

# Applying Quality Improvement Tools to Disorders Identified in Newborn Screening

Marc S. Williams, MD  
Director Intermountain  
Clinical Genetics Institute




# Acknowledgement

Intermountain Institute for  
Healthcare Delivery  
Research Dr. Brent James





# Objectives

- ◆ Review history of quality in medicine
  - ◆ Define process management and outcomes
  - ◆ Quality applications to inborn errors
- 



# Will Not Discuss

- ◆ PDSA cycles
- ◆ Six Sigma
- ◆ Other flavors of the month

**It's all process management!!**





# The Emergence of Modern Medicine

- ◆ ~1860-1910:
  - Standards of clinical education
  - Strict requirements for licensing
  - Clinical practice informed by research
  - Internal organization for Hospitals



# The Emergence of Modern Medicine

“... for the first time in human history, a random patient with a random disease consulting a doctor chosen at random stands a better than 50/50 chance of benefiting from the encounter.”

Harvard Professor L. Henderson  
1912

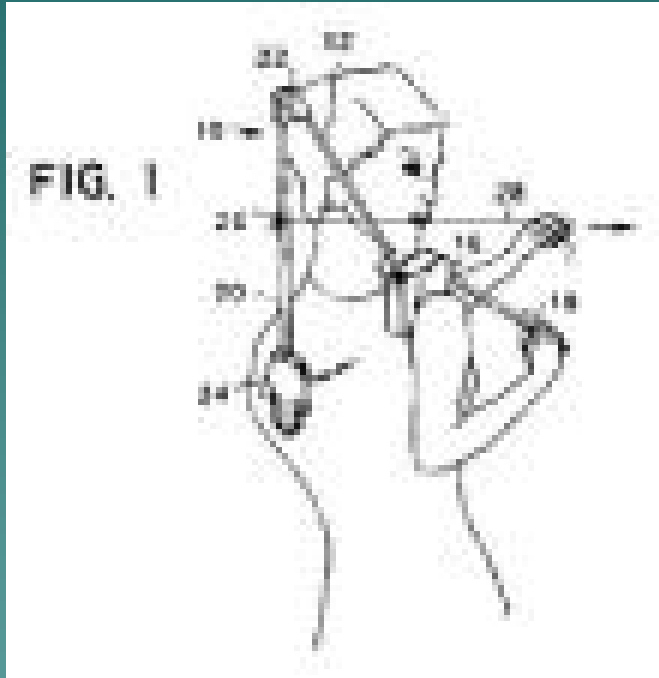




# The Success of Modern Medicine

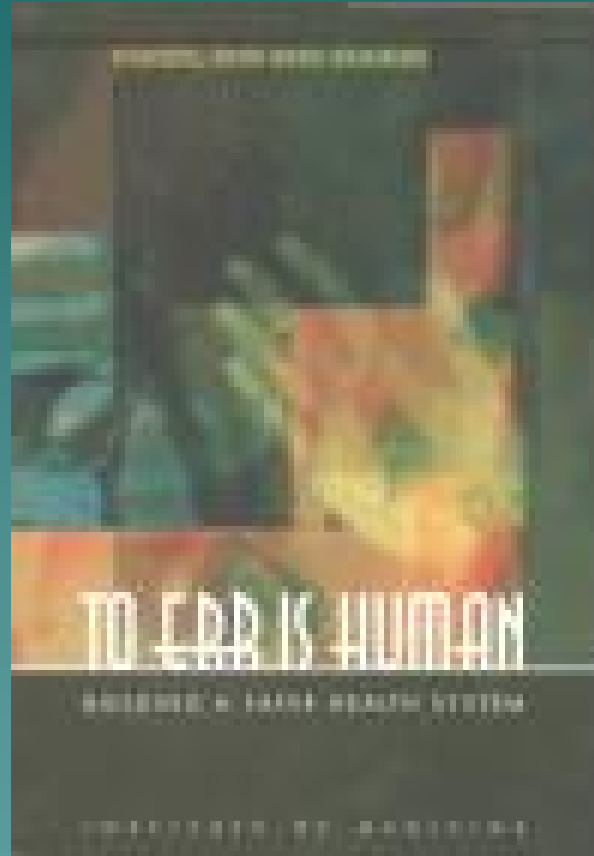
- ◆ Tangible examples
  - From 1900 to 2000, average life expectancy at birth increased from 49 to almost 80 years
  - Since 1960, age-adjusted mortality from heart disease has decreased by 56%
  - Since 1950, age-adjusted mortality from stroke has decreased by 70%

# Congratulations!!




Not so fast, my friend!!

