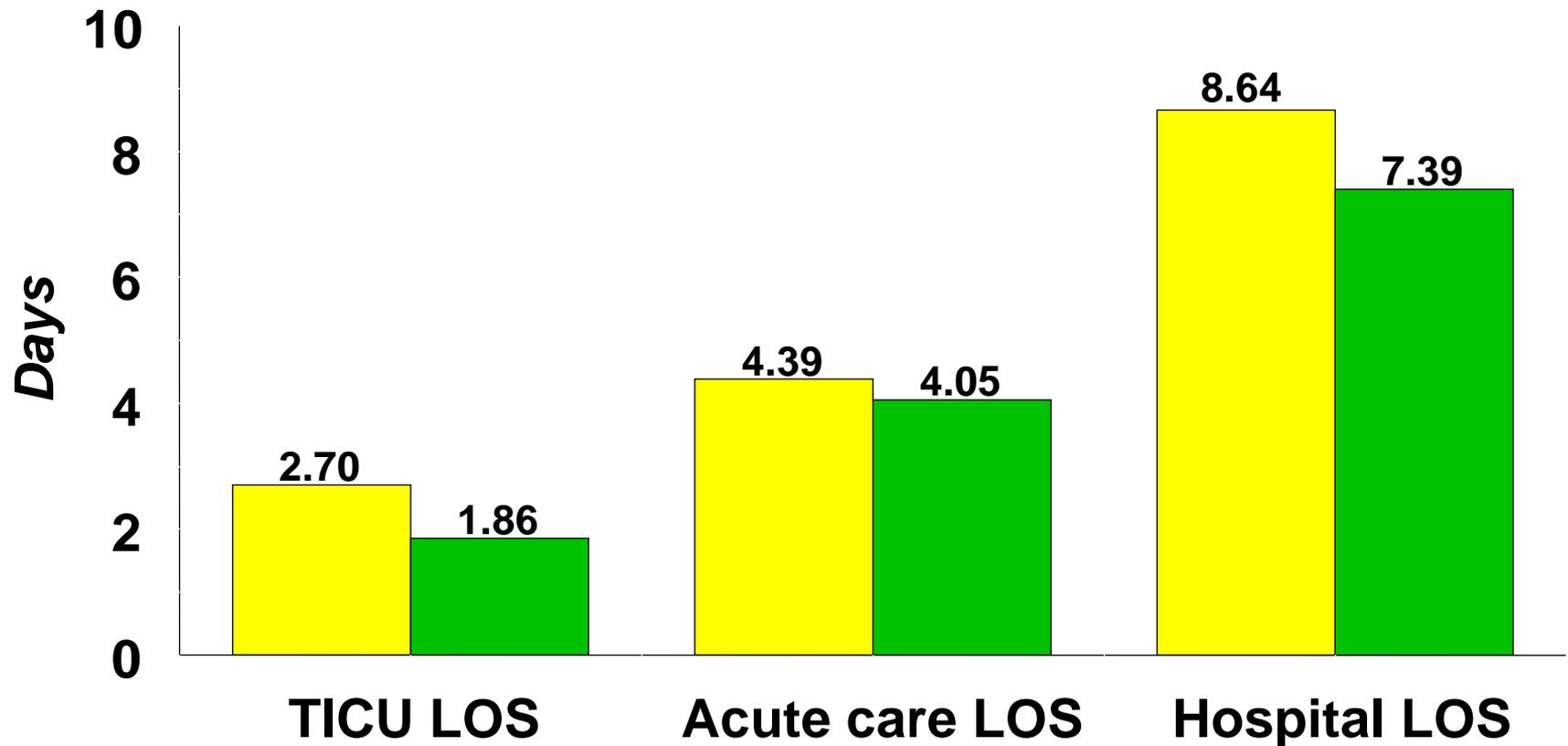
- Fast Track Extubation
 - Beta Blockers
 - Cardiac Discharge Medications
 - Impact on cost to system
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Fast-track extubation protocol

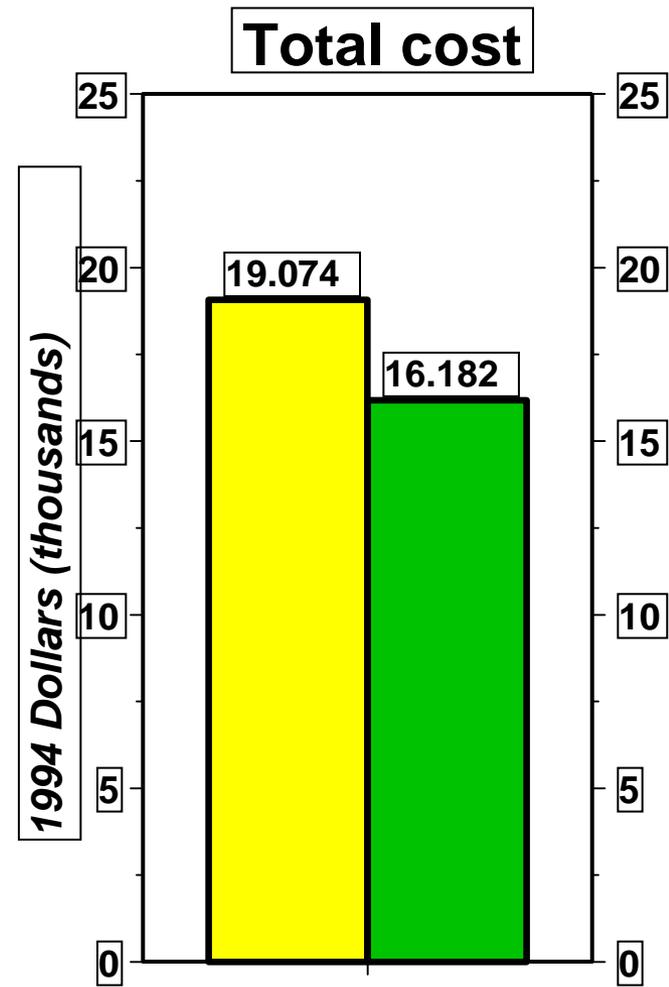
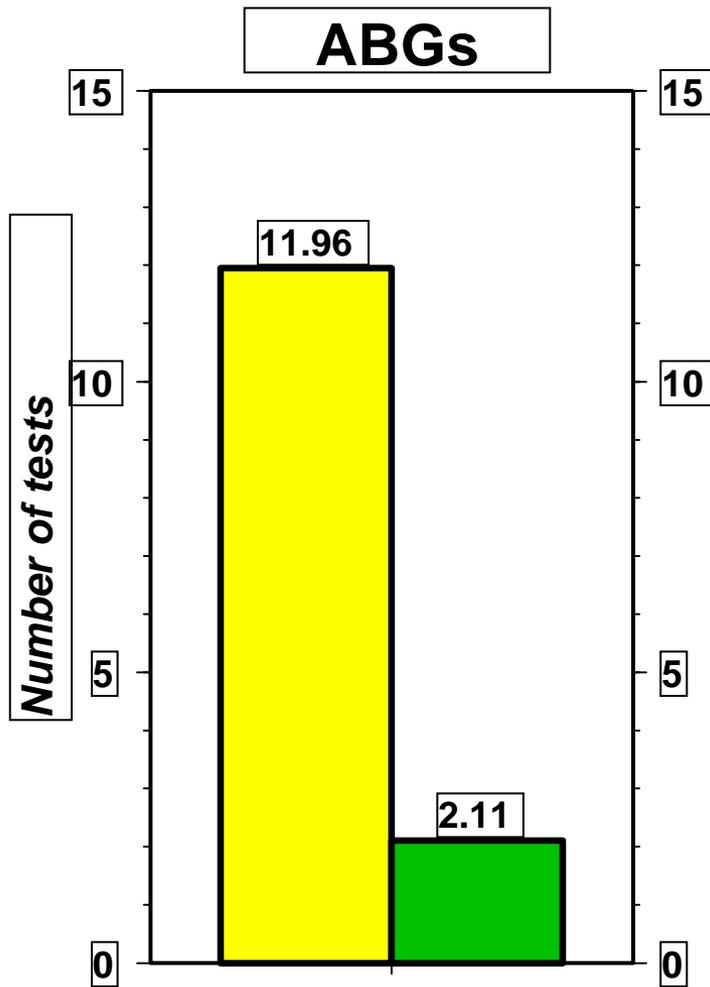
X-Bar Chart - 0.01 control limits



Fast-track extubation protocol



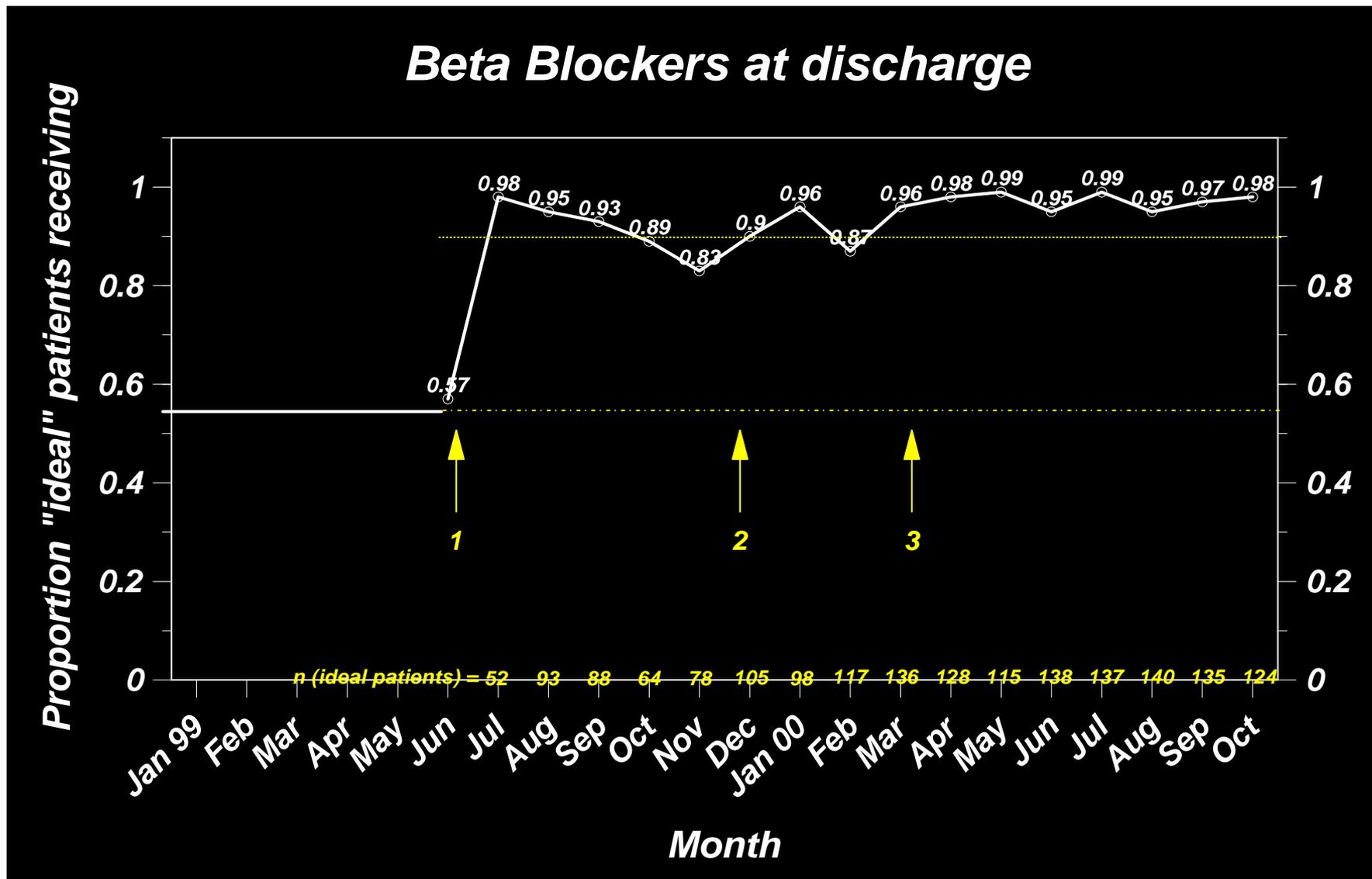
Fast-track extubation protocol



 **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>
Beta blockers	57%		41%
ACE / ARB inhibitors	63%		62%
Statins	75%		37%
Antiplatelet	42%		70%
Wafarin (chronic AFib)	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
Subtotal:	\$20.7
-- 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
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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
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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
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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
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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
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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)
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