Healthcare’s Transformational Journey:
Laboratory Medicine in the Year 2020

ROBERT L. MICHEL
Editor In Chief
THE DARK REPORT
Spicewood, Texas

Nat’l Lab Training Conference V
Orlando, Florida
June 12, 2009
My Goals Today!

- **One**: Describe how laboratory medicine is likely to be in the year 2020.

- **Two**: Explore how laboratory services must evolve/change to effectively support new healthcare objectives and needs.

- **Three**: Make some predictions about what public health laboratories may be doing in 2020.
Clinical Lab Market

- This gives us context for how the next decade may reshape and alter laboratory medicine as we know it today.
- After all, the year 2020 is only 126 months away.
- We are closer to January 2020 today than we are to June, 1998!
A simpler time in lab medicine?

- Independent lab sector with many local independent labs, about 10 major national laboratory companies.
- Most hospitals were independent and operated single-site laboratories.
- Anatomic pathology services were provided primarily by private pathology group practices.
- Even publicly-traded commercial lab companies outsourced all AP and much cytology to local pathology groups.
The year is 1990…

Where Are they Now?

- SmithKline Beecham Clinical Labs
- National Health Labs
- Damon Clinical Labs
- Allied Clinical Labs
- Nichols Institute
- Roche Biomedical Labs
- Bio-Reference Labs
- Universal Standard Medical Labs
- MetPath
- Meris Labs
- MetWest/Unilab
- DIANON Systems
- Home Office Reference Labs (LabOne)
Handful of independent local commercial lab companies.

Quest Diagnostics and LabCorp now multibillion-dollar behemoths.

Consolidation of hospital ownership triggered creation of a large number of consolidated hospital lab organizations serving multiple hospitals.

Hospital lab outreach programs relatively limited in number.
Fast Forward to Year 2009

Looking at Clinical Lab Services

- Dominance by the two blood brothers in national market for clinical lab testing.
- Entry of new billion-dollar competitor, as Sonic Healthcare, Ltd. buys CPL in Austin.
- Number of local independent commercial lab companies continues to dwindle.
- Since 2000, steady growth in the number of hospital laboratory outreach programs providing services to office-based physicians in surrounding communities.
Anatomic Pathology Market

- We discussed AP in 1990.
Landscape for Change-2000

Big Changes in Anatomic Pathology

- Emergence of national AP firms, such as UroCor, DIANON Systems, IMPATH.
- Some consolidation of pathology groups in large urban markets (related to consolidation of hospital ownership).
- Emergence of first specialty testing companies in molecular diagnostics, such as Myriad Genetics.
- As a profitable, growing sector, AP catches attention of two blood brothers.
Fast Forward to Year 2009

Looking at Anatomic Path Services

- Quest Diagnostics and LabCorp expanding into anatomic pathology. (Quest/AmeriPath now employees 900+ pathologists. LabCorp employs 400+ pathologists.)
- Growing number of national AP labs, such as Bostwick Labs, CBL Path, Clarient, Claris, Lakewood Pathology, OUR Labs.
- Specialty physicians, such as urologists and GIs, establishing in-house anatomic pathology services. (TC/PC arrangements.)
Fast Forward to Year 2009

Steady growth in numbers of specialty testing companies with proprietary or patent-protected diagnostic technology.

- Genomic Health, RedPath Innovative Pathology, Signature Genomics are just a few examples.

- These firms want the specimens so tests can be performed in their laboratories. Business goal is to be exclusive provider of these diagnostic technologies.
Today’s Market Segments

- Routine testing for office-based physicians (traditional market).
- National anatomic pathology lab firms.
- Specialized testing firms
  - Organized around specialty: Athena for neurology, DIANON for urology.
  - Offering patent-protected/proprietary diagnostics: Myriad for BRACA testing.
- Wide open segment: “knowledge-based” lab testing providers.
- Wide open segment: molecular diagnostics.
“In both the short term and long term, chronic disease will be treated in outpatient settings [physicians’ offices]. More of the testing, whether for cancer, for infectious disease, and for other illnesses, will be done in support of outpatient treatment.”

Thomas MacMahon, LabCorp CEO

THE DARK REPORT, April 14, 2003
Now to Demographics, or… Meet the “Silver Tsunami”

- 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
United States: 2000

Source: U.S. Census Bureau, International Data Base.

United States: 2050

Source: U.S. Census Bureau, International Data Base.
Meet Baby Boomer #1

- Generally recognized as the nation's first boomer—born in Philadelphia on Jan. 1, 1946, at 12:00:01 a.m.

- In 2008, the first wave of 3.2 million baby boomers turns 62—365 an hour!

- By 2030, Social Security's caseload will be 84 million people, up from 50 million today.

- Medicare will go from 44 million beneficiaries to 79 million.

