Lab Medicine Prepares for a New Era

Why Healthcare's Evolution Creates New Roles for Clinical Labs

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Poised on Razor's Edge

- What lies ahead for lab medicine?
- Is it tough financial times and deep cuts?
- Or will it be high value with molecular and genetic diagnostics?
- All developed countries face similar challenges.

Case for Tough Times Ahead

- Governments lack adequate funding for healthcare.
- Easy to cut lab budgets.
- Easy to cut lab test reimbursement.
- These are high risk strategies.
- Once lab infrastructure is gone, it cannot be quickly rebuilt.

Quick Look at World Scene

Australia

- Population: 23 million
- Since 1984, five-year contracts between government health department and pathology profession.
- Caps lab test spend with inflation factor.
- Utilization of tests increasing at “unsustainable” pace.
- Latest contract reduces amount of funding on per-test basis.

Canada

- Population: 35 million
- Almost three decades of cost reductions to lab testing infrastructure.
- Ongoing efforts to control lab test costs.
- Each province handles lab test services differently.
- Incidents of lab test errors in past decade not seen in other countries.

United Kingdom

- Population: 63 million.
- Few effective budget cuts to labs.
- In midst of “commissioning” to require providers to put lab testing up for bid.
- Efforts to consolidate labs regionally have had limited success.
- All providers will get flat budgets from 2014 through 2019.

Ireland

- Population: 4.6 million
- Labs were starved of capital from late 1990s to present.
- Thus, limited automation.
- Outsourced all Pap testing in 2008.
- Tests go to Quest Diagnostics, Sonic.
- Proposal to consolidate testing into two “cold labs.”
- Proposal to consolidate hospital testing from 40 hospitals into seven “hot labs.”

United States

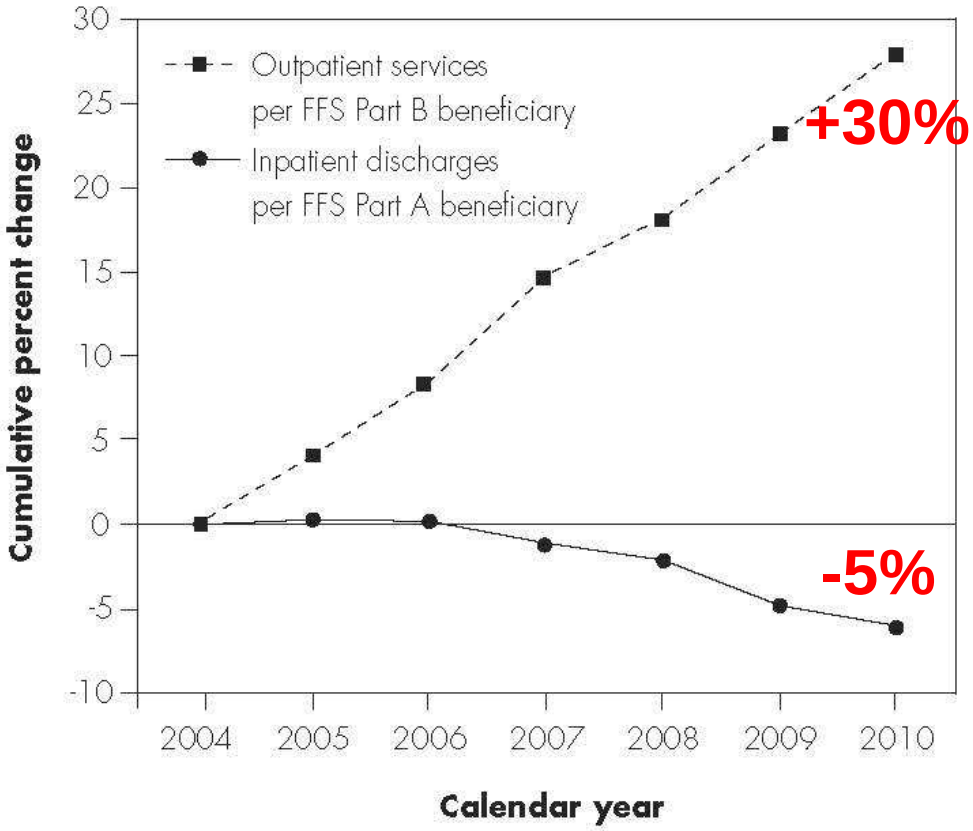
- Population: 314 million
- Healthcare system undergoing major evolution.
- Recent years: multiple cuts to lab test fees and anatomic path fees.
- Fee-for-service is dwindling.
- New forms of payment appearing.
- Lab and pathology group bankruptcies imminent.

