Evolution of a Diagnostic-Centric Healthcare Model: Implications for the Clinical Lab Industry

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Major Ideas to Be Addressed in This Lecture

- Discussion of early health model (EHM) and molecular medicine – forces behind the “diagnostic-centric” model
- Differentiating diagnostic domain from therapeutic domain; present and future role of prognosis & prognosticians
- Molecular imaging as a technology placing radiology & pathology/lab medicine on course for collision or merger
- Ten reasons why pathology/lab medicine & radiology should merge to form new specialty of Diagnostic Medicine
- Possible trajectory for discussions & merger of specialties; technical, political, and financial issues that come into play
Making a Case for a Major Change in Healthcare Present Only in Nascent Form

- Goal of lecture is to develop case for conversion/merger of two medical disciplines with history of only minor interactions

- Encourage many of you to disagree with these assertions and develop your own scenario for future of pathology/lab medicine

- Major forces are now at work in lab industry that will result in different model; important to understand how to react to change

- I take some comfort from two quotations attributed to the great hockey player Wayne Gretski:

  - *It has been proven beyond a shadow of a doubt that you miss 100% of the shots you do not take*

  - *The secret to my success in hockey has been getting to where the puck is going to be*
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Introduction to the Early Health Model: Discussion of Its Component Parts

*Early health model* (EHM) represents major shift in healthcare delivery with new emphasis on diagnosis of preclinical/presymptomatic disease

EHM, popularized by GE Medical, composed of five components:

- **Consideration of personal health characteristics**: e.g., environmental influences, personal lifestyle, and genetic predisposition to disease
- **Diagnosis of disease**: such an approach will include far greater emphasis on molecular diagnostics and medical imaging
- **Prognosis of disease**: more emphasis here based on greater scientific input will result in more patient satisfaction
- **Treatment of preclinical/presymptomatic disease**: this approach will include use of newer biotech drugs (“personalized medicine”)
- **Information technology**: this provides the “glue” that integrates and holds together the various the above four components of the EHM

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Why Early Health Model Disruptive for Players in Healthcare Delivery Process

- Healthcare payers unsettled because approach adds to cost of care; currently struggling to pay for clinically diagnosed disease
- MDs nervous because trained to diagnose disease based on current patient signs/symptoms and not anticipated problems
- Pharmaceutical companies nervous because clinical trials for current drugs are have been based on symptomatic disease
- Happiest group will be patients; dissatisfied with current approach; told by MDs to return to office when symptomatic
- Criticality of diagnostic methods in EHM model demands high degree of integration/collaboration across lab/path/radiology
Defining Molecular Medicine and Its Interplay with Early Health Model

As name implies, *molecular medicine* focuses on the molecular basis of disease and the biology of tumors.

Necessary to understand this molecular basis to diagnose, to determine prognosis, and to treat various lesions.

Understanding of *molecular medicine* enables and promotes the following advances in healthcare delivery:

- Early detection and treatment of disease; allied to EHM
- More effective monitoring of drug treatment efficacy, which is important for future drug development
- Selection of individualized (i.e., personalized) therapy
- Expansion of potential for screening programs & determination of genetic predisposition to disease
Why EHM and Molecular Medicine So Important for Pathology and Lab Medicine

- Essence of EHM is early dx; pathology/lab medicine will have no difficulty scientifically adapting to this approach.
- Molecular diagnostics pivotal to success of EHM because laboratory diagnosis first logical step in presymptomatic dx.
- Molecular imaging research centers devoting much of their resources to identification & testing of \textit{in-situ} biomarkers.
- If develop molecules that bind to \textit{in-situ} biomarkers, can also be used to deliver therapeutic agents to diseased cells.
- Theoretically and in long run, EHM may reduce cost of healthcare because treating disease in earliest stage.
Defining “Diagnostic-Centric” Model Resulting from EHM & Molecular Medicine

- Basic idea here is the center of gravity moving to clinical lab & radiology for guidance on diagnosis, prognosis, & therapy

- In a world of pre-clinical/pre-symptomatic dx, only large panels of biomarkers + imaging can detect early disease

- Another way to look at model: approximately 80% of all relevant clinical info will be generated in path/labs/radiology

- Most diseases will be treated on outpatient basis or with same-day surgery; oncology has moved in this direction

- The major role of clinicians will be interacting with patients, correlating/interpreting reports, and writing drug orders
$24 Billion Bet Placed by Siemens and GE on Convergence of Imaging with IVD

