

Big Changes to the Lab Testing Landscape
Why Healthcare's Evolution
Creates Opportunity to Redefine
the Value of Clinical Labs

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THE DARK REPORT

Spicewood, Texas

Lab Quality Confab

21 October 2014

New Orleans, Louisiana

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Understanding Lab Medicine's Four Biggest Sources of Change

- 1. Reimbursement**
- 2. Disruption in physician practice models**
- 3. Era of Personalized and Proactive Medicine informed by genetics**
- 4. Adoption of QMS by labs and all providers**

Force for Change #1

New Reimbursement Models

- Fee-for-Service is on the way out.
- In its place:
value-based reimbursement.
- Expect to see:
 - ◆ Bundled payments.
 - ◆ Capitation.
 - ◆ Pay for Performance (P4P).
- Transition is already underway
with Medicare and private payer ACOs.

Impact on Labs Is Huge

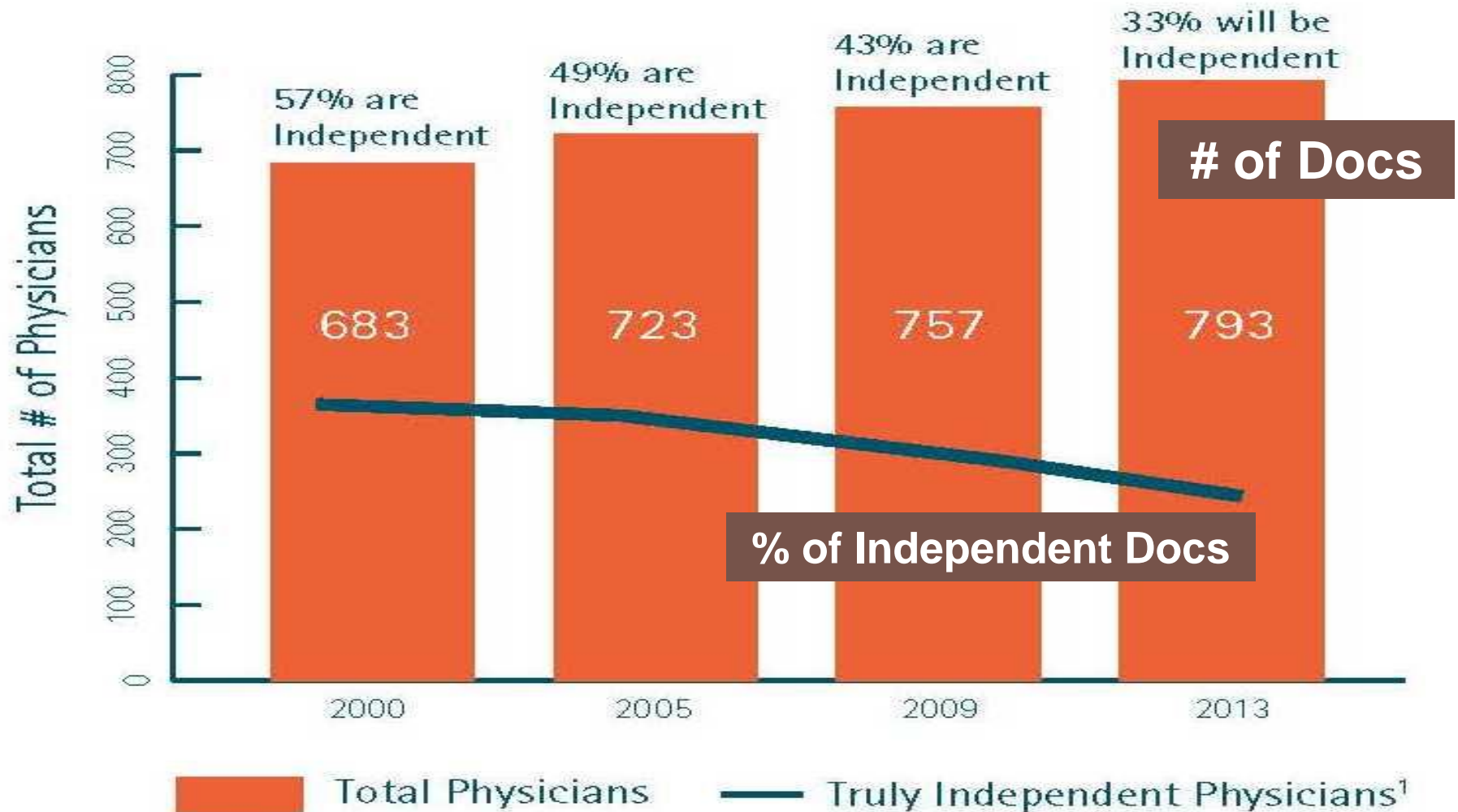
- Lab economics recognizes value of economies of scale when payment is fee-for-service.
- As fee-for-service disappears, labs will be paid according to how they add value to physicians and help improve patient outcomes.
- Big change for clinical labs, since high volume no longer guarantees success.

