Healthcare's New Reality:

Why Patients' Expectation of Error-free Care Raises the Stakes for Labs and Hospitals

ROBERT L. MICHEL
Editor In Chief

THE DARK REPORT
Spicewood, Texas

Lab Quality Confab
Atlanta, Georgia
October 29, 2009

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

My Goals Today!

- **One:** Review events that mark progress on patient safety and improved outcomes.
- **Two:** Explore how hospitals and laboratories are evolving/changing to effectively support these new healthcare objectives and needs.
- **Three:** Identify specific opportunities for laboratories to deliver added value to physicians, patients, and payers.

First… What Lies Ahead?

- Healthcare systems in all developed countries are under great stress.
- Too much demand for services.
- Not enough money to pay for services.
- Similar problems in most countries.
- Let's look at United States as an example.

Checklist of Change Agents-A

- Control/reduce annual increase in cost of care
- CDHPs / HDHPs / HSAs
- Transparency in provider pricing to patients
- Transparency in provider outcomes
- Provider pay-for-performance (P4P)
- Providers practice to accepted standards (reduce variability in care)
- Shift from reactive to proactive (acute care to early detection/early intervention)
- Patient safety—reduce medical errors

Checklist of Change Agents-B

- Emphasis on life style changes (Corporate wellness, NY City diabetes program)
- Recognition that Personalized Medicine is the future
- First Personalized Medicine services, with companion diagnostics
- EMRs in hospitals and physicians' offices
- Wireless technologies in healthcare
- National goal of universal patient health record (PHR)
- Quality management methods (Lean, Six Sigma)

Checklist of Change Agents-C

- Integration of patient data within health systems and local communities (eliminate paper records)
- Evidence-based medicine (EBM), driven by real-time collection of outcomes data
- Real-time patient eligibility and claims settlement for providers (including labs)
- ICD-10 implementation
- Use of Internet and World Wide Web for health services and health information
- Telemedicine

Checklist of Change Agents-D

- Issue of uninsured and underinsured
- Competition between concept of single payer (government) versus market-driven health
- Inadequate funding for state Medicaid programs
- Demographics of Medicare program
- Access to new health technologies
- Medical tourism and international competition

POINT: Many discrete forces of change!

Change Agent

New Technology in the Lab

- Steady stream of new diagnostic tests, many based on molecular technologies.
- Point-of-care testing (POCT) growing regularly in tests and capabilities.
- Different automation products available for pre-analytical, analytical, post-analytical. (Even middleware as automation.)
- Impact of these technologies magnified by enhanced informatics solutions.
- ***Remember: Labs' end product is info!***

Change Agent

Quality Management Methods

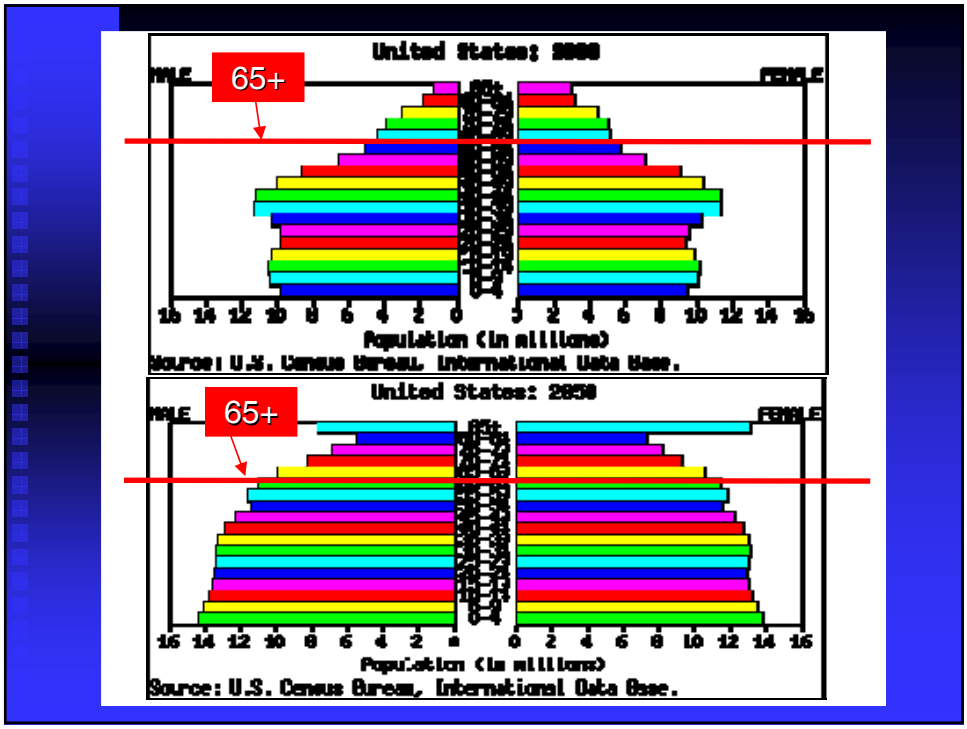
- Healthcare—with push from employers—becoming more comfortable with using quality management systems.
- Savvy hospitals and labs are learning that Lean/Six Sigma provides competitive advantage, once the organization embraces these quality methods.
- Quality requires accurate measurements, more on this later.
- **Lab Quality Confab**, every September.