- GE Medical purchased Amersham ($9.5B) in 2003 & attempted to buy Abbott Dx for $8.1B in early 2007

- Siemens Medical Dx purchased DPC ($1.9B) & Bayer Diagnostics ($5.4B) in 2006; purchased Dade ($7B) in 2007

- Two global corporations have thus “bet” total of $24 billion on convergence of imaging & molecular dx; more to come

- Pressure will be great from these companies on MDs to deliver “integrated” diagnostic reports/services to patients

- GE Medical already organizing national EHM conferences & enlisting support from prestigious health system partners
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What’s More Important -- Diagnosis, Prognosis, or Treatment of Disease?

- In ancient Greek times, there were two schools of thought that dominated the medicine of that time
  - Knidian which focused on *diagnosis* and the Hippocratic school which focused on *treatment and prognosis*
- Hippocratic approach emphasized treatment and more *generalized* diagnosis – became more widely adopted
- Medical practice today focuses on diagnosis & aggressive treatment of disease; prognosis growing in importance
- With proteomics/new imaging modalities, accurate diagnosis will become more routine; only beginning of the process
- Prognostics & therapeutics will now receive greater attention in healthcare; new opportunities for pathology & lab medicine
Rationale for the Inclusion of Prognosis in the Early Health Model

- Prognosis involves predicting likely outcome of a disease based on condition of the patient & progression of the disease.

- Less than five percent of research focuses on prognosis; textbooks cover disease prognosis less than 25% of time.

- In past, broad prognostic statements like five-year survival by tumor based on tables using tumor score & type of therapy.

- Now IVDMIA tests for breast ca like *Oncotype DX* & *MammaPrint* predict prognosis based on tissue microarrays.

- Prognosis takes advantage of genomic/proteomic science & greater understanding of biology of each tumor studied.
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Details About Molecular Imaging; How It Differs from Other Imaging Modalities

- Molecular imaging involves use of biomarker probes formulated to image various targets of interest in body.

- Biomarkers interact chemically with various tissues & alter medical image according to the molecular changes in tissue.

- Markedly different from previous imaging modalities that created images based on tissue densities or water content.

- Molecular imaging also allows for quantitative analysis such as precise tumor shrinkage, which adds objectivity to treatment.

- Research currently focusing on pre-disease states defined as molecular states that occur before onset of symptoms.
Biomarkers Discovery as Common Goal for Both Pathology and Molecular Imaging

- Both applied and research pathology/lab medicine have major focus on *in-vitro/in-vivo* biomarkers and predisease
- Molecular imaging based discovery on *in-situ* biomarkers; molecular diagnostics focuses on *in-vitro* biomarkers
- All of the new molecular imaging research centers around the world have a major focus on new biomarker discovery
- Complex imaging studies too expensive and capital-intensive for extensive use in pre-disease discovery & wellness testing
- More cost-effective to monitor serum for expression of abnormal or excessive proteins as means to select imaging
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Ten Reasons Why Pathology/Lab Medicine Should Begin to Converge or Merge

- Given this background, will now list ten reasons why I think this particular convergence/merger should occur

- Mindful of fact that medical specialty boundaries are relatively rigid; few precedents exist for such a merger

- Ambiguity around some specialty boundaries such as orthopedic surgery, physical medicine, sports medicine

- Some older disciplines imaging disciplines such as nuclear medicine have been largely absorbed by radiology

- Clinical hematology/oncology has morphed into oncology; much of cellular morphology turfed to hematopathologists
Large panels of biomarkers will become the most cost-effective method of choice for monitoring wellness/disease status.

More comprehensive & sensitive than current methods such as yearly cursory physical exam + small set of routine lab studies.

Lab panels more cost-effective and less risk than intensive medical imaging; only venipunctures needed to obtain samples.

Approach based on knowledge that diseased cells communicate by type/amount of proteins; challenge of how to interpret.