Force for Change #2

Physician Market Transforming

- Premise: traditional market for independent lab companies has been office-based physicians.
- These physicians were self-employed or owners of their medical practice.
- That is no longer true.
- New practice models evolving.
- Add to this the Gen X and Gen Y differences in attitude, work ethics.

Total Physicians vs. Truly Independent¹ – Projected Change, 2000–2013 (000s)



1.Estimated

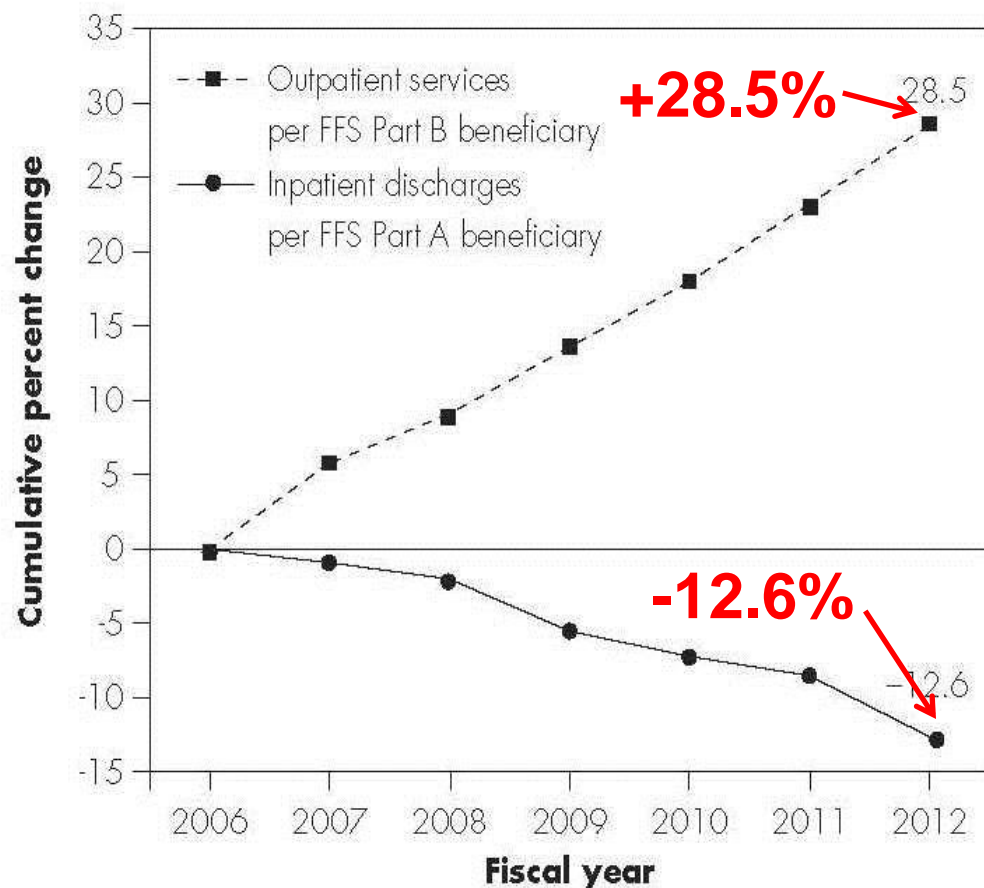
Sources: Accenture Analysis, MGMA, American Medical Association

Trend is Away from Inpatient Services

- Community hospital lab outreach programs 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
3-1**

Medicare inpatient discharges per beneficiary declined as outpatient visits per beneficiary increased



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

Source: Medicare hospital cost reports and Medicare outpatient claims data.