# November 30, 1999

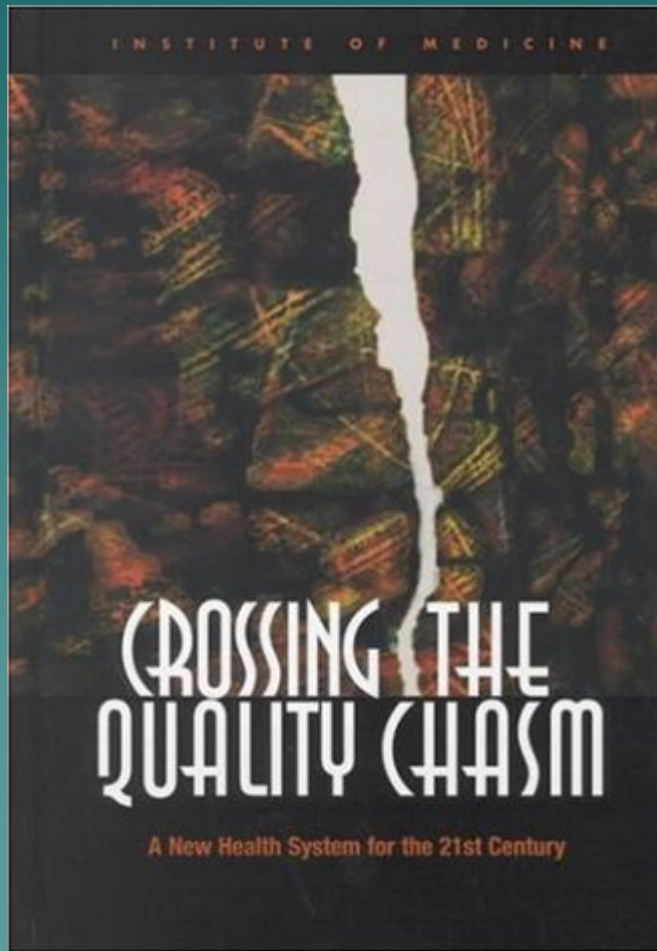




# To Err is Human Medical Injuries

- ◆ 44,000-98,000 deaths per year
  - ◆ More people die from medical errors than from breast cancer or AIDS or motor vehicle accidents
  - ◆ Direct health care costs \$9-15 billion/year
  - ◆ It's a conservative estimate!!
- 

# March 1, 2001



“Between the health care we have and the care we could have lies not just a gap, but a chasm.”





# How Good Are We?

- ◆ Only 50% of Americans receive recommended preventive care
- ◆ Patients with acute illness
  - 70% received recommended treatments
  - 30% received contraindicated treatments
- ◆ Patients with chronic illness
  - 60% received recommended treatments
  - 20% received contraindicated treatments

Schuster et al. How good is the quality of healthcare in the United States? *Milbank Quarterly* 76:517-63, 1998



# The Message

We're very good...

...but we could be so  
much better!!







# 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*




# Process Management Means...

- ◆ Having the right data
  - ◆ In the right format
  - ◆ At the right time and place
  - ◆ In the right hands (i.e. the clinicians operating the process)
- 



# Quality Improvement is the Science of Process Management

Health care delivery is a system made up of  
thousands of interlinked processes





# 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



# Medical Outcomes

- ◆ Appropriateness (referral and treatment indications)
- ◆ Complications (process failures)
- ◆ Therapeutic Goals
  - If goal not met, this is a process failure
- ◆ Functional status (as reported by the patient)



# Service Outcomes

- ◆ Clinician-patient relationship
  - Bedside manner
  - ‘caring and concerned’ clinician
- ◆ Access issues
  - Scheduling, travel, physical comfort, waiting
- ◆ Operate by a separate, general process that is independent of medical outcomes



# The Value Equation

$$\text{Value} = \begin{array}{l} \text{Medical Outcomes} \\ + \\ \text{Service Outcomes} \\ + \\ \text{Cost Outcomes} \end{array}$$

The goal is the best possible medical and service outcomes at the lowest necessary cost