Reasonable approach is to develop algorithms to more accurately assess the significance of changes in serum and cellular proteome.
#2: Substantial Overlap Between Disciplines Already Exists; Common Basis for Practice

- Radiology and pathology practices already similar; both generate diagnostic reports using sophisticated technology
- Have previously discussed how biomarkers are key to the evolution of molecular imaging; common basis for research
- Some IT vendors already considering or producing common viewers; review data/images from both the LIS & RIS data
- Radiologists more advanced re: image storage & accession with their PACS; pathologists now embracing digital path
- Both groups use cutting edge science & technology to render diagnoses; specialty approaches now converging
#3: Molecular Imaging Has Potential in Future to Compete with Surgical Pathology

- Most medical imaging (e.g., CT, MRI) seeks to identify the mass/shape of a lesion but does not address the “biology”

- PET scan makes three-dimensional image of functional processes in the body; can be integrated with other studies

- By linking radio-opaque substance to molecules that bind to biomarker(s), can make inferences about lesion behavior

- Molecular imaging has potential to locate a space-occupying lesion & also provide clues about dx & prognosis

- Surgical pathology is current diagnostic gold standard; wise approach at this time is to collaborate in order to validate
#4: Major Financial, Diagnostic, & Political Gains If Specialties Join Forces

- In large tertiary hospitals, budget of a merged department could reach $100M – creation of powerful political leverage
- Current estimate of 70% of dx’s based on lab testing; add to this the diagnostic yield of current medical imaging
- Some capital acquisitions in radiology could possibly be avoided with enhanced molecular diagnostic screening
- Strength of pathology: control over all in-vitro testing and surgical pathology/cytology (current gold standard for dx)
- Strength of radiology: control over most digital imaging + evolving molecular imaging & interventional radiology
#5: Imaging Studies Yield High Profit Margins; Most Lab Studies Commoditized

- Can’t ignore the economics of healthcare delivery; imaging studies yield profits margins as much as 40% for hospital

- Lab testing often viewed as commodity by hospital administrators; difficult to advocate for capital investment

- Part of attitude flows from the technology deployed in labs; automated assembly lines with low cost-per-test

- Because radiology viewed as profit center, little hesitation by administrators to invest in new imaging modalities

- With an integrated diagnostic departmental hub, some of “magic” could rub off on labs, particularly for molecular dx
#6: Potential Merger Already Being Promoted by Large Corporations

- Siemens and GE have made $24B bet on molecular imaging; these investments cannot help but shape future
- Companies are developing new vocabulary to describe this convergence with major marketing/education campaigns
- Press releases for molecular imaging discuss search for *in-situ* biomarkers; clinical labs quantify *in-vitro* biomarkers
- GE has launched “Re-imagining” campaign directed to both MDs & consumers; power of consumers in market
- Unknown currently to what extent new business model by for-profits can/will influence medical specialty boundaries
#7: Efficiency and IT Benefits Can Be Achieved by Closer Integration

- Currently, radiology & pathology/lab operate in two separate diagnostic silos with few interactions between the groups

- Closer integrated approach would yield quality & strategic benefits for both patients and for specialists themselves

- Radiology uses DICOM, a standard for handling, storing, printing, and transmitting information in medical imaging

- No coding system for radiology reports similar to the SNOMED system in pathology; report retrieval difficult

- With closer integration, radiology could adopt SNOMED & pathology a DICOM variant for image storage and retrieval
#8: Enhanced Quality of Reporting with Merged LIS/RIS/PACS Databases

- At earliest stage of technology allowing us to query image databases: find all previous instances of selected image
- From quality perspective, don’t yet fully comprehend value of integrated radiology, CP, & AP reporting + analysis
- Greater value than simply retrieving past dx’s; with merged databases, can track success of prior treatment
- Advocating analysis/integration of all preoperative \textit{in-vivo} and \textit{in-vitro} studies as part of surgical pathology reports
- Many current pathology residents inadequately trained to even integrate molecular dx results into surg path reports
#9: Constant Pressure for More Cost Effective Healthcare Delivery

- Key question for pathology & lab medicine: is it possible to lower cost of healthcare as dx/rx become more sophisticated?
- One possible answer: multiplexed biomarker testing for dx and monitoring may be less expensive than imaging
- For neoplasms, earlier diagnosis and targeted therapy may avoid expensive surgery and prolonged hospital stays
- Wellness monitoring and healthy lifestyles may avoid complications of chronic diseases like diabetes and CHF
- Major new healthcare option: walk-in clinics in retail drug stores/discount stores; begin to offer CLIA-waived testing

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#10: Merged Specialty Can Compete More Effectively in Today’s Environment

- Major threat to hospital-based labs are large commercial labs that compete for business & commoditize lab testing
- Major threat to radiology is procedure “leakage” to other medical specialists & off-shoring to lower cost providers
- Diagnostic-centric model proposed here requires sophisticated set of interactions/hand-offs between players
- Sophisticated computer-based work-flow will now need to be developed based on working diagnosis & new findings
- Such tight collaboration will be difficult within hospitals and impossible in near-term in remote large commercial labs
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A Hard Look at the Political Issues Underpinning a Possible Merger

- Majority of pathology/radiology departments currently feel little pressure to modify their *modus operandi* in any way.