Key Point

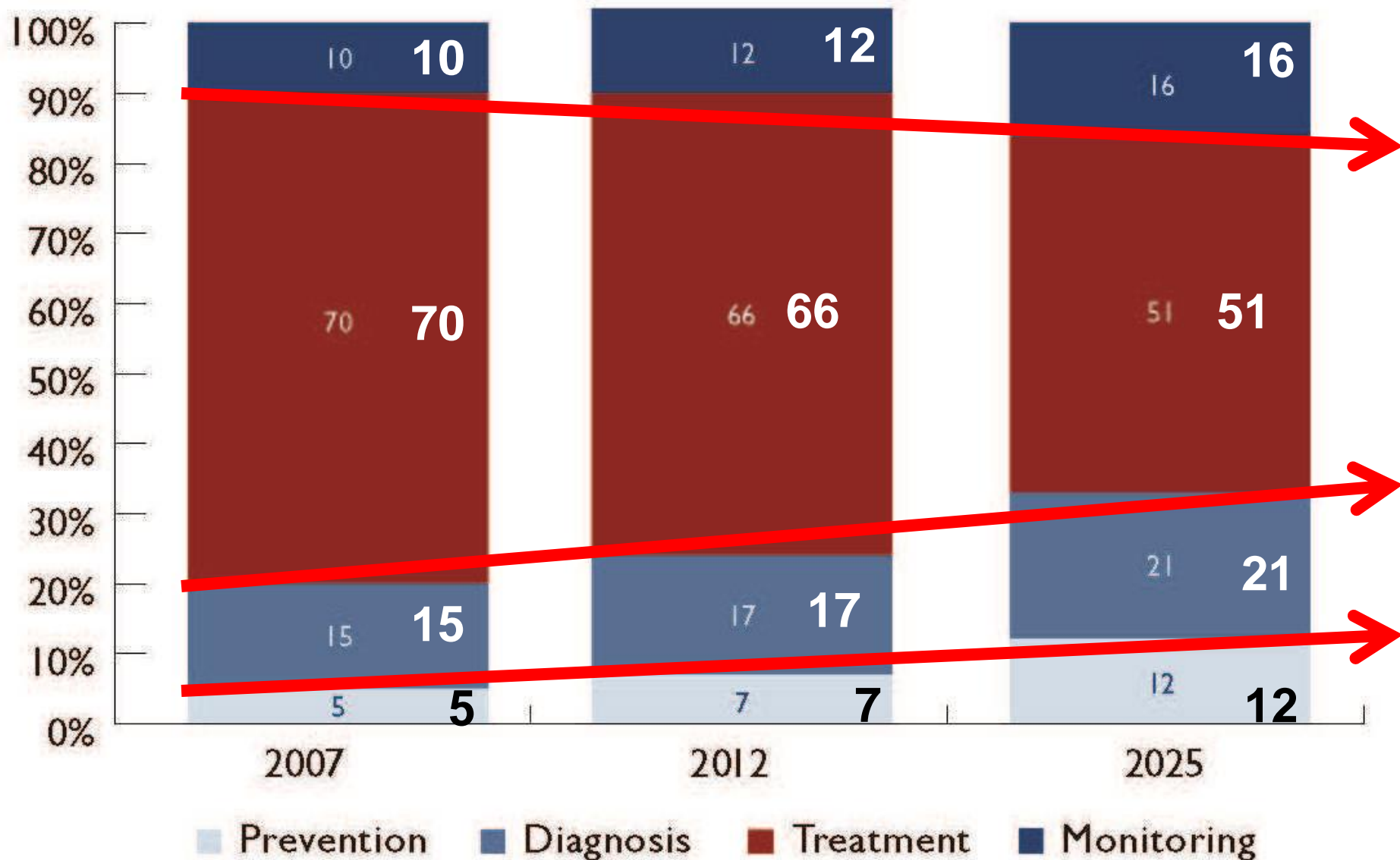
Inpatient procedures growing by single digits each year.

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 2014

Figure I: Healthcare spending by Type of Activity



Source: Frost & Sullivan analysis

Force for Change #3

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.