Trend is Away from Inpatient Services

- Community hospital lab outreach progams have interesting dilemma.
- Emphasis now on keeping people out of hospitals.
- Growing proportion of lab specimens will be originate in outpatient and outreach settings.

FIGURE 3–2

From 2004 to 2010, Medicare outpatient services grew while hospital inpatient discharges per FFS beneficiary declined



Note: FFS (fee-for-service). Data include general and surgical hospitals, critical access hospitals, and children's hospitals.

Source: MedPAC analysis of MedPAR and hospital outpatient claims data from CMS.

Key Point

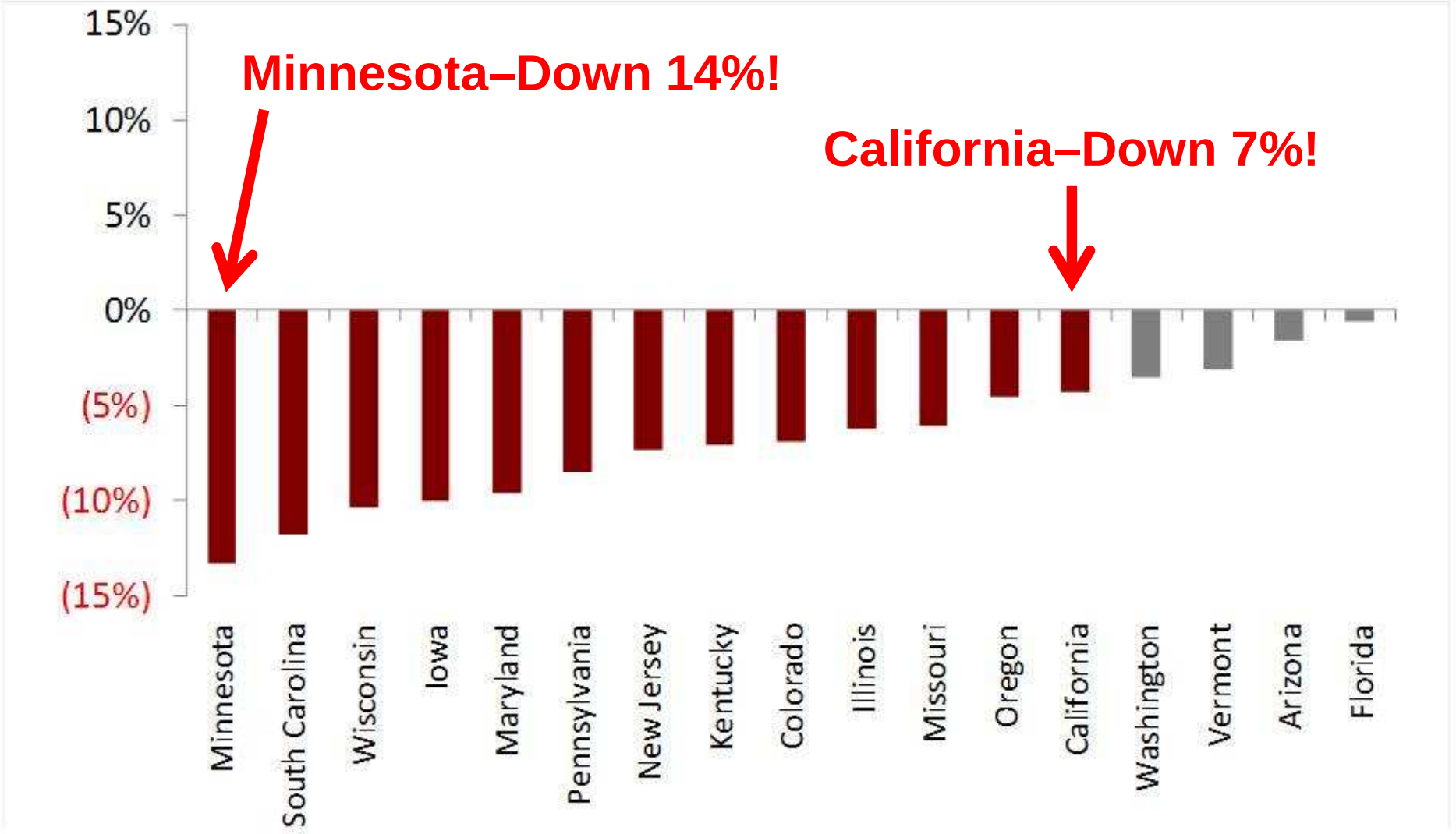
Inpatient procedures growing by single digits each year.

