How Labs are Transforming Clinical & Operational Services:

Gaining Competitive Advantage With Lean and Six Sigma

ROBERT L. MICHEL
Editor In Chief

THE DARK REPORT
Spicewood, Texas

Lab Quality Confab 2008
Atlanta, Georgia
September 24-25, 2008

rmichel@darkreport.com
ph: 512-264-7103
fax: 512-264-0969

Three Goals Today!

- **One:** Offer the premise that a transformation is under way in the nation's laboratories and hospitals.
- **Two:** Identify ways that Lean, Six Sigma, and similar improvement methods are involved in this transformation.
- **Three:** Look at specific examples and successes of laboratories and hospitals in applying Lean and Six Sigma to healthcare's challenges.

My premise today…

Quality Management Is Transformational in Healthcare

- Forces currently at work in healthcare will eventually drive *all* providers to adopt quality management methods.
- Laboratories, hospitals, and health systems currently using Lean and Six Sigma programs are raising the bar for clinical outcomes and patient satisfaction.

Four Basic Sources of Change In U.S Healthcare Market

- **One:** Consumers as primary buyers of healthcare. (Private and Medicare/Medicaid.)
- **Two:** Major commitment to universal electronic medical record (EMR) and integration of healthcare data.
- **Three:** New diagnostic & lab technology: genetic-based lab tests, automation, POCT.
- **Four:** Widespread introduction of Deming-based quality management methods into healthcare and clinical laboratory profession.

Observation #1

- Improving patient safety is a national goal.
- Joint Commission asks hospitals to measure existing performance, then demonstrate improvement by next inspection.
- That forces hospitals to adopt tools of continuous improvement and system of prevention.

Observation #2

- Medicare and Private Payers ramping up “pay for performance.”
- Providers now have incentive to closely measure outcomes in real time.
- Providers motivated to use root cause analysis and similar methods to identify gaps in care and implement improvements.
- Lean and Six Sigma can play a role.

Observation #3

- Deming: only your customer can define quality.
- Joint Commission requires hospitals to survey patient satisfaction, then document increased patient satisfaction scores by the next inspection.
- Why the laboratory often scores lowest of ten clinical services.
- Lean and Six Sigma help providers better meet customer expectations for quality and service.

Observation #4

- Medicare and private payers announce they won't reimburse hospitals for "never" events.
- Medicare policy becomes effective on October 1, 2008.
- For first time, health establishment tells public that these errors occur—and that now hospitals won't get paid for treating a medical condition they caused by systemic failures in their work processes.

These are paradigm shifts in thinking!

What is Quality Management?

- It is *not* QA/QC.
- It is a comprehensive management philosophy appropriate for use in all operational and service areas of the enterprise.
- Key differences from earlier management paradigms:
  - Continuous improvement.
  - Customer defines quality.
  - System of prevention.
  - Rigorous use of real time data.

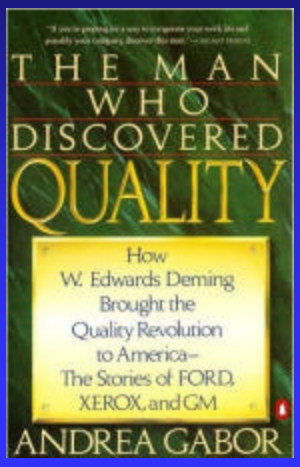
Quality Management Guru:

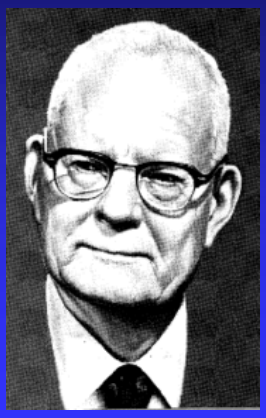
W. Edwards Deming

- 1900-1993
- Statistician
- "Deming is regarded as having had more impact upon Japanese manufacturing and business than any other individual not of Japanese heritage." *(www.wikipedia.org)*
- Deming's 14 Points
- Deming's 7 Deadly Diseases

W. Edwards Deming, "Man Who Discovered Quality"

- **"The Man Who Discovered Quality: How W. Edwards Deming Brought the Quality Revolution to America"**
- By Andrea Gabor (Published 1992)