Now to Demographics, or…
Meet the "Silver Tsunami"

(All developed countries have a similar demographic situation)

- Today: 303 million Americans
- Currently 65+ = 38,690,169 (17%)
- Baby Boomers = 80,000,000 (26.4%)
- In 2050: 420 million Americans (est.)
- In 2050: 65+ = 86,705,637 (20.5%)

Source: U.S. Census Data



Silver Tsunami's Direct Implications for Lab Medicine

- Utilization of lab tests is about to skyrocket over the next decade!
- 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: 9 tests X 80 million!

Worsening Health in the U.S.

- United States is experiencing declining health at a startling rate.
- Parallel trends in other developed countries, like the United Kingdom.
- Widespread incidence of chronic diseases.
- Younger people show symptoms of chronic conditions typically seen in middle-aged adults.
- Obesity, hypertension, Adult-onset diabetese are examples.

Medicine's Evolution: Reactive to Proactive

- Old model: wait for patient to show up in doctor's office or the hospital.
- New ideal: proactive health services.
  - Early detection of disease
  - Active intervention to prevent chronic conditions and acute episodes
  - Use of genetic-based technologies assess patient's risk of disease over the course of his/her life.

What's Changing with Public?

- Today's public is smarter, more informed, and more demanding than at any time in the history of the world.
- Since 1980, major manufacturers and service firms have improved their products and services using "system of prevention" quality approaches.
- These two trends reinforce each other.

Raising the Bar

Can you guess the companies?

- "Commitment to Excellence!"
- "When it absolutely, positively has to be there overnight!"
- "Quality is Job One!"
- "Everything is easier on a Mac!"

Why Customers Expect More

- Book air travel instantly on the Internet *(without a travel agent)*
- Get a boarding pass and confirm seat *(without standing at the check-in counter)*
- Conduct banking over the Internet *(without visiting a bank branch)*
- Buy a book (Amazon)…or anything else (without walking into a store)

- It's why your customers/patients expect more of your hospital and laboratory!

Don't Forget their Employers

- Many consumers now work in companies with quality programs.
- This educates them about the source of errors.
- It also educates them about the ways to fix systemic errors.
- Lean, Six Sigma, ISO 9001 mean something positive to these consumers.
- This direct knowledge and experience makes them more demanding customers, with higher expectations.

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:
  - Customer defines quality.
  - Continuous improvement.
  - **System of prevention**.
  - Rigorous use of real time data.

Labs Meet "Lean"

- In United States in 2003, first laboratories launched Lean projects, primarily in chemistry and hematology.
- By 2006, these labs were introducing Lean into their histology labs.
- "First mover" pathology labs in the United States are combining Lean with automated histology solutions.