Outpatient procedures growing at double-digit rates annually.

Labs must have access to outpatient and outreach specimens!

Source:
MedPac Report to Congress: Medicare Payment Policy, March 2012

Figure 2. 2006-2011
Change in Inpatient Use Rates per 1,000



Source: Decline In Utilization Rates Signals A Change In The Inpatient Business Model, Health Affairs Blog, March 18, 2103; Grube, Kaufman, and York

Force for Change
Personalized, Proactive Medicine Informed by Genetics

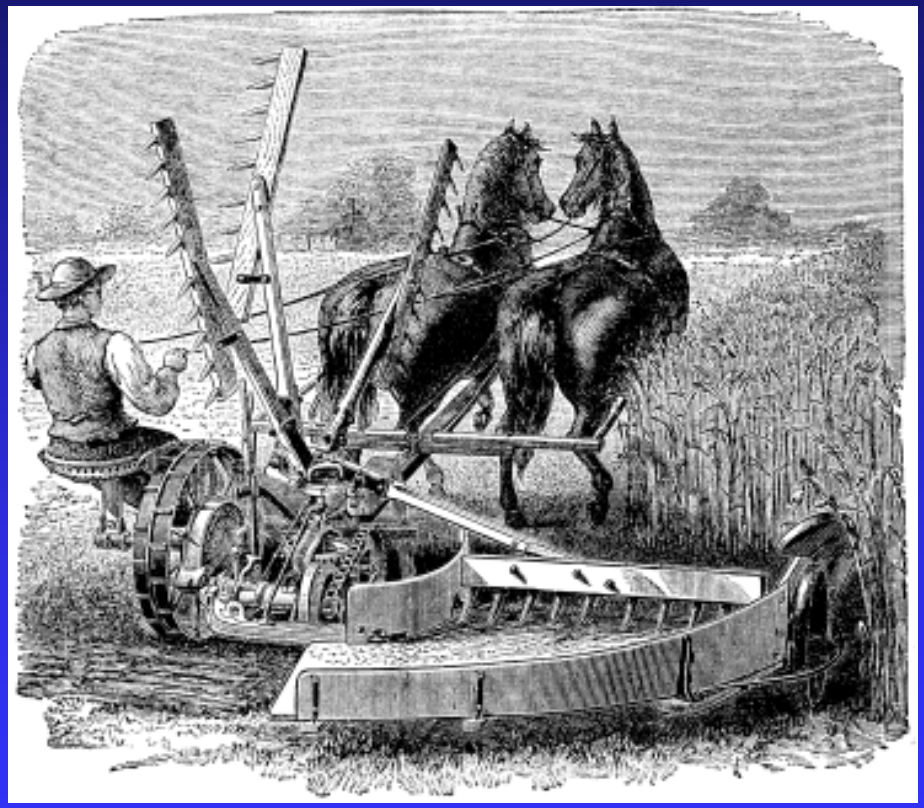
- During your career: reactive medicine and acute care.
- Coming soon to a provider near you:
  - Proactive Medicine.
  - Personalized Medicine (Precision Medicine).
  - Genetic analysis; whole human genome sequencing.

