

Interpreting the Tea Leaves: Ten Trends in Healthcare, Lab Medicine, and Pathology Informatics

Bruce A. Friedman, M.D.
Active Emeritus Professor of Pathology
University of Michigan Medical School
Ann Arbor, MI 48109
President, Pathology Education Consortium
My email: friedman@labinfotech.com
My blog: www.labsoftnews.com
Twitter: @labinfotech

Setting the Stage for Major Changes in Healthcare Delivery & the Clinical Labs

- This lecture based on my choice for top ten trends in healthcare & clinical lab industry; selected using lab/IT lens
- Many relate to the current emphasis on soaring cost of healthcare & necessity to increase quality & efficiency
- Most of my career centered on pathology informatics; logical that my mind drawn to computers & automation
- Not difficult task to relate macro trends to IT; irrefutable that IT will be major driver for most changes in healthcare
- First major theme today is: ***IT will be the foundation for most changes and reform in healthcare on global basis***

Criticality of Diagnostics in Emerging Model for Healthcare Delivery

- Second major theme for lecture today: ***emergence of new healthcare model with more emphasis on diagnostics***
- Result of better technology & science; prominence of the field will be enhanced by *integrated diagnostics* (see later)
- Also opportunity to reshape relationship of labs ⇒ consumers; lab medicine can shape new direct connection
- Relationship to consumers will require greater familiarity with web; source of both information & links to consumers
- Limitations/barriers will *not* be erected by marketplace; determined by ambition/skill set of lab professionals

**State of Wellness
(Absence of Diagnosable Disease)**

Early Health Model Domain

**Preventive
Medicine,
Predictive Medicine,
Alternative
Medicine**

**Genomic
Medicine/
Predisposition
to Disease**

Wellness Domain

Pre-Disease

**State of Diagnosable Acute Disease
(Short-Term, Self-Limiting)**

**Diagnostics
pushing in
this direction**

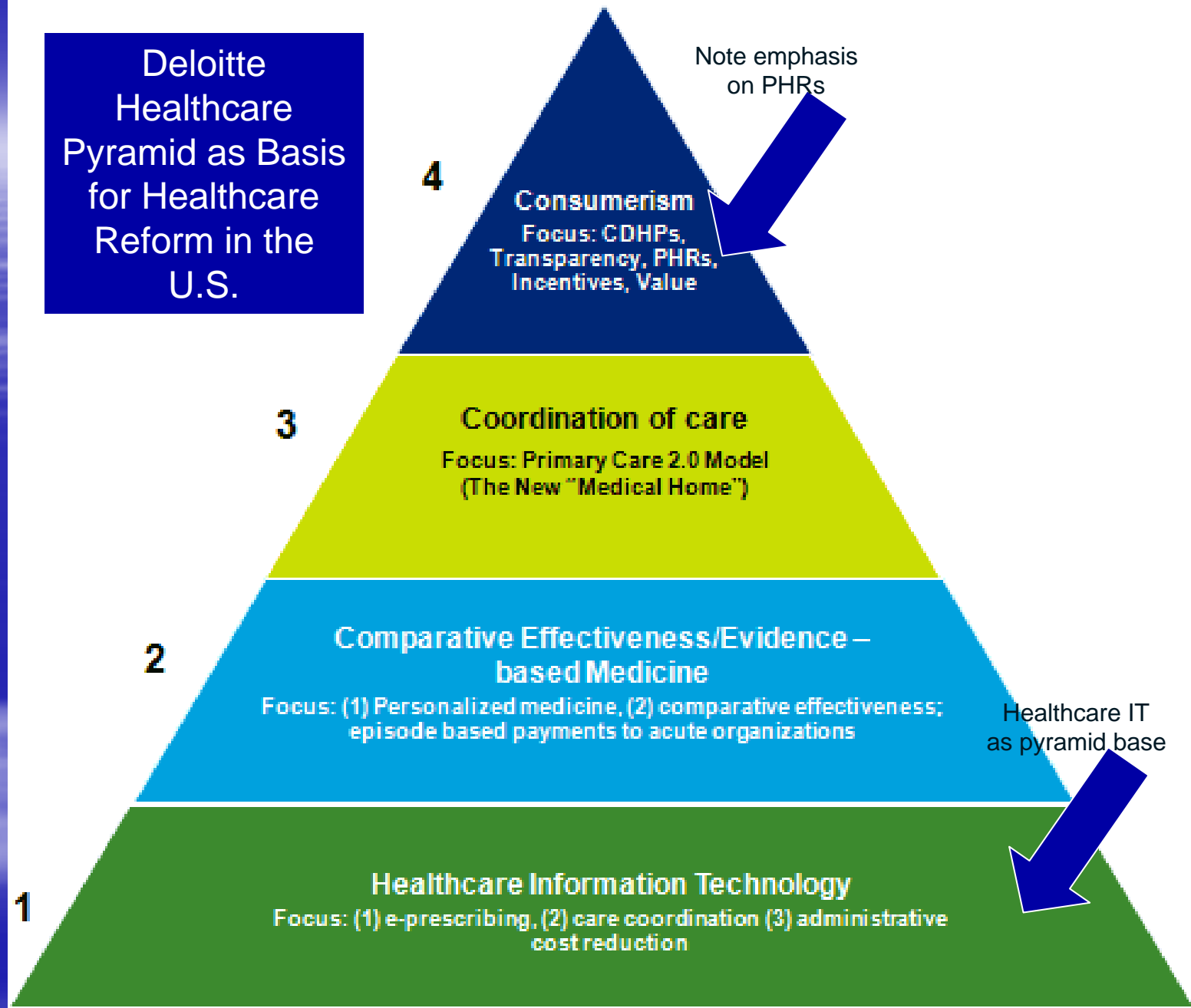
**State of Chronic Diagnosable Disease
(Long Duration and/or
Frequent Recurrence)**

