Integrated Diagnostics: Innovations for a Leaner, Greener Healthcare System

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State of Wellness (Absence of Diagnosable Disease)

Preventive Medicine/Alternative Medicine

Early Health Model Domain

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

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

Genomic Medicine/Predisposition to Disease
Symptomatic or asymptomatic patient

Patient enters diagnostic, therapeutic, & efficacy process

Medical imaging procedures

Molecular lab testing

Determination of variations in genes, gene expression, proteins, & metabolites, of patient, diseased tissue, and/or tumor; extent of lesion.

Lab & imaging processes to determine optimal drug therapy

Mandated lab companion testing to assess efficacy

Additional genomic/proteomic testing for measure efficacy and side-effects

Appropriate drug therapy initiated

Continuing medical imaging during therapy to assess efficacy/side effects

Continuing molecular lab testing during therapy to assess efficacy/side effects

Therapeutic drug monitoring (TDM) to determine adequacy of dosing & prevent drug toxicity
Ten Reasons for Merging Pathology/Lab Medicine with Radiology

- In October, 2006, I posted on Lab Soft News a list of ten reasons why path/lab medicine should merge with radiology.

  - Already substantial overlap between the specialties in terms of work processes, digital imaging, information management
  
  - Enhanced clinical & research value of the merged LIS, RIS, and PACS databases; emergence of integrated dx systems
  
  - Possibility of development of higher quality integrated reports, yielding substantial quality benefits for patients
  
  - Multinational companies like Siemens making big bets on convergence of in-vitro diagnostics & medical imaging
  
  - Molecular imaging & molecular dx converging in terms of both science and technology; emphasis on biomarkers

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Ten Reasons for Merging Pathology/Lab Medicine with Radiology (cont.)

- Medical specialties like cardiology siphoning off procedures from radiology; greater political clout for the merged entity
- Large cadre of trainees in “diagnostic medicine” could extend the reach and capabilities of the new specialty
- Much of technology used in surgical pathology is badly outdated & would benefit from infusion of new ideas
- New specialty would benefit from the inflow of new capital + R&D funds to develop new “merged” dx modalities
- Future of radiology, pathology, & lab medicine equally dependent on IT, molecular dx, & imaging technology
Early Attempts to Define What Is Being Called “Integrated Diagnostics”

- *Integrated diagnostics* defined as close collaboration, or even merger, of pathology, lab medicine, & radiology

- Overarching goals behind merger: increased quality, decreased cost, decrease time required to diagnosis

- *Digital pathology* defined as conversion of images in pathology & lab medicine from current analog to digital

- Goal of integrated dx will be difficult to achieve without accelerated adoption of digital pathology; catch-up ball

- Digital pathology adoption a necessary but insufficient condition to achieve integrated dx; other factors in play
Some of the Many Barriers to Adoption of Digital Pathology

- Established pathologists reluctant to adopt digital pathology; radical change to workflow & skill set demands
- Questions about the return-on-investment; different than new imaging modalities that are introduced in radiology
- Still some questions about the equivalence of digital pathology to well established histopathology techniques
- The FDA last week began an examination of digital pathology quality issues; may not be quickly resolved
- Adoption process is similar to that experienced by digital radiology but absence of historical “standard” of practice
Integration of CP & AP: A Precondition for Pursuit of Integrated Dx

- Ironically, clinical pathology & anatomic pathology not integrated today; different information systems symbolic of this schism

- Surgical pathology becoming more quantitative; research in tissue biomarkers will accelerate this trend and continued blending

- Goal on a five year horizon will be to abandon CP/AP labels; focus will be on the dx of disease based on both serum & tissue analysis

- CP/AP integration/digital pathology will be resisted by some senior surgical pathologists who are comfortable with status quo

- Change will be gradual & top-down/bottom-up; support from chairmen + individuals collaborating on interesting projects
Adoption of Integrated Dx Requires Change from Two Directions

- Top-down agenda: *Making the political and economic case*
  - Goal is to convince departmental chairman, leaders of societies, prominent MDs, & C-suite execs that specialties better off post-merger
  - This may be more of a challenge than bottom-up because most chairmen are comfortable with status quo; they understand the rules/goals
  - Need for objective evidence that current silo-based business model will not suffice in the long-run; must convince leaders that change desirable

- Bottom-up agenda: *Development of collaborative projects*
  - Individuals in specialty practice most interested in ways to increase the efficiency of their practices; will respond to specialized projects
  - Question of how to seed ideas for such projects & provide incentives that promote such projects; build momentum toward large movement
Moving from *Status Quo* in Pathology, Lab Medicine, Radiology