New Clinical Care Paradigms

- Keep patients out of hospitals!
- Detect disease early, when it is more easy to treat.
- Actively help patients manage their chronic diseases.
- Use incentives to encourage positive lifestyle choices and activities.
- Support these goals with genetic knowledge as it is developed.

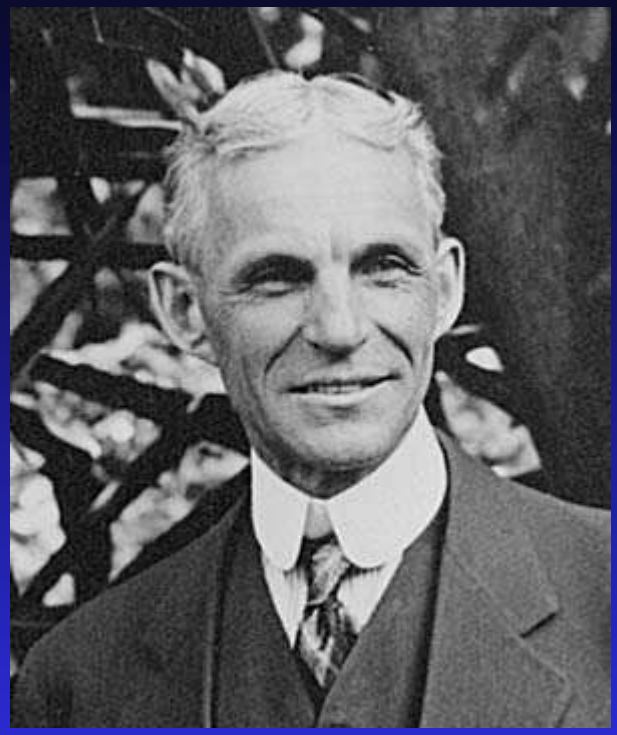
Entering a New 'Age'!

- Remember your history?



Agricultural Age ends about 1780...

Then came…



Henry Ford
Industrialist

Industrial Age through end of 20th Century...

That Gave Way to…

Bill Gates

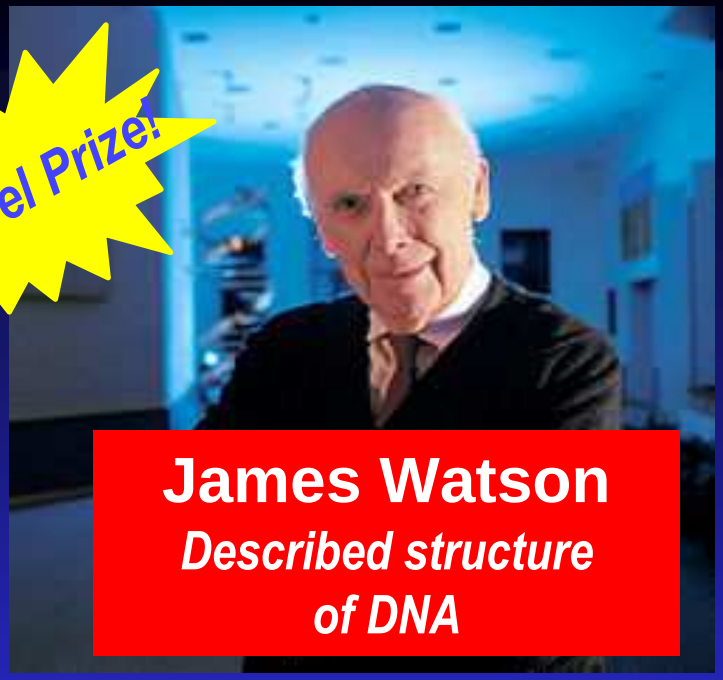
World's Richest Man!