Overt Disease Domain

Wellness vs. Overt Disease; Emergence of Pre-Disease as Significant Category

- In previous diagram, major separation between wellness and overt disease; most MDs trained to diagnose latter
- Sophisticated dx techniques uncovering genetic predisposition to disease & pre-diseases in earliest forms
- Because MDs & hospitals focus on overt disease, consumers tilting to complementary/alternative medicine
- In U.S., CAM accounts for 1/3 of out-of-pocket spending on prescription drugs & 1/4 of spending on healthcare visits.
- Lab professionals should place more emphasis on predictive/preventive medicine; capture more of this market

**Deloitte
Healthcare
Pyramid as Basis
for Healthcare
Reform in the
U.S.**



Further Discussion about the Deloitte Healthcare Reform Pyramid

- Critical element in most healthcare reform proposals in U.S. is more support for IT; much more emphasis on EMRs than LISs
- Much of current healthcare reform research focuses on comparative effectiveness of treatment; related to EBM
- Reimbursement for episodes-of-care as alternative to fee-for-service; lab testing will be a metric to assess value of care
- Coordination-of-care poses challenge in the U.S.; burden falls on primary care practitioners (PCPs) who are in short supply
- Note consumerism and personal health records (PHRs) at top of pyramid; opportunity to engage consumers in their own care

The World of Hospital EMRs, Office EMRs, LISs, and PHRs

- Attention in U.S. focused on proven lack of success of many hospital EMRs; assumption that funding will solve problem
- In contrast, LISs, RISs, PACSs have long history of success; selected by professionals use them daily for productivity
- EMR problem relates more to following: systems expensive & outdated; shift greater work to MDs; difficult to maintain
- EMRs largely unable to store & display complex molecular data & images generated in both pathology & radiology
- Tethered, web-based PHRs like HealthVault emerging; MS creating strategic hospital alliances; will consumers adopt?