# Cardiac discharge meds

	<u>Before</u>	<u>After</u>	<u>National 2000</u>
<b>Beta blockers</b>	57%	97%	41%
<b>ACE / ARB inhibitors</b>	63%	95%	62%
<b>Statins</b>	75%	91%	37%
<b>Antiplatelet</b>	42%	98%	70%
<b>Wafarin (chronic AFib)</b>	10%	92%	<10%

	<b>Mortality at 1 year</b>			<b>Readmissions w/ in 1 year</b>		
	<u>Before</u>	<u>After</u>		<u>Before</u>	<u>After</u>	
<b>CHF</b> (n = 19,083)	22.7%	17.8%	331	46.5%	38.5%	551
<b>IHD</b> (n = 43,841)	4.5%	3.5%	124	20.4%	17.7%	336
<b>Total</b>			455			887

# Clinical QI at IHC-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>	<u>\$20.7</u>
-- 30+ additional successful clinical projects --	?



# Quality and Clinical Genetics

- ◆ Greendale et al. Quality Assurance in the Clinical Genetics Setting *J Genet Counsel* 3:169-198, 1994.




# Quality Assurance

- ◆ Guidelines or standards developed (internally or externally) and goals set
  - Usually developed by experts without input from 'consumer' of service
- ◆ Measurements are for adherence to guideline/standard (compliance)
- ◆ Deficiencies identified
- ◆ Feedback provided
  - Frequently punitive



# Quality Assurance Insufficient

- ◆ Hospital QA programs mandated by JCAHO since early 1990s
- ◆ No significant improvement in care seen
  - Reliance on education
- ◆ Many measures are trivial
- ◆ QA has a role (crucial in labs), but will not result in substantial improvement without tools of process management and outcome measures

