Integrated Diagnostics and Its Relationship to Digital Pathology: A Strategic Analysis

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Topical Outline for This Presentation

• Definition of digital pathology & integrated dx; status of these technologies today; differences between radiology/pathology

• Fragmentation of healthcare delivery; integrated dx as possible sol’n; development of “multidisciplinary dx teams” & super-diagnosis

• Lessons to be learned from digital and nighthawk radiology; the digital experiment in radiology with relevance for future of pathology

• Synergies of digital technology in integrated diagnostic centers (IDCs); moving dx integration upstream to the diagnosticians

• Challenges & opportunities of deployment of new technology/science in pathology; capitalizing on the current golden era of diagnostics
Dictionary Definitions for Integration

1. An act or instance of combining into an integral whole.

2. An act or instance of integrating a racial, religious, or ethnic group [or work processes in a organization].

3. An act or instance of integrating an organization, place of business, school.

4. Behavior, as of an individual, that is in harmony with the environment.
A Working Definition for Integrated Diagnostics

- *Integrated diagnostics* is defined as the seamless collaboration among the diagnostic specialists, most notably pathologists and radiologists.

- Goal of integrated diagnostics is to reduce time & expense of diagnostic processes and provide clinicians with *practical, actionable* results.

- Integrated diagnostics dependent on/enables (1) digital technologies; (2) computer algorithms; (3) clinical workflows; (4) enhanced lab reporting.

- Goal of this lecture is to *blend* concepts of integrated dx and digital pathology to demonstrate a proposed model of care (e.g., int. dx. centers).

- A number of barriers need to be overcome for success: modes of practice, retraining of practitioners, and modifications of existing technologies.
Working Definitions: Digital Pathology & Whole Slide Imaging (WSI)

• Only a simple definition here for the purposes of this lecture; much more details to follow in later presentations of Drs. Balis and Asa

• Digital pathology is conversion of thin-section paraffin histology slides to digital files & their subsequent analysis/manipulation

• Whole slide imaging involves the automated process of “scanning” a stack of slides in preparation for interpretation by a pathologist

• Process involves conversion of analog continuous signals to digital images; pathologist needs to swap light microscope for monitor

• A glass slide & attached tissue section is unique and fragile; image can be viewed anywhere, anytime, & by anyone (significance?)
How Integrated Dx May Evolve in the Short Term; Tentative Early Steps toward Adoption

- Can consider as blending of *in-vivo* diagnostics (radiology) with *in-vitro* diagnostics (pathology) with support by *in-silico* diagnostics

- Pathology, lab medicine, and radiology currently embedded in specialty silos (see later); need to stimulate broader view of disease

- First step will be closer integration of clinical pathology & anatomic pathology; hematopathology provides good long-standing model

- Pathology first needs to blends its “internal” subspecialty groups and also broadly adopt digital pathology for parity with radiology

- This will be harder than it sounds; CP and AP are viewed as different subdisciplines; more closely linked in previous eras
Closer Collaboration Between Pathology & Radiology Sub-Specialties as Next Step

- Because of “silo issues” (see later), little enthusiasm at this time for integration of specialities but some interest in closer collaboration

- Feasible next step would be discussion of “vocabularies” that have evolved in fields; create difficulties in comparison of reports

- Another early step would be computer-driven, automatic review of preexisting reports/diagnoses rad/path reports for significant lesions
  - Legal suits have occurred based on failure of surgical pathologists to be familiar with previous radiology reports

- Greater hospital political impact if chairmen of pathology/radiology were to act in concert; responsible for most dx activity in hospital
“Blending” LIS, RIS, and PACS to Create an Integrated Diagnostic Information System (DIS)

• My primary interest is lab computing; appropriate to speculate about how integrated diagnostics will affect lab computing in future

• I predict that LIS/RIS/PACS vendors will soon begin to experiment with development of diagnostic information systems (DISs)

• Vendors will not invest in such systems until they are sure that the market (labs + radiology) will demand such new systems

• As pathology moves to digital image capture & storage, pathology can make use of radiology PACS systems for image storage

• Emergence of a commercial DIS will increase efficiency of work-ups in the Integrated Diagnostic Centers
A Logical First Step in Hardware: An Integrated Diagnostician Dashboard or Console

- A key element in integrated dx & creating a super-diagnosis (see later) is ability to simultaneously access all dx information for patient

- Dx. dashboards/consoles have been available for years on limited basis; multiple monitors with interfaces to dx. legacy systems

- Allows simultaneous viewing of dx data for a patient from the EMR, LIS, AP-LIS (surgical path reports), radiology & pathology PACS

- Technology such as this could be used by members of the multidisciplinary dx team to render their super-diagnoses virtually

- This technology has not been adopted yet; no demand from pathologists; don’t require “dashboards” for generation of reports
Digital Pathology & Whole Slide Imaging: Broad Strategic Consequences

- Conversion of paraffin histology sections with slide scanner into whole slide images; then viewed, analyzed, stored, managed

- Process converts physical object into digital file that can be transmitted broadly; *digital technology destroys time and distance*

- Two subsequent speakers will address technical & practical implications of digital pathology; I will focus on strategic issues

- Strategy deals with long term planning to achieve goal; strategic consequences: anticipated events as a result of an action.