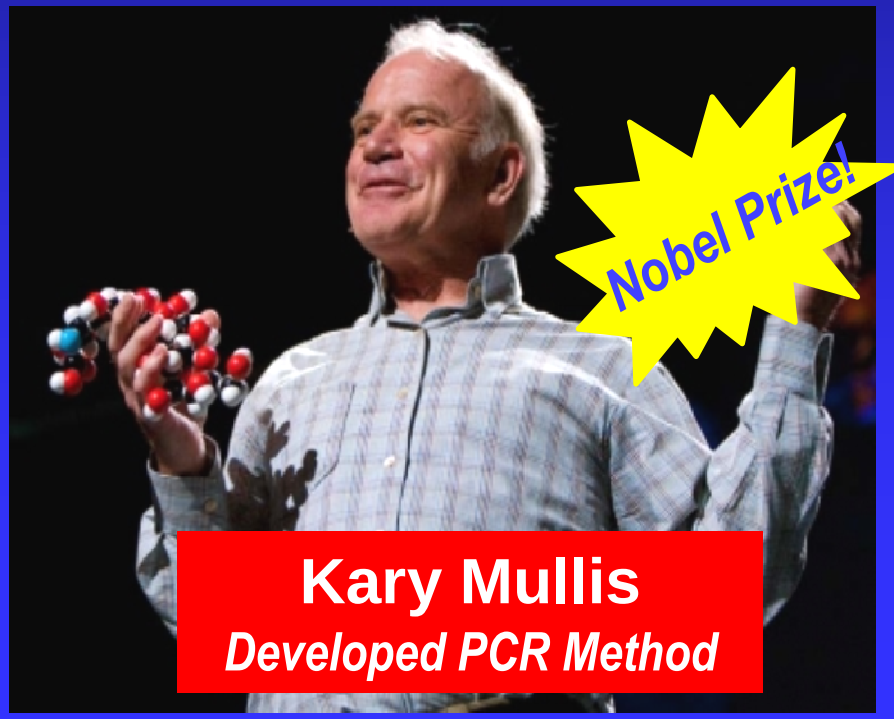
And what did he own?

Information Age in 1990s...

