

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

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Setting the Stage for Some Radical Changes in Healthcare Delivery

- Will list my favorite ten trends in healthcare & clinical lab industry, selected because of effects on the clinical labs
- Many relate to the current emphasis on soaring cost of healthcare & necessity to increase quality & efficiency
- Clinical lab testing one of the greatest bargains in healthcare but often draws the attention from cost-cutters
- New factor for IVD industry, not previously seen, is the influence of educated & informed healthcare consumers
- Special efforts will be required on part of lab professionals to capitalize on these emerging opportunities & options

New Theme for Clinical Lab Industry

- Most of my trends relate to common theme: emergence of new healthcare model with more emphasis on diagnostics
- Opportunity to reshape relationship of labs ⇔ consumers; ongoing monitoring of genome and previous tissue dx's
- Suggestions about emerging rx options based on new medical discoveries & new drugs coming to the market
- Result of better technology & science; prominence of the field will only be enhanced by integrated diagnostics
- Limitations/barriers will *not* be erected by marketplace but determined by ambitions of lab professionals themselves

State of Wellness
(Absence of Diagnosable Disease)

Early Health Model Domain

Wellness Domain

Preventive
Medicine,
Predictive Medicine,
Alternative
Medicine

Genomic
Medicine/
Predisposition
to Disease

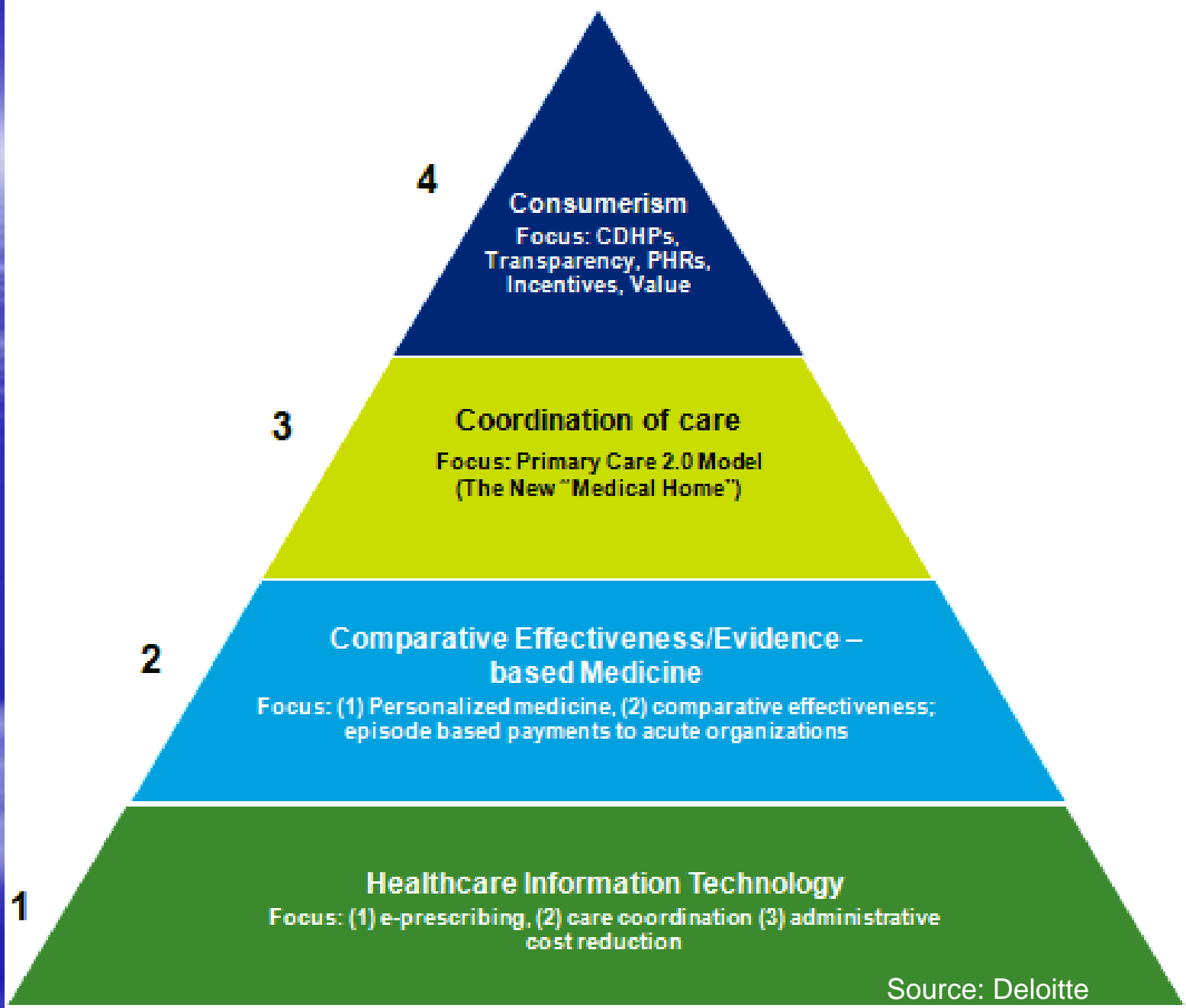
pre-Disease

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



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 provide “quicker, better, cheaper” care 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 and Siemens Diagnostics, which are attempting to integrate 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 ⇒ 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?

Trend #4: Growth of Molecular Diagnostics & IVDMIAs

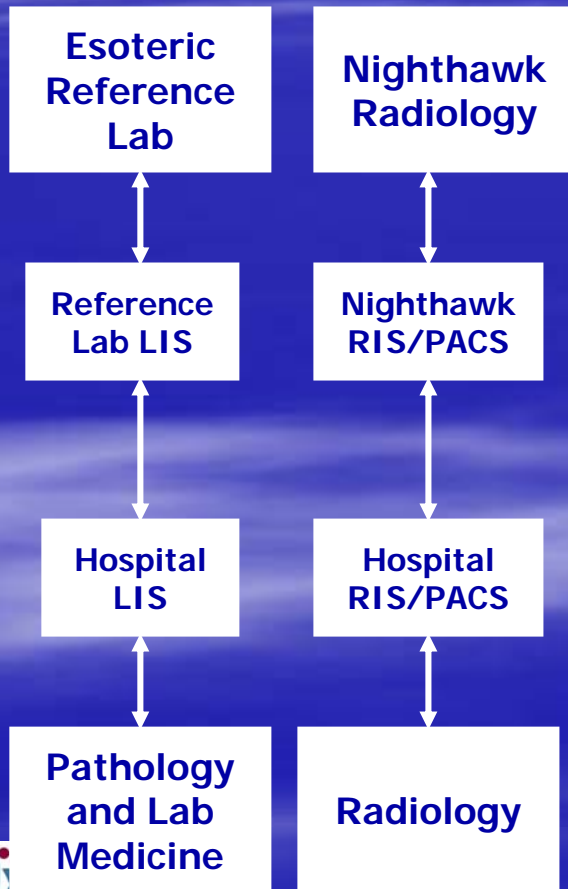
- Sophisticated genomics/proteomics ushering in era of diagnosis of *predisposition to disease & pre-disease*
- Consumer genomics (see later) provides consumers with access to knowledge not necessarily available to their MDs
- With IVDMIAs, interpretive algorithms integral to test methodology & reports; 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

Trend #5: Integrated Diagnostics Attracts Attention & Converts

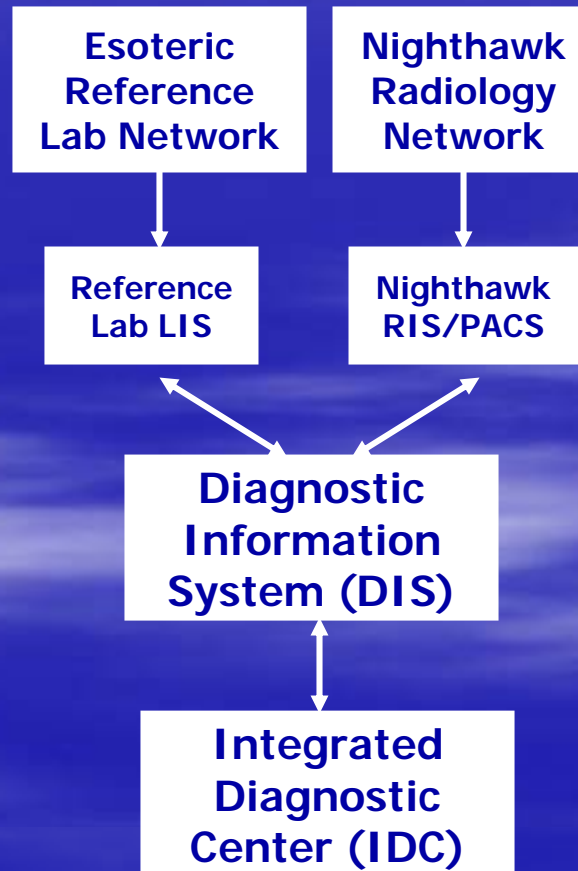
- Integrated diagnostics consists initially of collaboration of pathology, lab medicine, and radiology (later cardiology)
- Look for emergence of new medical discipline of Diagnostic Medicine/Integrated Diagnostic Centers (IDCs)
- Will spawn new software products: merged LIS+RIS+ PACS; also integrated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