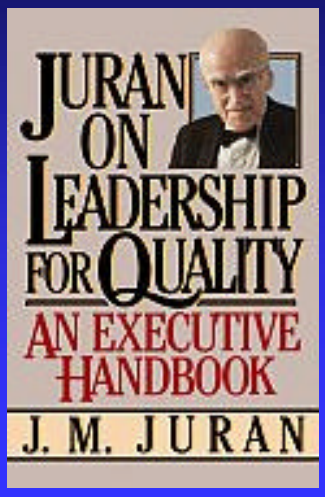


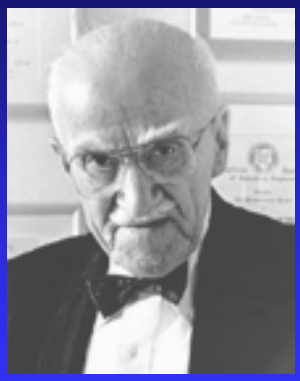
Quality Management Guru: Joseph Juran

- 1904 to February 28, 2008; born in Romania
- **After World War II, Japan was experiencing a crisis in product quality. Japanese goods were thought to be cheap, easily broken and in general extremely poor quality. The Japanese Union of Scientists and Engineers (JUSE) recognized these issues and invited Juran to Japan in 1954.**
- **Working independently of W. Edwards Deming (who focused on the use of statistical quality control), Juran - who focused on managing for quality - went to Japan and started courses (1954) in Quality Management. The training started with top and middle management. The idea that top and middle management need training had found resistance in the United States. For Japan, it would take some 20 years for the training to pay off. In the 1970s, Japanese products began to be seen as the leaders in quality. This sparked a crisis in United States due to quality issues in the 1980s. *www.wikipedia.org***
- Juran discovered Pareto Principle (80/20 Rule) in 1941.
- Joe DeFeo, CEO of Juran Institute, invited to speak at Executive War College, 2003.

Joseph Juran, "On Leadership for Quality"

- **"Juran on Leadership for Quality: An Executive Handbook"**
- By Joseph Juran (Published 1989)



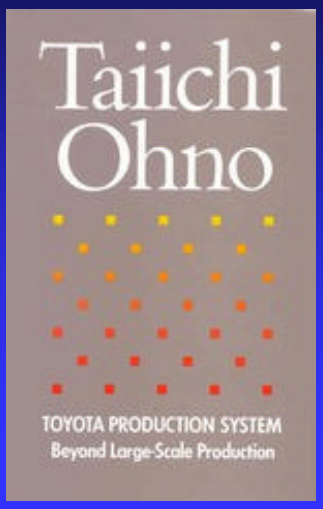


Quality Management Guru: *Taiicho Ohno*

- 1912-1990
- Developed the Toyota Production System, based, in part, on the work of Henry Ford during the 1910-1930 period.
- Just-in-Time (JIT).
- Concepts of "pull" and single piece work flow.
- Next came what we describe as "Lean."
- Described "Seven Wastes."

Taiichi Ohno, "Toyota Production System"

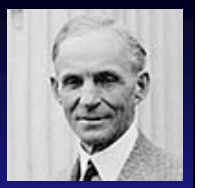
- **"Toyota Production System: Beyond Large Scale Production"**
- By Taiichi Ohno (Published 1988)



Quick History of Quality

- WW II into the 1960s: value engineering/value analysis; Larry Miles, industrial engineer at GE.
- In the 1970s, Japanese products began to capture market share in the United States: autos, consumer electronics, copy machines. *(Savin versus Xerox)*
- ISO (International Standards Organization) developed to improve manufacturing quality of military suppliers selling to NATO.
- 1980: "If Japan Can Why Can't We?" on NBC in l980. 90-minute TV special includes 15 minutes on W. Edwards Deming.

Don't Forget Henry Ford



- "Henry Ford Production System" was often used by Taiichi Ohno to describe the body of Henry Ford's productivity improvement methods and principles.
- Henry Ford Health System is codifying a new "Henry Ford Production System" for use in healthcare.
- Pathologist Richard Zarbo, MD of HFS will discuss the principles in surgical pathology at *Lab Quality Confab*.

A Word about Westgard

- **Dr. Westgard is a Professor in the Department of Pathology and Laboratory Medicine at the University of Wisconsin Medical School and Faculty Director of Quality Management Services for the Clinical Laboratories at the University of Wisconsin Hospital and Clinics. He is also a co-founder and principal in Westgard QC, Inc.**
- **His interest in quality control began in 1976-77 when he was on sabbatical leave at Uppsala University in Sweden where he worked with Professor Carl Henric deVerdier and Drs Torgny Groth and Torsten Aronsson. This work led to the multi-rule control procedure, often referred to as "Westgard Rules." His extensive work on quality control is summarized in the book "Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes," authored with Patricia Barry and published by AACC. He currently chairs the NCCLS working group on Quality Control that is revising document C24-A2 (Internal Quality Control Testing: Principles and Definitions).**
- **Early voice in laboratory medicine advocating the principles of modern quality management—when few in healthcare were paying attention to the revolution in manufacturing and business management.**

