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

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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 & link 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)

- Preventive Medicine, Predictive Medicine, Alternative Medicine
- Genomic Medicine/Predisposition to Disease

Diagnostics pushing in this direction

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

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

Wellness Domain
Early Health Model Domain

Overt Disease Domain

(See next for more details)
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.

1. **Healthcare Information Technology**
   - Focus: (1) e-prescribing, (2) care coordination, (3) administrative cost reduction

2. **Comparative Effectiveness/Evidence-based Medicine**
   - Focus: (1) Personalized medicine, (2) comparative effectiveness; episode based payments to acute organizations

3. **Coordination of Care**
   - Focus: Primary Care 2.0 Model (The New "Medical Home")

4. **Consumerism**
   - Focus: CDHPs, Transparency, PHRs, Incentives, Value

Note emphasis on PHRs

Healthcare IT as pyramid base
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 “silos”
- 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; websites that provide guidance in self-help & link patients to 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 ⇒ superior service and information product ⇒ 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
Possible Evolutionary Sequence for IDCs, DISs, and Diagnostic Lab Network

Current Model
- Esoteric Reference Lab
- Reference Lab LIS
- Hospital LIS
- Pathology and Lab Medicine
- Nighthawk Radiology
- Nighthawk RIS/PACS
- Hospital RIS/PACS
- Radiology

Evolved Model
- Esoteric Reference Lab Network
- Reference Lab LIS
- Hospital RIS/PACS
- Diagnostic Information System (DIS)
- Integrated Diagnostic Center (IDC)

Hyper-Evolved
- Nighthawk Radiology Network
- Nighthawk RIS/PACS
- Super National “Diagnostics” Network

(See next for more details)
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
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.
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 ⇔ 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.
Participatory medicine is a branch that stresses the role that the patients themselves play in their own health maintenance.

So-called lifestyle issues (obesity, alcoholism, lack of exercise & sleep) contribute to the 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; in U.S., center-of-gravity moving toward EMRs
- 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

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