Trend #1: Pressure to Quickly Contain Costs as Part of Healthcare Reform

- Greater public and political attention on excessive costs and inefficiencies of the U.S. healthcare delivery system
- Clinical lab testing provides greatest value per dollar spent in system; product of lab automation & emerging science
- Why, then, is lab testing singled out for criticism of over-utilization compared to, for example, medical imaging?
- Answer: Cost of testing often inflated in hospital/office bills; labs provide convenient whipping-boy for critics of system
- Clinical labs, as always, well-positioned to continue to provide critical services because of expertise in automation

Trend #2: Early Health Model with Emphasis on Diagnostics

- Early Health Model emphasizes pre-clinical, pre-symptomatic diagnosis; brings diagnostics to front of stage
- Promoted by GE Medical & Siemens Diagnostics; attempting to integrate their IVD investments with imaging
- Often stated that early diagnosis is less costly; based on basic idea that less complicated disease easier to treat
- This idea needs to be explored further; could provide rationale for transfer of funds from rx to dx “silo”
- EHM synergistic with molecular dx & integrated diagnostics (see later); early dx also holds great appeal for consumers

Trend #3: Health 2.0, Participatory Medicine, & Consumer Empowerment

- The web has spawned the Health 2.0 phenomenon by providing easy access to quality healthcare information
- This has resulted in consumer empowerment, enabling consumers to engage in useful dialogues with providers
- Another consequence is participatory medicine; web sites that provide guidance in self-help & link patients \Rightarrow patients
- The clinical lab world “participating” in phenomenon via direct access testing (DAT) sites & consumer genomics
- Lab test results are a key element in participatory medicine; loved by consumers; how can this be leveraged?

History of Direct Access Testing; Consumer-Oriented Lab Services

- At least a ten-year history of DAT web site that allow consumers to directly order broad range of lab tests
- Consumers pay directly for testing & lab reports delivered back to them; sites have workaround in states where illegal
- One major commercial reference lab provides the actual testing services; same lab used by many MD practices
- In many cases, the cost of DAT services to consumers may be less than the co-pay for same tests for insured patients
- DAT testing has never captured large portion of market; service not marketed & most consumers find inconvenient

Trend #4: Rapid Growth of Molecular Diagnostics & IVDMIAs

- Sophisticated genomics/proteomics ushering in era of diagnosis of *predisposition to disease* & *pre-disease*
- Consumer genomics (see later) provides consumers with access to knowledge not necessarily available to their MDs
- With IVDMIAs, interpretive algorithms integral to test methodology & discoverable; drawing attention of FDA
- I am opposed to regulatory oversight over interpretive algorithms as medical devices; would inhibit progress
- Agree that need for more transparency and/or self-regulation by industry; major goal is more/better tests

Possible Regulatory Oversight Over Diagnostic Algorithms

- The Food & Drug Administration (FDA) has shown interest in regulating the algorithms associated with IVDMIAs
- Prompted, in part, by hesitancy of some diagnostics companies to make public the details about algorithms
- FDA also has concern about the research studies & serum sample banks used for clinical validation of some IVDMIAs
- I am nervous about any regulatory oversight about clinical diagnostic algorithms; may inhibit progress in the field
- FDA oversight over the blood banking modules of LISs caused a number of lab software companies to exit market

Trend #5: Wide Adoption of Targeted Therapy & Companion Diagnostics

- Pharma companies now approaching IVDs for development of companion tests before clinical trials
- This allows the optimization of research subject selection; also guarantees that companion test required down-stream
- I prefer use of term “targeted therapy” over “personalized medicine” because of common misunderstanding of latter
- Regardless, both of these emerging areas require molecular diagnostics as means to select appropriate pts.
- Dialogue about comparative effectiveness research rarely cites lab testing as key element in rx choice & monitoring

Extension of Diagnostics into Therapeutic Decision-Making

- One of my hopes is that companion diagnostics & IVDMIAs will increasingly blend diagnosis with therapeutic decisions
- This is the norm in cancer hospitals where multidisciplinary teams collaborate in arriving at best therapeutic regimens
- This concept is suggested in the term “companion therapeutics”; notion that therapy flows from dx workup
- This may be a pipe-dream but not inconceivable that choice of most chemotherapy may be semi-automatic in future
- Most diagnosticians not comfortable with participation in therapeutic decision-making; MDTs will help solve problem