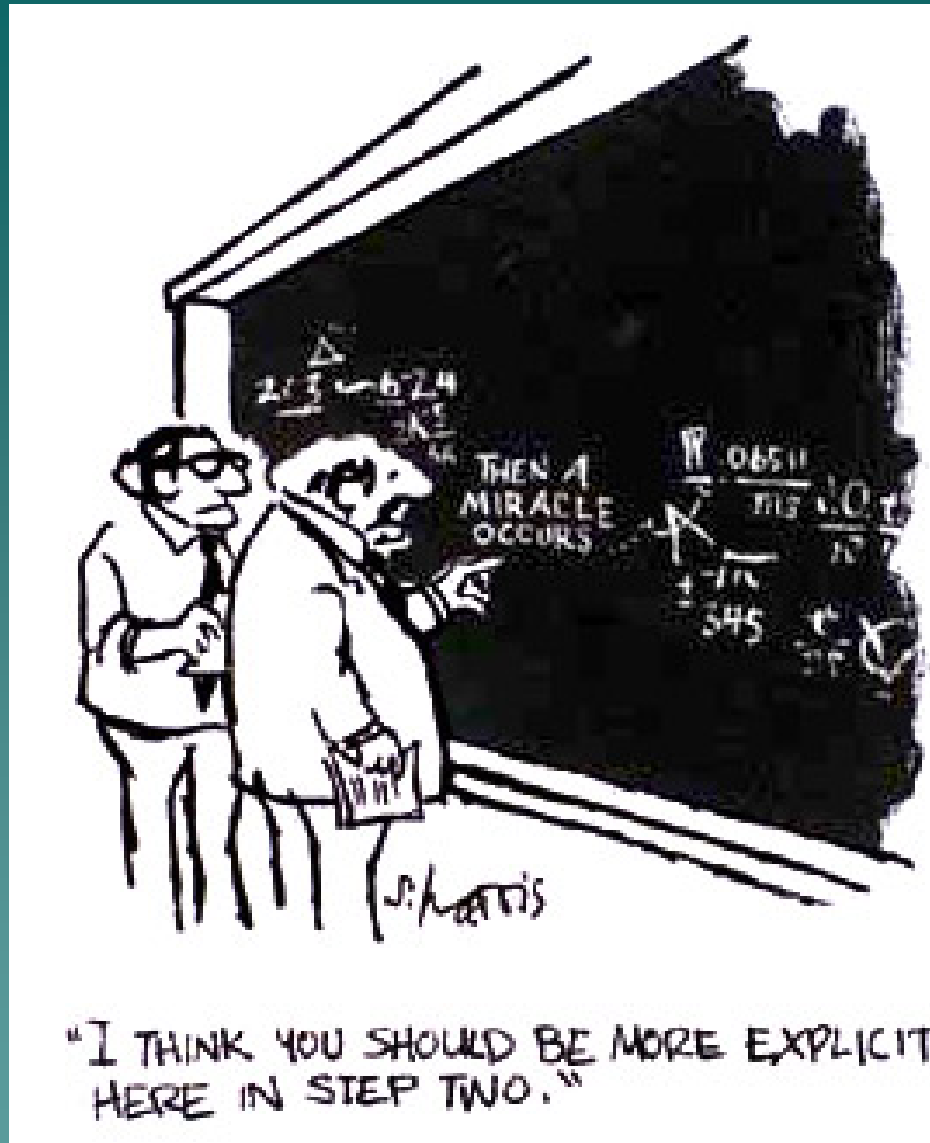


# Quality and Clinical Genetics Literature

- ◆ QA of genetic counseling encounter
  - Professionally defined elements
  - Measure of adherence to elements
  - Measure of transfer of information
  - Little data on how affects medical or service outcomes
    - ◆ No agreement as to what constitutes a successful outcome

# Quality and Clinical Genetics Literature-Medical Outcomes







# The Cystic Fibrosis Story

- ◆ Highly variable approaches to care
- ◆ Markedly different outcomes between centers
- ◆ Perceived competition limited collaboration
- ◆ Little publicly available data for comparison



# The Cystic Fibrosis Story

- ◆ Enter the Cystic Fibrosis Foundation
  - Assessed status quo as unsatisfactory
  - Initial discussions were not fruitful
  - Brought in QI experts to teach QI AND all participants needed to perform a project
  - Patients were engaged early and are a key component of the QI process




# The Cystic Fibrosis Story

- ◆ Demonstrated improvement was possible
- ◆ Anonymous data sharing revealed high variability between centers
  - CFF had insisted on anonymizing data
  - Centers that were performing poorly insisted they needed to talk to high performing centers to see how they were doing
  - Many site visits and exchanges




# The Cystic Fibrosis Story

- ◆ Care improved in all centers
  - Medical outcomes
  - Service outcomes
- ◆ All centers did some things well
- ◆ All centers did some things not so well
- ◆ Participation in the QI activities of the CFF is mandatory to be accredited as a CF center



# Models for QI in Newborn Screening

- ◆ Cystic Fibrosis
- ◆ Children's Oncology Group
  - Not specifically focused on QI
  - Collaborative transparent data sharing facilitates 'mass customization' (standardization with variance based on individual patient factors with data capture on variance)



# Models for QI in Newborn Screening

- ◆ National NICU/PICU networks
  - Focus is on traditional hypothesis driven research
  - Beginning with some QI research around glucose control
  - Central data repository with access to all participants



# QI in Newborn Screening What's Needed?

- ◆ Centralized data repository
- ◆ Care guidelines and protocols (shared baseline)
  - These are never 'right'
  - Must capture variance from protocol to see where modifications are needed
  - Protocols are updated in real time to rapidly improve care



# QI in Newborn Screening What's Needed?

- ◆ Identification of key outcome measures
  - Medical and Service
  - Ideal outcomes can be measured at frequent intervals to inform protocols
    - ◆ Not always possible (developmental outcomes)
  - Primary and secondary outcomes
    - ◆ Primary-# of episodes hyperammonemia in Urea Cycle disorders
    - ◆ Secondary- $\Phi$  levels in women with PKU of child bearing age (outcome of interest is # PKU embryopathy)



# QI in Newborn Screening What's Needed?

- ◆ Data transparency
- ◆ Sharing of best practices between centers (based on published outcomes)
- ◆ Involvement of patients and parents along with all members of the care team



# QI in Newborn Screening

## How

- ◆ Identify local quality 'gurus'
- ◆ Books and journals
- ◆ Attend a course
  - Institute for Healthcare Improvement [www.ihc.org](http://www.ihc.org)
  - Intermountain IHCDR Advanced Training program  
<http://intermountainhealthcare.org/xp/public/institute/>
- ◆ Consider the CFF model and create a customized program



# QI in Newborn Screening

## Why

- ◆ Clearly the way medicine is headed
  - Just added to EMOC of ABMG
- ◆ If we don't, quality may be defined and imposed by those who don't understand genetics
- ◆ It will improve care of our patients
- ◆ Quality care saves money
- ◆ It's the right thing to do

# QI in Newborn Screening Why



They're counting on us!!



"Knowing is not enough;  
we must apply.  
Willing is not enough; we  
must do."

-Goethe

This is the motto of the Health Care  
Services Board at the IOM.