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

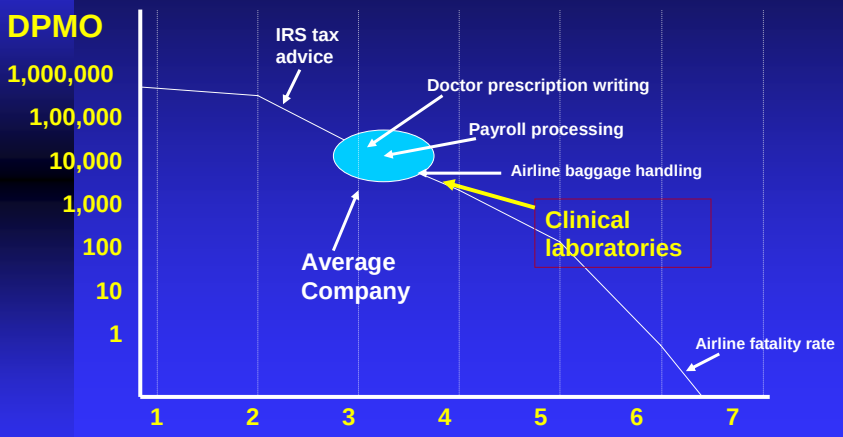
Core high-volume chemistry/hematology lab

Each Lean project lasted 12 to 16 weeks

Understanding 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%

Where Does the Laboratory Industry Stand?



Six Sigma for Lab Processes

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.

Lean Management Methods

- **Patient safety trend** creates the need to reduce errors and mistakes.
- **Measuring provider outcomes** creates the need to develop management systems which, by design, generate consistent and high quality outcomes.
- **Complexity of molecular testing** creates need to develop systems which are simple for lab to use and to manage.
- **Budget constraints and cost increases** create need for a lab system which produces at lowest cost.

The Joint Commission

- January 17, 2002: Leapfrog Group announces hospital quality rating system.
- January 16, 2002: The Joint Commission announces it accepted invitation to join Leapfrog Group.
- Leapfrog's 96 members employed 28 million people and spend $52 billion per year on healthcare.

The Joint Commission

- In January 2002, *Quality Management in Healthcare* published a study.
- Researchers determined that hospitals with Joint Commission accreditation did not get statistically better health outcomes than hospitals accredited by other sources.
- Since 2002, The Joint Commission has built outcomes and continuous improvement into accreditation requirements.

Patient Satisfaction and Change in Hospitals

- In patient satisfaction surveys, labs typically rank 9 or 10 out of 10 clinical services.
- That's because patients only "see the lab" at blood draws.
  - Most patients don't like needles or being stuck.
  - A surprisingly large number of patients are afraid of needles.

This Triggered Changes

- Hospital CEOS began spending money to improve the phlebotomy experience.
- In many health systems in last few years, decentralized phlebotomy has been centralized under lab's supervision.
- All because of the hospital's need to improve patient satisfaction with laboratory services and raise its survey scores.

New Paradigm in Lab Management?

- Acceptance of quality management methods in lab medicine signals new paradigm in pathology management.
- Use of detailed, real time information to allow tight management of work processes in pre-analytical, analytical, and post-analytical.
- Tools provided to sustain continuous improvement.
- Customers (clinicians, patients, payers) define quality, so lab can organize to deliver that quality.

Evolution or Revolution?

- We can argue about pace of change…
- …but it is clear that healthcare systems in many developed countries will undergo radical makeovers during the next decade.
- Many laboratories already adapting to these changes and striving to maintain their clinical value to clinicians.

Labs Must be Adopters

- Ready to offer new technologies and new services as clinical efficacy is demonstrated.
- Must incorporate “system of prevention” management methods to achieve required standards of quality.
- Proactive at serving needs of tomorrow’s health consumer: a patient with *high* expectations!
- Willing to be an active and available consultant to clinicians as normal course of business.

Value Added Opportunities

- Expedite the effectiveness of EMRs.
- Create clinical knowledge from lab test data that raises patient outcomes.
- Use of quality management methods, to reduce and eliminate errors that affect test integrity and accuracy.
- Contribute to evidence-based medicine that advances medical care.
- Develop specific capabilities as a consultation resource for clinicians.

Some Final Thoughts

- Don’t overlook IT! A lab test result delivered on paper will soon be an impediment to superior healthcare.
- With medicine becoming more complicated, laboratories that add value to clinicians will be paid extra for that value.
- Tomorrow’s laboratory winners will be extensive users of IT.
- These lab winners will be savvy and innovative in deploying IT.

One more thing…
Genetic Medicine…

- Genetic medicine and molecular diagnostics have true revolutionary potential.
- Labs are positioned to lead that revolution.
- Laboratory medicine is at a crossroads, yet most lab professionals unprepared for the coming swift transformation.

-30-