Quality Management's Evolution:
From an Operations Tool to Boosting Analytical Integrity in Laboratory Testing

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A New Premise In Lab Testing

Medical laboratories must now perform to a higher standard of quality—and that standard is increasing.

What It Means To You…

- Clinical labs and pathology groups will need to step up the quality of their service.
- Quality and integrity of lab's daily activities will be monitored closely.
- More external and internal quality monitors are coming.
- Patients will compare your lab's quality with quality of competing labs.

Lab Quality Confab Is Unique

- Only lab industry conference or association focused exclusively on use of quality management in clinical laboratory organizations.
- Launched five years ago, and thriving.
- First-rank national lab organizations use Lab Quality Confab to achieve and sustain peak performance.

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 Gurus

- Two individuals made greatest contribution.
- Each was seminal thinker.
- Worth reading their original work.
- Most quality management methods and approaches trace back to their groundbreaking work.

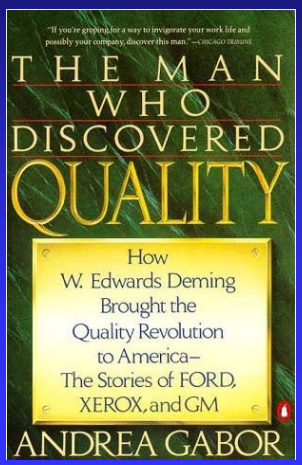
Quality Management Guru:

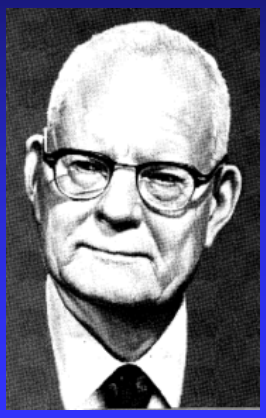
W. Edwards Deming

- 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)





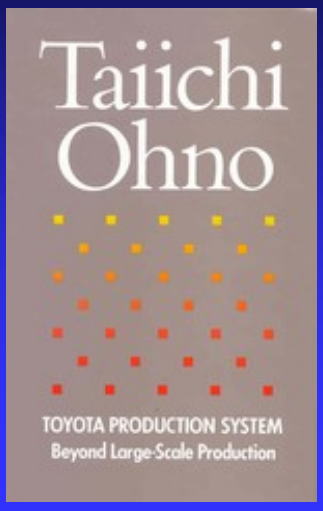
Quality Management Guru:

Taiicho Ohno

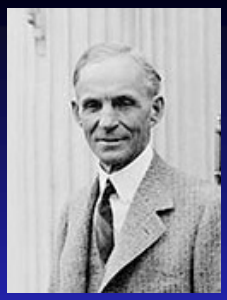
- 1912-1990
- Developed the Toyota Production System, based, in part, on the work of Henry Ford during the 1910-1930 period.
- Just-in-Time (JIT).
- Concepts of “pull” and single piece work flow.
- Next came what we describe as “Lean.”
- Described “Seven Wastes.”

Taiichi Ohno, “Toyota Production System”

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



Don't Forget Henry Ford



- Won't steal Dr. Zarbo's "Thunder."
- "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.

How Is "Quality" Changing In Laboratories?

- Primary emphasis: increased precision of analytical test results that directly support improved patient outcomes.
  - *Integrity, accuracy, reproducibility, quality*
- Secondary emphasis: quality service as experienced by patients.
  - *Lab appointments, specimen collection, billing, patient service calls, and more*

Internal & External Quality

- **Internal:** all individual processes and work flows across all activities within the laboratory organization.
- **External:** how "customers" of a medical lab receive services that add value.
- Pressures on labs to perform internally with higher quality and reduced cost.
- Physicians, patients, and payers expect more value from lab testing services.

Your Job's Getting Tougher

- **One:** Not enough money to sustain growth in healthcare spending.
- **Two:** New care models require integration of clinical care and healthcare informatics.
- **Three:** Standards for lab performance are tightening for lab test accuracy and reproducibility.
- **Four:** Labs dealing with more complex diagnostic technologies—more chance of error.

Now Let's Drill Down…

- New Federal health legislation will dramatically change existing healthcare landscape.
- Most mandates happen one to five years down the road—short term impact is uncertain.
- One thing is sure: increased taxes on providers and medical suppliers, as well as less reimbursement.

Baby Boomer's Direct Impact on Lab Test Utilization

- Utilization of lab tests to skyrocket!
- Commercial lives (under 65 years), average about 2 lab tests per person per year in the United States.
- Medicare lives (65 or older) average about 9+ lab tests per person per year in the U.S.
- 80 million baby boomers are rapidly advancing into this age cohort.
- **Do the math: 80 million X 9 tests**
- **160 million vs. 720 million tests!**

What We Know…

- More elderly…
- More chronic disease…
- Shift to proactive medicine…
- Advent of personalized medicine…
- Genetic medicine supported by rapid gene sequencing and whole human gene analysis…

Quality Is Front & Center

- More labs adopting quality tools.
- Often starts with Lean, Six Sigma, and process improvement projects.
- Quality Management Systems (QMS), like ISO 15189.
- Middleware solutions that give give lab managers “real time” dashboards on work flow in the lab.
- Experts and case studies on all these areas at Lab Quality Confab.