Trend #6: Integrated Diagnostics Attracts Attention & Converts to Idea

- Integrated diagnostics consists initially of conversion of pathology, lab medicine, and radiology (later cardiology)
- Look for emergence of new medical discipline of Diagnostic Medicine/Integrated Diagnostic Centers (IDCs)
- Will spawn new software products: merged LIS+RIS+ PACS; also integrated pathologist/radiologist dashboard
- Also opportunity for new workflow software that will manage the rapid hand-offs from clinical labs to radiology
- Opportunity for hospital labs to compete with national reference labs; can't offer competitive diagnostic services

Defining the Integrated Diagnostic Center (IDC)

- An IDC is a clinic with the goal of diagnosing patients with lesions using a multidisciplinary team (MDT)
- MDT consists of clinicians, pathologists, & radiologists who collaborate to quickly diagnose referred patients
- MDT has many advantages: intra-team communication, referrals, & hand-offs are facilitated
- In the UK, Patients with breast masses are referred to IDCs, which are called “one-stop” breast clinics
- No reason why IDCs cannot be used to dx diseases other than breast such as GU ,GI, lung lesions

How Are Breast Masses *Currently* Diagnosed in a Community Setting?

- Breast masses identified by PCP, surgeon, or internist, who then assumes responsibility for the dx process
- Requires coordinating multiple appointments with radiology & pathology; interpretation of multiple reports
- Within an IDC, the unit assumes coordination & integration burden; also generated integrated report
- Initially, IDC processes are integrated by team collaboration & proximity, quickly reducing complexity
- In time, IDCs will develop automated workflow algorithms that will further increase unit efficiency

Basis for Claim that IDCs are Faster, Better, and Less Expensive

- Faster: result of MDT, enabling integrated & efficient communication & scheduling of work processes
- Better (i.e., higher quality): mistakes in healthcare result from errors in communication & hand-offs
- Less expensive: result of integrated administrative processes within IDCs such as reporting/scheduling
- Faster, better, & less expensive \Rightarrow superior service and information product \Rightarrow competitive advantages
- In terms of patient satisfaction, compare a final dx for a lesion in days compared to current performance

Expansion of Services Offered by Integrated Diagnostic Centers

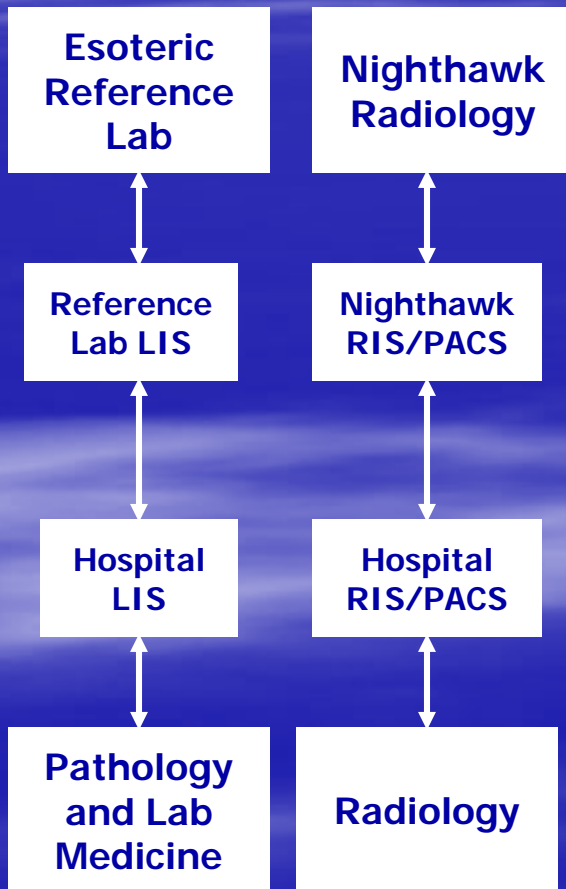
- In time, IDCs will add to their set of diagnostic services & pursue predictive/preventive medicine
- Logical extension of the Early Health Model; diagnosis of pre-clinical, pre-symptomatic disease
- It is primarily diagnosticians who can operate in this space; clinicians trained mainly to dx/rx overt disease
- Molecular imaging will reinforce the dx acumen of radiologists; based largely on biomarker technology
- Having an internist as part of MDT ensures single locus of case management & interface for patients