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

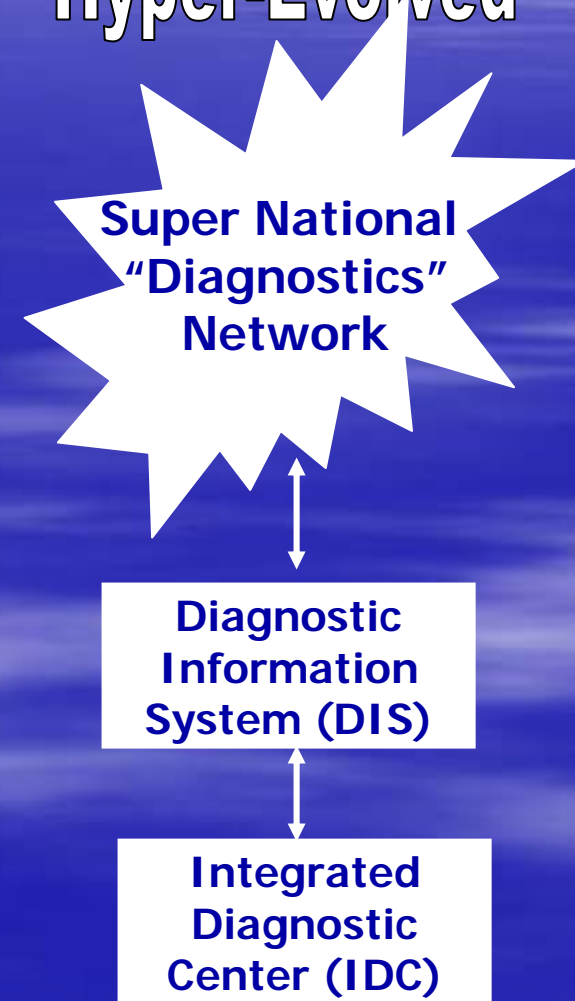
Current Model



Evolved Model



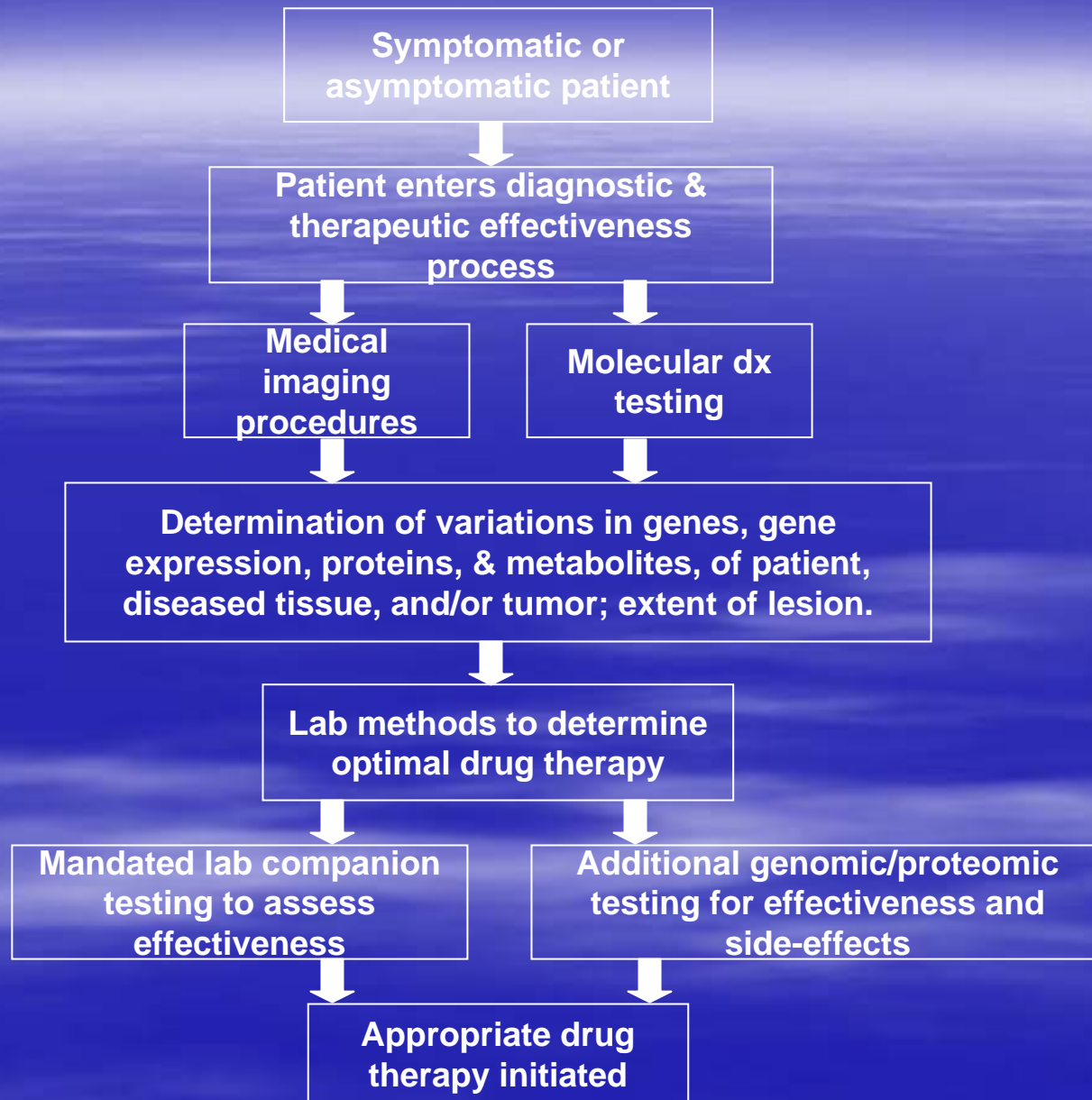
Hyper-Evolved



Trend #6: Growth 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 ensures that companion testing 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

Diagnostic Work Flow Diagram Underlying Personalized Medicine



Trend #7: Growth of Predictive & Preventive Medicine

- Given growth of dx & consumer interest in prevention, increased emphasis on predictive/preventive medicine
- Unlikely that most physicians & healthcare systems will readily embrace this trend; inclination is to treat disease
- Huge market even now; closely aligned with field of alternative medicine; techniques accorded more respect
- Also closely aligned with Health 2.0 and participatory medicine; empowering consumers to engage in self-help
- Clinical labs & pathology could leverage expertise in dx to promote predictive/preventive medicine within IDCs

Trend #8: Greater Attention on Chronic Diseases to Reduce 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

Trend #9: Broader Adoption of Digital Pathology Despite “Inadequate” ROI

- 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
- “Killer app” for digital pathology will be “image search”; compare areas of interest against reference databases
- Progress will be made “one funeral at a time”; some older pathologists not eager for necessary retraining/culture shift

Trend #10: More Corporate Emphasis on Client Education & Training

- Aperio example of company that needed to embrace client education in order to expand digital pathology market
- Goal achieved by expanding their user group conference to “unbranded” conference; embrace of blogging & webinars
- Professional societies like AACC, CLMA, CAP, ASCP will be unable to keep their members abreast of all changes
- Moreover, web-based teaching techniques such as webinars and digital videos on YouTube are inexpensive
- One of key elements on this new approach will be to harness energy & talents of customers to create materials

Take Home Lessons Relating to This List of Top Ten Trends

- 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 and pathology informatics critical enabling technology but 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; we must seize opportunities