- Majority of chairmen in academic pathology departments focus on research; also disinclined to make any changes.

- Academic radiology leadership has been more vocal and entrepreneurial in responding to “leakage” of procedures.

- Most specialty leaders are risk averse & conservative; need concrete evidence that change has major benefits.

- Initiatives will come from “change junkies” who will derive national attention from their “organizational innovations.”
Turf Wars in Radiology & Cardiology Have Sparked More Collaborative Efforts

- Cardiac CT drawing attention from cardiologists, who long ago mastered angiography, echocardiography, & nuclear

- Has prompted concerns by radiologists who worry about self-referral, inappropriate utilization, and lost turf

- Groups around the country are seeking integrated practice models that promote collaboration and not competition

- Ventures are based on idea that both specialties bring expertise to cardiac imaging & also allow for “politics”

- Precedents thus exist for integration across nominally rigid practice boundaries, avoiding destructive competition
Spark That Will Ignite Closer Collaboration Between Two Specialties

- Clear agreement that surgical path is gold standard for tissue dx; will retain this title for probably a decade or more in future

- Surgical pathologists not looking at cells *in-vivo*; they fix, dehydrate, & stain tissue to create system of “their” artifacts

- Pathologists have learned to schematize their artifacts; create reports that accurately predict biologic behavior of disease

- Radiologists work with “their” artifacts to detect tissue abnormalities that are also very useful in diagnosing disease

- Now critical for two specialties to begin to validate conclusions derived from molecular imaging against surgical pathology dx’s
Possible Trajectory for Discussions & Eventual Convergence of Two Departments

- I believe that the first step for early discussions will be bench research collaboration relating to biomarkers.
- Second step for discussion will be IT convergence; examples include common viewers & integrated image databases.
- Third step will be some type of integrated reporting functions:
  - When necessary and appropriate, all radiology/lab/pathology reports should comment on both diagnosis and prognosis.
  - Cadre of *diagnostics specialists* will adopt multi-disciplinary approach; review & analysis of all *in-vitro* *in-vivo* data for pts.
- While this is taking place, pathology training programs need to begin to emphasize criticality of molecular diagnostics.
IT Issues as They Relate to a Merged Department of Diagnostic Medicine

- Aspyra already marketing integrated CIMSs (clinical image management systems) for all clinical images in health system
  - This would capture images from radiology, pathology, clinical labs, ophthy, GI, cardiology, dermatology, etc.

- Availability in the market of such CIMSs may provide a stimulus for some degree of convergence between depts.

- Perspective of EHR vendors is that all of the integration should take place at the level of their central clinical system

- I support the view of a “federated architecture” with deployment of “best of breed” systems across enterprise
Evolution of Specialist Orientation in a Department of Diagnostic Medicine

- I currently [optimistically] view radiologists and surgical pathologists as having more similarities than differences.
- With advent of molecular imaging, radiologists now also developing keen interest in biomarkers/molecular dx.
- Would be impossible for “diagnostic medicine” specialists to cover the entire gamut of disease with competence.
- In academia, both radiologists/pathologists have evolved sub-specialty niches because of market/subject complexity.
- Logical arc of evolution: *in-vivo* image, *in-vitro* tissue, and biomarker expert for specific organ and/or disease process.
Summary and Take-Home Points from Lecture

- New vocabulary now being hatched to encompass diagnostic/prognostic/therapeutic continuum
  - *Early health model* and *molecular medicine* cover medical imaging, molecular imaging, molecular dx, & surgical path.

- With new biology (genomics + proteomics), diagnosis will be rendered quickly; art of medicine in prognosis + therapy

- Molecular imaging evolving quickly; amalgam of sophisticated imaging technologies + *in-situ* biomarkers

- Merger/convergence between pathology/lab medicine/radiology makes political, economic, and quality sense

- First step will be research collaboration with IT support; next will be integrated reports across diagnostic continuum