- That will leave barely more than two workers paying payroll taxes for every retiree.

Kathleen Casey-Kirschling
Grandma or Active Boomer?

- Early coverage of her showed her like the kindly Grandma typical of the past generations of Senior Citizens
But, This Boomer is not your average grandma!

- She owns a yacht moored in Maryland.
- Has residences in Florida, New Jersey.
- She won’t be scrimping in her retirement, dependent on SS, Medicare.

Plus, look what else she has!

Kathleen Casey-Kirschling will get her first Social Security check in January... She is photographed on the back of her boat "First Boomer."
“Kathleen Casey-Kirschling, with press agent Lisa Stringham, talks about being the first Baby Boomer Thursday at Lake Mead.”

At Social Security office, using the Web site to apply for her benefits

Getting her first social security check!
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.
- Medicare lives (65 or older) average about 9+ lab tests per person per year.
- 80 million baby boomers are rapidly advancing into this age cohort.
Just a Reminder...

- “Follow the Money!”
- Middle class patients want access to healthcare and the latest technology.
  - They’ll pay, just like they willingly pay their dog and cat veterinary bills today.
- Vendors, providers, hospitals want to preserve access to patients and provide services in fee-for-service arrangements.
- These are powerful constituencies for Congress to ignore.
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!
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 is one example.
Obesity Trends Among U.S. Adults between 1985 and 2007

Definitions:

- Obesity: Having a very high amount of body fat in relation to lean body mass, or Body Mass Index (BMI) of 30 or higher.

- Body Mass Index (BMI): A measure of an adult’s weight in relation to his or her height, specifically the adult’s weight in kilograms divided by the square of his or her height in meters.
Obesity Trends Among U.S. Adults between 1985 and 2007

Source of the data:

- The data shown in these maps were collected through CDC’s Behavioral Risk Factor Surveillance System (BRFSS). Each year, state health departments use standard procedures to collect data through a series of monthly telephone interviews with U.S. adults.

- Prevalence estimates generated for the maps may vary slightly from those generated for the states by BRFSS (http://aps.nccd.cdc.gov/brfss) as slightly different analytic methods are used.
Obesity Trends* Among U.S. Adults
(*BMI ≥30, or about 30 lbs. overweight for 5’4” person)

Source: CDC Behavioral Risk Factor Surveillance System.
Shift to Proactive Medicine

- Shift from reactive medicine (acute/episodic care) to proactive medicine (early detection, active prevention, active intervention).
- This is huge paradigm shift across the entire healthcare system.
- It is active goal today in most developed countries.
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.
Consumers expect medicine to reduce and eliminate medical errors across the healthcare system.

This encourages wider use of “system of prevention” management methods.

Expect more Lean, Six Sigma, ISO 9000, ISO 15189 in laboratory management and other sectors of healthcare.
Consumers begin to expect very high accuracy in lab testing.

Labs will measure and manage to “errors per million events.”

Community and regional variations in how lab tests are standardized and validated will become a concern.

Use of universal EMR will play a role in creating greater accuracy and uniformity in lab testing across regions of the USA.
Understanding Six Sigma Quality

<table>
<thead>
<tr>
<th>Sigma Level</th>
<th>Defects per Million Opportunities</th>
<th>Yield</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>3.4</td>
<td>99.9997%</td>
</tr>
<tr>
<td>5</td>
<td>233</td>
<td>99.977%</td>
</tr>
<tr>
<td>4</td>
<td>6,210</td>
<td>99.379%</td>
</tr>
<tr>
<td>3</td>
<td>66,807</td>
<td>93.32%</td>
</tr>
<tr>
<td>2</td>
<td>308,537</td>
<td>69.2%</td>
</tr>
<tr>
<td>1</td>
<td>690,000</td>
<td>31%</td>
</tr>
</tbody>
</table>
Where Does the Laboratory Industry Stand?

DPMO

1,000,000
1,00,000
10,000
1,000
100
10
1

Average Company

IRS tax advice
Doctor prescription writing
Payroll processing
Airline baggage handling
Clinical laboratories
Airline fatality rate

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

*Conversion using table with allowance for 1.5s shift

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.
Integrated Health Informatics

- Goal of universal electronic medical record (EMR).
- Goal of eliminating paper.
- Goal of allowing information to move seamlessly throughout the entire healthcare system.
- This has many implications for public health laboratories.
Integrated Informatics…

- By achieving a universal EMR, it should become feasible:
  - To collect patient data in real time and make it available to relevant parties.
  - This might allow public health authorities to track diagnoses of patient visits to doctor’s offices and hospitals throughout the course of a single day.
  - This would be an invaluable tool for tracking and managing outbreaks of infectious disease.
Adoption of ICD-10 & ICD-11