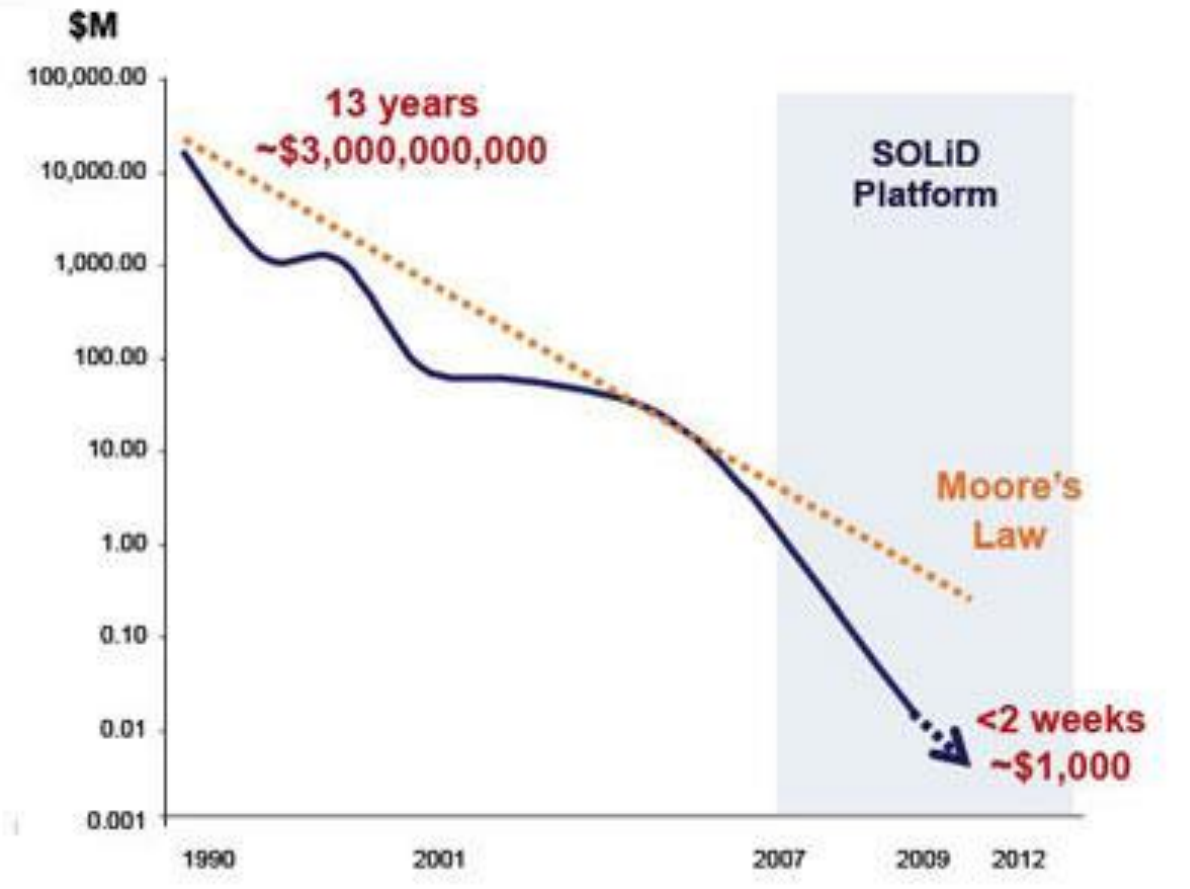
New Clinical Care Paradigms

- 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.

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.

Cost per Human Genome



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

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

Gene Sequencing

- November 19, 2013: FDA cleared Illumina's MiSeqDX instrument and reagents.
- January 9, 2014: Quest Diagnostics to use Illumina platform for next gen gene sequencing.
- January 20, 2014: LabCorp to use Illumina platform.
- Illumina says a whole human genome sequence can be done for \$1,000.

Force for Change #4

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.



CMS Encourages QMS

- Det Norske Veritas (DNV) granted deeming status in September 2008.
- DNV offers hospitals accreditation to Medicare COP and ISO 9001.
- American Association of Laboratory Accreditation (A2LA) granted deeming status in March 2014.
- Can now accredit labs to CLIA and Medicare COP and ISO 15189.