Clinical Labs More Exposed to "Systemic Errors"

- Labs dealing with more complexity.
- Labs testing more specimens with fewer resources, less staff.
- News headlines offer examples of system errors in labs.
- An effective quality management system can prevent systemic errors and allow early detection.

International Incidents Reported in the News

Lab Error Events Since 2000

- 2004: Maryland General Hospital Lab
- 2005: Breast cancer testing errors in Newfoundland and Labrador
- 2000-06: Nichols Institute Diagnostics (NID) manufactures and distributes inaccurate test kits, per Dept. of Justice
- 2007-08: Pap testing issues in Ireland
- 2008: Pathology testing problems in Ontario, Manitoba, New Brunswick

Lab Error Events Since 2000

- 2007-2008: Inaccurate Vitamin D results at Quest Diagnostics Incorporated *(Estimated that as many as 500,000 patients affected over 18 months)*
- *And, reported August 6, 2010:*

The Washington Post

Georgetown U. Hospital closes lab after problems with breast cancer tests

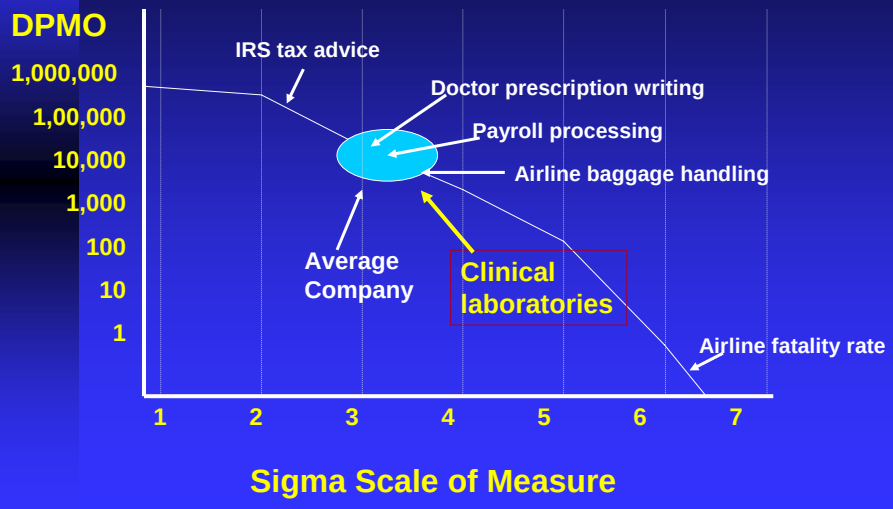
By Lena H. Sun and Carol D. Leonnig
Washington Post Staff Writer
Friday, August 6, 2010; A01

ent to outside labs, Stephen Evans, the hospital's chief medical officer, said this week. He said the suspension was unprecedented. Federal officials are

Reminder about Six Sigma Quality

Sigma Level	Defects per Million Opportunities	Yield
6	3.4	99.9997%
5	233	99.977%
4	6,210	99.379%
3	66,807	93.32%
2	308,537	69.2%
1	690,000	31%

Clinical Lab Industry Performs "About Average"



Six Sigma for Lab Processes

Q-Probe QUALITY INDICATOR	% ERROR	DPM	SIGMA*
TDM timing errors	24.4	**244,000**	2.2
Cytology specimen adequacy	7.32	**73,700**	2.95
Surgical pathology specimen accessioning	3.4	**34,000**	3.3
PAP smear rescreening false negatives	2.4	**24,000**	3.45
Order accuracy	1.8	**18,000**	3.6
Surg path froz sect diagnostic discordance	1.7	**17,000**	3.6
Duplicate test orders	1.52	**15,200**	3.65
Laboratory proficiency testing	0.9	**9,000**	3.85
Wristband errors (not banded)	0.65	**6,500**	4
Hematology specimen acceptability	0.38	**3,800**	4.15
Chemistry specimen acceptability	0.3	**3,000**	4.25
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.

Understand Role of Quality

- Today: you'll hear strategic case studies from labs delivering added value to patients and referring physicians.
- Listen for how lab staff is making the transition from "system of inspection" to "system of prevention."
- Examples:
  - Laboratio Fleury
  - Henry Ford Health System
  - Laboratory Corporation of America

QMS, Medicare, CLIA

- Tomorrow has special keynote sessions!
- Opportunity to learn about intersection of regulatory requirements and quality management systems.
- Explore how labs can improve patient safety.
- Gain insight on improving analytical accuracy in ways that support better patient outcomes.

Leverage Good Information

- Recognize the reforms now reshaping healthcare in the United States.
- Be diligent in connecting how quality improvement projects and case studies can provide a road map for your lab.
- Take advantage of the networking opportunities at Lab Quality Confab.
- Don’t forget: lab consultants and IVD firms have deep lab consulting experience that your lab can tap.

In Summary…

- Understand how quality is a journey.
- Continuous improvement will be essential for labs to deliver added value.
- It will not be possible to manage clinical laboratories using 1990s operational models.
- Quality management systems are the future of clinical lab operations and management.