Six Sigma: As Tool vs. System

- "One of Motorola's most significant contributions was to **change the discussion of quality from one where quality levels were measured in percentages (parts per hundred) to a discussion of parts per million or even parts per billion.** Motorola correctly pointed out that modern technology was so complex that old ideas about acceptable quality levels were no longer acceptable."
- Excerpted from "The Complete Guide to the CQE" by Thomas Pyzdek. *1996-Tucson: Quality Publishing Inc.*

Quality in Healthcare—1990s

- Intermountain Health gets attention.
- Little adoption by hospitals, doctors.
- Quest Nichols Institute: ISO-9001 certification in 1997.
- ISO-9001 certification in 1998 by Quest labs in Miami, FL and Wallingford, CT.
- Quest Diagnostics launches corporate Six Sigma program.
- "To Err is Human", 1998, Institute of Medicine.

Quality in Healthcare-Early 2000s

- Some hospitals use Motorola, GE and others to teach and implement quality.
- Johnson & Johnson goes "Lean and Six Sigma"—commits to Quality consulting group within Ortho-Clinical Diagnostics.
- Kaiser Permanente Northwest: Lab certifies ISO-9001 in 2000; builds new facility using quality management principles, opened in 2003.
- JCAHO shifts to measuring outcomes.
- 2003-Year of Lean "first movers" among hospitals, health systems, and labs.

First Lean Project Outcomes...in 2003

	TAT reduced	Pre-Lean MTs	Post-Lean MTs
Naples General Hospital (Florida)	**51%**	**7**	**2**
West Tennessee (Tennessee)	**42%**	**6**	**3**
Fairview Southdale Hospital (Minnesota)	**50%**	**7**	**3**

Core high-volume chemistry/hematology lab

Each Lean project lasted 12 to 16 weeks

Six Sigma for Lab Processes-2000

Q-Probe QUALITY INDICATOR	% ERROR	DPM	SIGMA*
Order accuracy	1.80%	18,000	3.6
Duplicate test orders	1.52	15,200	3.65
Wristband errors (not banded)	0.65	6,500	4
TDM timing errors	24.4	244,000	2.2
Hematology specimen acceptability	0.38	3,800	4.15
Chemistry specimen acceptability	0.3	3,000	4.25
Surgical pathology specimen accessioning	3.4	34,000	3.3
Cytology specimen adequacy	7.32	73,700	2.95
Laboratory proficiency testing	0.9	9,000	3.85
Surg path froz sect diagnostic discordance	1.7	17,000	3.6
PAP smear rescreening false negatives	2.4	24,000	3.45
Reporting errors	0.0477	477	4.8
*Conversion using table with allowance for 1.5s shift			

The following Sigma metrics are drawn from Nevalainen D, Berte L, Kraft C, Leigh E, Morgan T.: "Evaluating Laboratory Performance on Quality Indicators with the Six Sigma scale." *Arch Pathol Lab Med 2000*;124:516-519.

Leading Edge Labs & Hospitals Gaining from Lean & Six Sigma

- Lots of examples at *Lab Quality Confab*.
- This morning, UPMC and St. Görans Hospital share their stories.
- Today and tomorrow, Quest Diagnostics Miami, Lab Networks in Ontario, and Piedmont Medical Laboratory.
- Plus 50 sessions and cases studies about using quality management techniques in all settings of labs and hospitals.

Competitive Advantage from Use of Lean & Six Sigma

- Healthcare in United States is moving toward more transparency.
  - Public access to outcomes and performance rankings.
  - Public access to accurate prices.
  - Public access to patient satisfaction data.
- Thus, labs and hospitals using process improvement effectively will enjoy greater support by patients, physicians, and payers.

How to Use Lab Quality Confab

- Our goal is to provide you with:
  - Strategic and macro understanding about quality management (general sessions).
  - Specific knowledge and instruction in the principles and methods of quality management (morning master classes).
  - "Best practices" and innovations by labs and hospitals (breakout case studies).
  - Lean/Six Sigma poster presentations to foster exchange of ideas.
  - Exhibition to provide access to vendors, consultants, and other resources.

Powerful Networking

- Only the second time for a national gathering of quality practitioners in diagnostics.
- International delegates are also here: Australia, Bermuda, Brazil, Canada, Denmark, Mexico, New Zealand, Singapore, Sweden, United Kingdom.
- Use your networking opportunity to expand contacts, knowledge, resources.

A Final Reminder…

- To meet and exceed your expectations, let us know…
  - Your suggestions for new topics
  - Your ideas for adding features and services
  - Your enthusiasm for continuing Lab Quality Confab in 2009!

Now it's time to hear for successes, innovations, and breakthroughs in improvement…