Now we begin…

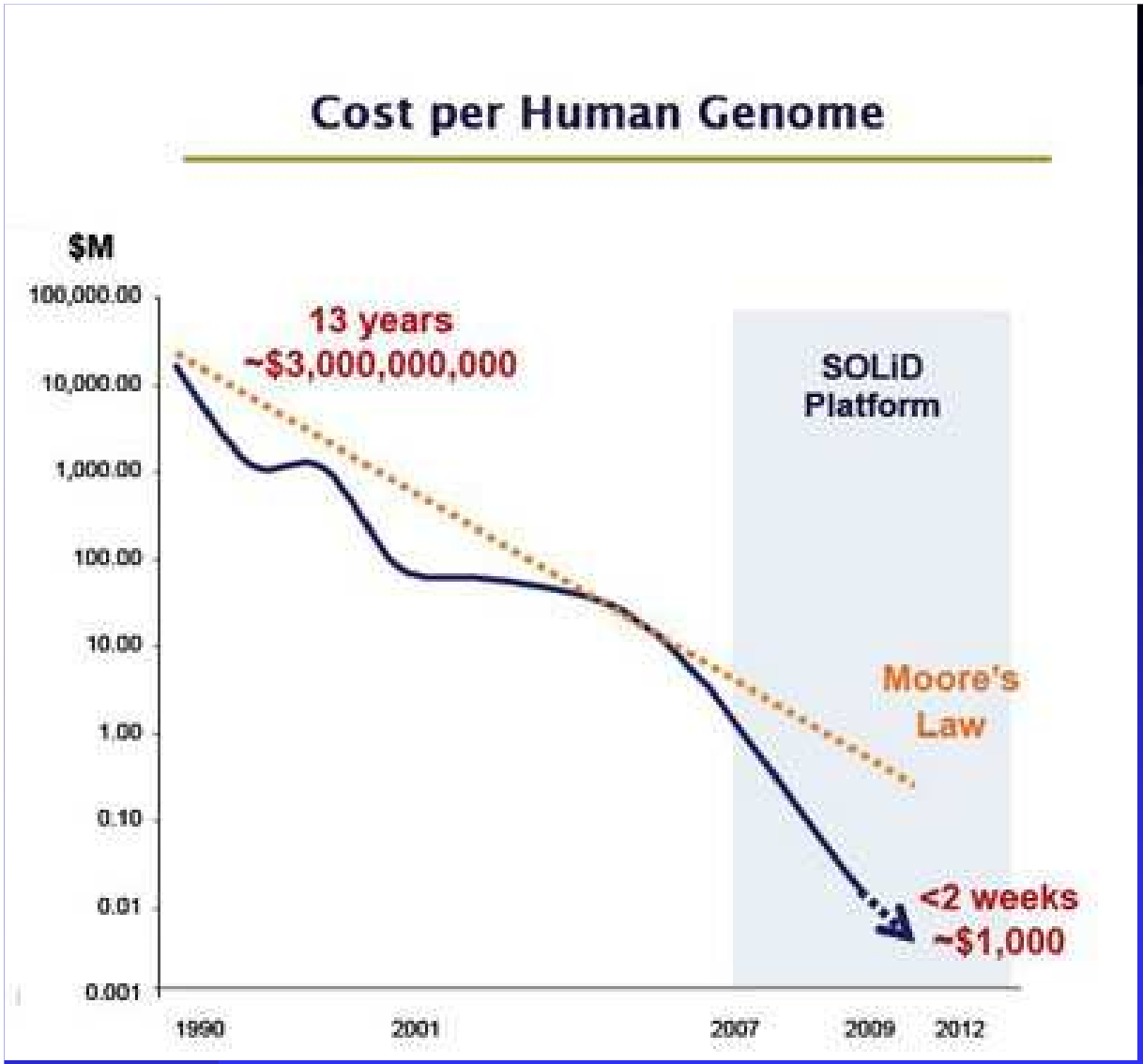
Genetic Age in 2010s...





Genetics Is Lab Opportunity

- First time in history that man is learning about genetics and how to harness its power.
- Pathologists, PhDs, and lab scientists can lead this field.
- Molecular and genetic testing will be the source of great value to healthcare system.



Forbes Magazine

Trend predicts that whole human genome sequence can fall below $100!

Moore's Law is seen in declining cost of sequencing base pairs

Force for Change

Adoption of QMS

- Quality Management System (QMS).
- ISO 9001 (certification).
- ISO 15189: Medical Laboratories (accreditation).
- CLSI Document GP-38.
- Perfect complement to Lean, Six Sigma, process improvement methods.

Survive?

- Can any lab survive if it continues to operate in the traditional way?
- System of Inspection is no longer good enough.
- “Traditional Labs” operate at 3-4 Sigma.
- That’s not good enough!
- Patients won’t tolerate these error rates.

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.

Adding Value with Lab Tests

- Goal is to improve patient outcomes while reducing the cost per episode of care.
- Lab can spend a bit more money, but contribute to millions in cost savings.
- Example of John T. Mather Memorial Hospital in Port Jefferson, NY.
- 248 beds, lab runs 2.3 million tests annually.