- These diagnostic code sets are richer and appropriately-detailed for current and next generation medicine.
- After adoption in the USA, use of ICD-10 will provide never-before accessible detail about patient health issues.
- This will transform evidenced-based medicine (EBM) as we know it today.
Evidence-Based Medicine

- Speaking of EBM, this will be primary tool to evaluate new clinical procedures, prescription drugs, medical devices, and laboratory tests.
- Because of patient safety…
- Because of limited funds for health…
- New medical advances will be required to demonstrate clear clinical benefit, with minimal side effects to patients, at a reasonable financial cost.
Key Trends for the Next Decade

Personalized Medicine

- This is another paradigm shift in healthcare.
- Move away from giving all patients the same “accepted standard of care.”
- Move toward individualizing care based on individual patient’s:
  - Age, sex, family history, genetic and proteomic make-up, and evaluation of individual’s complex metabolism, among other factors.
Personalized Medicine

Currently, much of medical practice is based on “standards of care” that are determined by averaging responses across large cohorts. The theory has been that everyone should get the same care based on clinical trials. Personalized Medicine is the concept that managing a patient’s health should be based on the individual patient’s specific characteristics, including age, gender, height/weight, diet, environment, etc.

Source: www.wikipedia.com
Key Drivers (Follow $s & Rs!)

Starting point is “companion diagnostics”

Briefly stated, [companion diagnostics] is a strategy pursued by some IVD companies, Roche Diagnostics in particular, whereby the company develops a gatekeeper biomarker assay. This is a lab test that serves to qualify a patient for treatment with a particular drug. The most common example of such a test is the HER-2/neu assay that is required prior to treatment with Herceptin.

Source: Bruce Friedman, M.D., www.labsoftnews.com
Define genetic medicine as knowledge rooted in DNA, RNA, Proteomics.

Will allow detailed understanding about individual patient’s current health: potential for cancer, inherited diseases and other illnesses; and risk of recurrence.

Genetic medicine will require major transformation of laboratory testing and diagnostics as practiced today.
Key Trends for the Next Decade

**Multi-Modality Diagnostics**

- Earliest steps toward integration *in vivo* and *in vitro* diagnostics are underway.

- Health informaticians are working to bring imaging, histopathology, and other clinical data into a single software program, then use algorithms to evaluate and guide clinician to the correct diagnosis.

- In next decade, pathologists and laboratory professionals will be interacting with care team and patients.
Key Trends for the Next Decade

**Molecular Diagnostics**

- Pathology and clinical laboratory testing will be organized around molecular technologies.
- Expect radical new types of specimens for laboratory tests.
- For example: breath, volatile organics coming off the skin.
- Analyzers already exist that demonstrate diagnostic accuracy and reliability using these specimen types.
Key Trends for the Next Decade

**Multi-Analyte Assays**

- Already seeing the spear point of this trend in diagnostic use.
- Luminex with its micro-bead capability of 512-analyte assays—done in seconds on a finger stick sample of blood.
- Microarrays, with tens of thousands of analytical points for DNA, RNA, proteins.
- Whole human genome sequencing as a one-time diagnostic procedure.
Peeking into the Future

Role of Public Health Laboratories is not likely to change.

But what will change are:

- Technology for lab testing at central labs.
- More easy, fast point-of-care testing.
- Ability to gather patient data in real time to better track infectious disease outbreaks.
As Lab Testing Moves Out From Core Laboratory

- More patient self-testing and home testing, with results uploaded via Internet to patient health record (PHR).
- More point-of-care and near-patient testing by clinicians, with results uploaded via wireless to PHR.
- In the future, complete patient record, in real time, accessible by both clinicians and public health officials.
By 2020, Integration Is Theme

- Collectively, these trends point to a healthcare system with integrated flow of real-time, complete information about the patient to all providers.

- More precise molecular tests will give public health labs capabilities for both high volume core lab testing during outbreaks and accurate, rapid point-of-care testing.

- From an infectious disease perspective, future technologies will favor the mission of public health laboratories.
By 2020, New Responsibilities?

- With early detection and active intervention as emerging themes, might public health labs gain new missions?
- In New York City, example of adult-onset diabetes monitoring.
- In New York City, example of restaurants posting calorie counts on menus.
Final Thoughts

- Primary missions of public health laboratories are not likely to change much by 2020.
- What will change are tools to accomplish these missions.
- Key technologies:
  - health informatics and integration of data flow;
  - more precise molecular tests that can generate results rapidly.
And Remember!

- Change creates new winners and new losers in the marketplace.
- That same change also creates new opportunities.
- Thus, be alert for how new technologies and events create change, and position your laboratory organization to benefit from those opportunities!
Thank You!

Contact me at:
RMICHEL@DARKREPORT.COM
Or: 512-264-7103

Research, news, reports at:
www.darkdaily.com
and
www.darkreport.com