Some of the Consequences of Emerging Diagnostic Networks

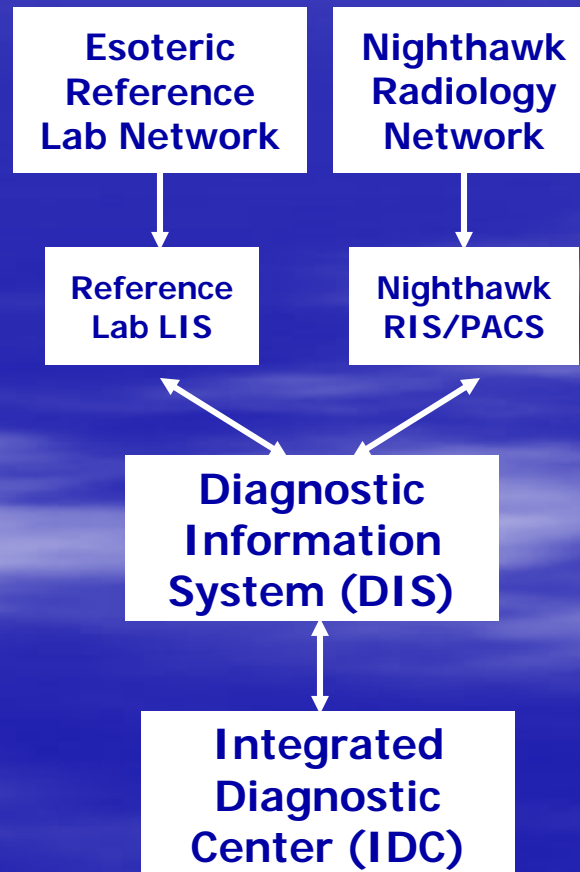
- Concept of a diagnostic network pioneered by Nighthawk; offering off-hours interpretation of images in the U.S.
- Concept morphing into dayhawk; services being offered during daylight hours; radiology groups losing contracts
- New companies like Telerays offer competitive bidding by hospitals for radiologist services; network opens market
- Hospital labs have LIS interfaces to esoteric reference labs for many years; more efficient lab test ordering/reporting
- Acceleration of this process; smaller hospital labs may be unable to mount molecular dx + interpretation programs

Possible Evolutionary Sequence for IDCs, DISs, and Diagnostic Lab Network

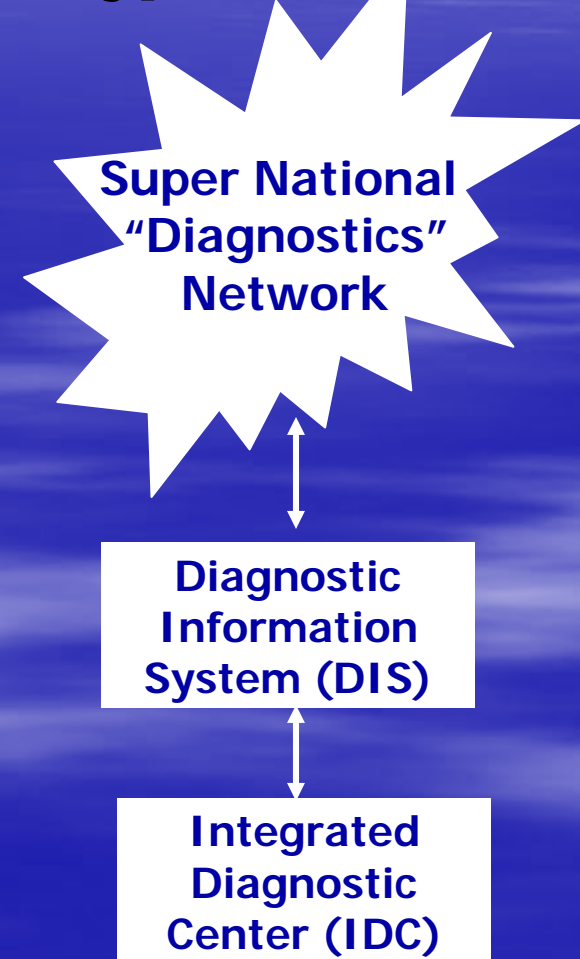
Current Model



Evolved Model



Hyper-Evolved



(See next for more details)