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

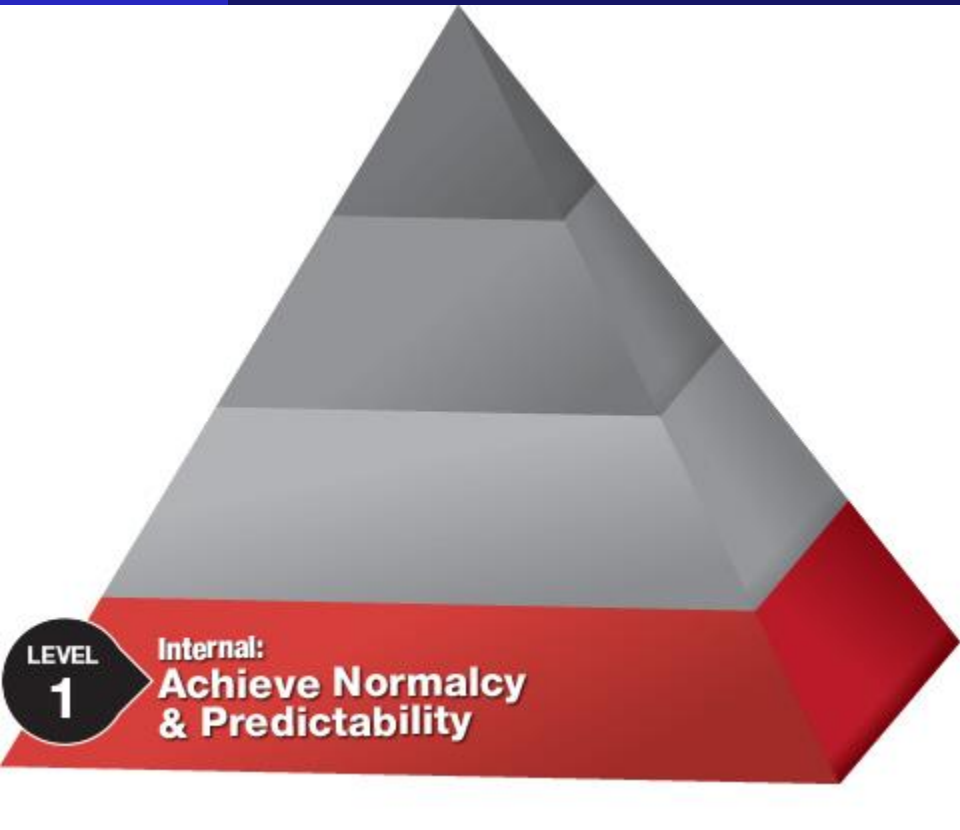
Net Savings Due to Prevention

\$1,511,600

Meet the 'Laboratory Value Pyramid'

- What path can clinical labs follow to respond to healthcare's transformation?
- Introducing the concept of the **"Laboratory Value Pyramid."**
- Provides lab leaders with a four-step road map from current state to ideal future state.
- Incorporates all concepts of modern business and quality management systems.

Level One: Achieve Normalcy and Predictability



- Shift the lab organization away from system of inspection and adopt the **system of prevention**.
- Shift to a system that incorporates real-time, visible performance metrics of lab processes alongside traditional QC data.
- Shift to the mindset of continuous improvement.
- Shift to a culture that regularly engages outside experts to help lab staff understand key issues and develop appropriate solutions for further improvement throughout the lab.

Level Two: Establish Standards & meet Standards of Value



- Establish criteria for value via benchmarking within the lab.
- Transition from a lab-result-only mentality to one of a lab performance mentality.
- Incorporate quality in patient results, customer & employee satisfaction, production best practices, supply chain best practices, financial best practices, and similar.
- Manage the lab as a well-run business with all the accountability that comes with running a well-run business.
- Lab staff can identify tasks that are value-added and those that are non-value-added and uses Lean and Six Sigma to continually improve value.

Recognizing Level Two

- Lab is competent at this level when those outside the lab—including your boss and your boss' boss—to want to know about the core competencies you have established, how you did it, what benefits it provided, then ask you to help them do something similar in another area of the organization.

Level three: Deliver value that Exceeds Expectations



- Shift from service provider of lab results to a vital contributor in generating clinical value.
- Apply knowledge of your core competencies that were created in level one and level two to other areas outside the walls of the lab.
- Shift from a state of being held hostage by IT, LIS, HIS, and middleware to one of being proactive and in-charge based on value creation.
- Cost justify IT projects that integrate essential lab patient info into algorithms that diagnose more accurately and sooner, thus contributing to shorter hospital stays, reduced diagnostic workups, and less chance of readmission within 30 days.

Recognizing Level Three

- Your lab is competent at level three when your reputation and outcomes are recognized outside of your hospital and institution by your peer groups.
- Regular requests for speaking engagements, requests for publications, citations in publications and similar outside recognition start to happen.

Level four: Use Benchmarks to Achieve Best-in-Class



- Your lab's practices and competencies are recognized as best-in-class by your peer groups and third party reviewers.
- You are consulting with other hospitals and systems to help them replicate what you have done within your institution.
- Your lab is recognized as among "the best in the business" because of how your lab team uses all the attributes from the first three levels.
- Examples of world-class labs can be found within prestigious institutions like Mayo, Stanford, Vanderbilt, MGH, Cleveland Clinic.
- Extra credit! Your lab has created the database structure that allows it to mine the value of lab test data.

But Don't Forget!

- There are 320 million Americans who continue to need clinical lab tests and anatomic pathology services.
- Someone will do this work.
- Message is for your laboratory to get out ahead of these trends.
- Be one of the labs that do this work... by delivering clinical value.

Thoughts on Leadership...

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

–Bill Gates



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

–General George S. Patton