- Cost-savings for integrated dx not yet proved but could avoid unnecessary procedures; promote research to establish evidence
- Time-savings also not yet proved: integrated dx practice allows more rapid dx & cost-savings; will require algorithm-driven hand-offs
- Higher quality not yet proved; tighter multidisciplinary integration avoids errors; fewer steps in complex procedures avoids errors
- Great patient satisfaction; patients will appreciate greater speed, efficiency, error avoidance, and one-stop shopping
- Greater political power with an integrated face on diagnostic enterprise; more bargaining power for salaries & capital projects
Components for a Full-Service “Integrated Diagnostics Vendor”

- Broad suite of IVD analyzers and reagents; helpful to have superior product lines in molecular diagnostics, IVDMIAs, & tissue biomarkers
- State-of-the-art EMR, LIS, RIS, and PACS; integrated results require complex reports; opportunity to blend these three systems into DIS
- Launch effort to create pathologist/radiologist integrated dashboard; access all images/clinical data in order to generate diagnostic reports
- Sophisticated, validated workflow rules, constantly updated & improved, to manage patient hand-offs across dx tests/modalities
- If healthcare migrates from FFS to “episodes of care,” need comparative effectiveness tools to demonstrate savings from IntDx
Key Components and Drivers for Integrated Diagnostics

Customer (Hospital, Physician) Drivers: cost, velocity of change, quality

Payor Drivers: cost, quality, efficiency, healthcare reform

Government Drivers: cost, quality, efficiency, healthcare reform

Pathology/Lab Medicine

Radiology

Molecular Imaging

LIS+RIS+PACS

Molecular Dx

Dx Info. System

Government Drivers: cost, quality, efficiency, healthcare reform

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A Quick Look at the Advantages of the “Virtopsy” or “Catopsy”

- In parallel with discussion of integrated diagnostics, useful to also consider the advantages of the “virtopsy” AKA “catopsy”

- Idea that autopsies should be preceded by a total-body CT scan to identify disease followed by minimally invasive bx’s

- Combination of two types of procedures yields higher quality and better documented information about cause of death

- Goal would be to generate final reports in 1-2 days and reverse inexorable trend of declining autopsy percentage in hospitals

- Virtopsy/catopsy service will provide ideal training ground for dx medicine trainees of future; broad exposure to range of lesions
Defining the Integrated Diagnostic Center (IDC)

- An IDC is a clinic, or section of a clinic, with the goal of diagnosing patients quickly using a multidisciplinary team.

- MDT commonly consists of clinicians, pathologists, & radiologists who collaborate to diagnose referred patients.

- Team approach has many advantages: intra-team communication, referrals, and hand-offs are all facilitated.

- Patients with lesions, commonly breast masses, are referred to IDCs, which are called “one-stop” breast clinics in the UK.

- No reason why IDCs cannot be used to diagnose diseases other than breast; GU and GI disease come quickly to mind.
How Are Breast Masses **Currently** Diagnosed in a Community Setting

- Breast masses or other lesions may be identified by PCP, surgeon, or internist; he/she then manages the dx process

- This involves coordinating appts. & schedules with radiology & pathology; obligation to integrate & interpret multiple reports

- With IDC, dx unit assumes coordination & integration burden; patient arrive with lesion & leaves with diagnosis

- Initially, various IDC processes are integrated by team collaboration & proximity; this tends to reduce complexity

- In time, IDCs will develop integrated information systems (LIS+RIS+PACS) & automated work process algorithms
Basis for Claim that IDCs are Faster, Better, and Less Expensive

- **Faster**: result of MDT, enabling more integrated & efficient communication & scheduling of all processes leading to dx

- **Better** (i.e., higher quality): many of mistakes in healthcare delivery result from errors in communication & hand-offs

- **Less expensive**: result of streamlined and integrated administrative processes such as reporting/scheduling

- Faster, better, & less expensive results in superior product which, in turn, provides competitive advantages in market

- In terms of patient satisfaction, compare a final dx for a lesion in days compared to previous standard of weeks
In time, I believe that IDCs will naturally add to their set of diagnostic services & pursue predictive/preventive medicine.

This is logical extension and pursuit of the Early Health Model; diagnosis of pre-clinical, pre-symptomatic disease.

It is primarily diagnosticians who can are able operate in this space; clinicians today trained mainly to dx/rx overt disease.

Inevitably, biomarkers and IVDMIAAs will detect diseases in their earliest stages; molecular imaging also moving this way.

Having an internist as part of MDT ensures single locus of clinical case management & interface for incoming patients.
Summary and Take-Home Points for This Lecture

- Idea of Integrated Diagnosis Centers (IDCs) taking hold with current emphasis on quality and cost effective care
  - IDCs staffed by multidisciplinary teams (MDT) that facilitate communication and hand-offs in the pursuit of diagnoses
  - IDCs provide faster, better, and less expensive diagnoses; clinicians, notably oncologists, will welcome this service
  - IT will be key element in evolution of IDCs; need integrated information systems & algorithms to enhance workflow
  - IDCs will also attract new business; establish new standards in the community and also set higher patient expectations