Trend #7: Broader Adoption of Digital Pathology: Precursor for Integrated Dx

- Conversion to digital pathology will take longer than digital radiology; won't result in higher margins/new procedures
- Technology has also taken longer to mature; challenge of whole slide imaging and huge file storage requirements
- Digital pathology will be prerequisite for deployment of integrated diagnostics given that radiology 100% converted
- One “killer app” for digital pathology will be “image search”; compare slide “areas of interest” with image databases
- Another important enabling technology is the pathology cockpit or dashboard; whole slide images + all clinical data

Trend #8: Algorithm-Driven Diagnostics as Precursor to “Blended” CP and AP

- Great progress in development of “companion algorithms” for automated scoring of digitized IHC & FISH tumor slides
- Theoretically, this approach can minimize inter-observer variation and subjectivity in interpretation of special stains
- This approach with a special billing code for automated interpretation allows improved ROI for capital investment
- As noted previously, molecular dx & IVDMIAs moving toward algorithm-enabled CP diagnoses incorporated in reports
- Possible that CP and AP will coalesce around basic concept of computerized algorithms converting data \Rightarrow diagnoses

Trend #9: Growing Gap in U.S. Between Office/Clinic & Hospital Domains

- At least in the U.S., growing gap between hospital practice compared to MD offices, multispecialty clinics, and ASCs
- Many primary care physicians (PCPs) have lost skill set necessary to care for acutely ill hospitalized patients
- Hospitals employ [mainly] internists as so-called hospitalists; manage general & critical care in hospitals
- Large clinical groups (e.g., GU, GI) creating their own histopathology in-office labs & hiring their own pathologists
- Separation of these healthcare delivery domains being accentuated by development of separate clinical IT islands

Fragmentation of Pathology; What Will the Future Hold for the Specialty?

- Except in academic centers, pathologists have largely exited from clinical labs; emphasis on surgical pathology
- Small biopsy work (see previous) being taken over by clinical groups because generates additional revenue
- Much of diagnostic/corrective surgery becoming minimally invasive; migrating to ambulatory, office, & ASC settings
- Irony is this departure from clinical labs at a time when serum & tissue biomarkers becoming more essential
- Solution involves young physicians entering pathology will high interest in genomics/proteomics; will revitalize field

Trend #10: Greater Attention to Chronic Diseases to Reduce Healthcare Costs

- Chronic diseases such as heart disease, diabetes, prostate & breast cancer responsible for 75% of all healthcare costs
- Diabetes alone costs more than \$130 billion per year in medical expenses and lost productivity in the workplace.
- Many of these problems can be prevented by changing diet, exercise, weight loss & smoking cessation programs
- Changing lifestyles to prevent/ameliorate disease difficult; tools available to assist consumers: PCs, smart phones
- Clinical labs important in strategy to prevent & ameliorate chronic diseases; emphasis on participatory medicine

Linkage of Participatory Medicine to Rx & Prevention of Chronic Diseases

- Participatory medicine is branch stressing the role that the patients themselves play in their own health maintenance
- So-called lifestyle issues (obesity, alcoholism, lack of exercise & sleep) contribute to majority of healthcare costs
- Chronic diseases, lifestyle diseases, & participatory medicine form a continuum that requires more attention
- By training & lacking reimbursement incentives, MDs devote little/no attention to wellness & health maintenance
- Key to participatory medicine surely lies with the web; information access, self-help groups, access to PHRs

Weaving All of These Trends into Future Vision for Pathology and Lab Medicine

- Health 2.0 and participatory medicine have potential to reduce costs; possible new lab relationship with consumers
- Molecular dx, genomics/proteomics, & IVDMIAs driving toward pre-symptomatic, pre-clinical disease discovery
- Healthcare & pathology informatics key enabling technologies; look for blending of LISs, RIS, and PACSs
- Emerging role of IVD & digital pathology companies in client education/training in parallel with ongoing CME
- Potential for new golden era for dx and lab professionals but will not occur by default; they must seize opportunities