Reduced cases of MRSA at Mather Mean Better Outcomes, Reduced Costs

Costs

- **Screened high risk patients**
- **2008:** 88/mo = 1,050/yr
- **2009:** 139/mo = 1,663/yr
- **2010:** 176/mo = 2,107/yr
- **2011:** 182/mo = 2,181/yr
- **2012:** 164/mo = 1,967/yr

- **PCR Assay ~ $50 per test**

- **Total Screening Cost $448,400**

- **NO ADDITIONAL FTES**

- **MRSA testing performed 24/7**

Savings

248 bed hospital

82,373 patient days/91% occupancy

Rate of Infection/1000 Patient Days

- 0.90/1,000 = 74.0 infections (2007)
- 0.59/1,000 = 48.0 infections (2008)
- 0.29/1,000 = 23.0 infections (2009)
- 0.25/1,000 = 19.0 infections (2010)
- 0.17/1,000 = 13.0 infections (2011)
- 0.23/1,000 = 18.0 infections (2012)

(2007 vs 2012)

Difference = 56.0 fewer infections @ $35,000
Decrease in 2008 hospital costs = $910,000
Decrease in 2009 hospital costs = $875,000
Decrease in 2010 hospital costs = $140,000
Decrease in 2011 hospital costs = $210,000
Increase in 2012 hospital costs = $175,000

$1,960,000 cost avoidance
Net Savings Due to Prevention
$1,511,600

New Laboratory Algorithm Generates Substantial Benefits for C. *difficile* Testing

Costs

Total Testing Volume

- **2009:** 275/mo = 3,107/yr
- **2010:** 148/mo = 1,774/yr
- **2011:** 160/mo = 1,919/yr
- **2012:** 122/mo = 1,522/yr

- Simultaneous EIA- $12 per test
- PCR Assay ~ $40 per test

- **Cost 2010:** $ 26,968
- **Cost 2011:** $ 33,108
- **Cost 2012:** $ 26,384

Total Testing Cost: $86,460

NO ADDITIONAL FTES

C. diff testing performed 24/7

Savings

248 bed hospital

82,373 patient days/91% occupancy

Rate of Infection/1000 Patient Days

- 0.95/1,000 = 70.0 infections **(2009)**
- 0.57/1,000 = 46.0 infections **(2010)**
- 0.65/1,000 = 50.0 infections **(2011)**
- 0.34/1,000 = 26.0 infections **(2012)**

(2009 vs 2012)

Difference = 44.0 infections @ $35,000

Decrease in 2010 hospital costs = $840,000

Increase in 2011 hospital costs = $140,000

Decrease in 2012 hospital costs = $840,000

$1,540,000 cost avoidance

Net Savings Due to Prevention

$1,453,540

Conclusion: Challenges Ahead for All Labs

- On multiple fronts, labs will see less payment and reduced budgets for lab testing services.
- Market poised for fundamental restructuring and much disruption to status quo.
- Innovative labs will rely on vendors for help across all aspects of lab management and operations.

THE WALL STREET JOURNAL.

Updated September 8, 2013

Elizabeth Holmes: The Breakthrough of Instant Diagnosis

A Stanford dropout is bidding to make tests more accurate, less painful—and at a fraction of the current price.

- Founder of Theranos, Silicon Valley
- Established 2003—secretive!
- $100 million in venture funding
- CLIA lab in Palo Alto
- Finger stick specimen—Patented technology
- Priced at 50% of Medicare
- Will offer testing at 8,117 Walgreens' stores nationally!
- Bigwigs on Board of Directors

Thoughts on Leadership…

"Never tell people how to do things. Tell them what to do and they will surprise you with their ingenuity."

–General George S. Patton

"As we look ahead into the next century, leaders will be those who empower others."

–Bill Gates