- Key question at hand: If digital pathology is broadly deployed in pathology, how will patient care and the specialty itself change?
Technology Can Turn Local Service Like Surgical Pathology into International One

- **Scenario #1**: small biopsy on single slide; “local” pathologist in Anytown wants second opinion from expert in Bigcity

- **Scenario #2**: small hospital in Anytown loses its pathologist and can’t replace him; challenge of how to replace his services

- **Option #1** is for local histotechnician to process the tissue locally or transport slides by overnight courier to Bigcity for support

- **Option #2** is to process locally, scan, & then transfer digital files theoretically anywhere in world; report returned via same route

- **Scanner + internet converts a local service into national/international one; part of basis for opposition to digital pathology**
What Is the Appeal for Medical Specialists to Practice Medicine in Silos?

- Medical knowledge today is vast and growing daily; research and practice
- Impossible to grasp the full breadth of knowledge in any medical speciality
- Solution is to narrow the focus of knowledge that one is required to learn
- Insurance companies exacerbate problem; higher rate for specialists/procedures
- Additional training years offset by the higher salaries & more attractive on-call schedules

Physicians, like corn and soybeans, are happiest when staying in their silos.
What Are the Disadvantages of Medical Silos?

• Medical silos are not conducive to integrated care and continuity of care, particularly when the EMR does little to plug the gaps.

• Medical silos can also lead to “disease myopia” with cardiologists, for example, attributing most pt. symptoms to cardiovascular disease.

• Medical silos can also lead to polypharmacy with geriatric patients, for example, on multiple drugs; each specialist adds to the mix.

• Despite pleas for training more primary care physicians (PCPs), there is little hope in U.S. of greatly increasing their numbers.

• Many PCPs function primarily to triage patients to proper specialists; increased reimbursement pressure to see more patients per hour.
Information Technology as Means to Reintegrate Separate Components of Healthcare

• It will be extremely difficult to reverse the medical silo/fragmentation problem from the perspective of physician specialization

• Notion of medical specialty integration (e.g., Diagnostic Medicine) could serve as counterweight to the fragmentation of medical specialties

• The only practical current method to reintegrate the separate components of healthcare is with information technology

• Major challenge today with hospital systems is need for greater automation of the hand-offs from one set of MDs/nurses to next shift
Multidisciplinary Teams: An Efficient, Practical Method for Delivering Care to Complex Patients

- Some of the best care is being delivered in academic cancer hospitals which frequently utilize multidisciplinary teams (MDTs)

- MDTs composed of physicians from all relevant medical disciplines: surgery, oncology, radiation oncology, pathology, radiology

- Goal is to arrive at the best therapy for patients & “suppress” the specialty practice inclinations of the individual MDs on the team

- In this era of fragmented care, I believe that a team approach is the optimal choice in arriving at both diagnostic & clinical decisions

- Such a team approach not always practical because of physical constraints; certainly true for outpatient care compared to inpatients
Multidisciplinary Diagnostic Teams as an Analogue for Multidisciplinary Teams

• Important for the diagnostic specialities to also model this multidisciplinary team approach to render dx’s for complex patients

• Teams would consist of specialty pathologists (CP & AP) plus specialty radiologists; integrate dx data at key points of care

• Dx MDTs would convene virtually (i.e., teleconference) at end of day; integrate all pathology/radiology reports into super-diagnosis report

• This “dx integration” step is moved upstream from the clinician who now receives and “integrates” the info. from the diagnosticians

• In this era of specialization and molecular dx/genomics, this integration step NEEDS to be moved upstream for efficiency/clarity
Will Clinicians Balk at “Super-diagnosis” Reports, Perceive as Attack on Their Turf

• Historically, the diagnostic units would send reports to the test-ordering clinician; he or she integrates data into working diagnosis

• This process has been disrupted by the super-specialization of diagnosticians, fragmentation of care, disruption of continuity

• I have come to view the “diagnostic enterprise” as already operating in a semi-autonomous way, often generating orders independently

• Good example is so-called reflex testing in which additional lab tests generated by algorithms on basis of previous positive tests

• Clinicians are often overworked; will resonate to advances in healthcare work flow that lead more rapidly to correct diagnoses
Origins of “Nighthawk” Radiology; Opening the Door for Commercialization of Teleradiology

- Radiologists referred in past to night & weekend radiology work as “nighthawk”; they were willing & able to turf work to others

- Nighthawk Radiology was first company to provide remote “nighthawk” coverage for hospital-based radiology groups

- Fully-boarded radiologists were located in Australia & India; countries selected in different time zones to “chase the sun”

- Service welcomed by U. S. radiology groups; when they resumed coverage, they then provided “preliminary reads” of images.

- Providers have proliferated (e.g., Teleradiology Solutions, US Radiology On-Call, NightShift); growing at 15% annually in U.S.
More on Early History of the “Nighthawk” Teleradiology Business

- The Radlinx Group & Virtual Radiology Consultants became multi-million $ companies; business model meet need in market

- In 2010, private equity firm acquired and took Virtual Radiologic private; Virtual Radiologic & NightHawk then merged

- Nighthawk continues as a wholly-owned subsidiary of vRad; turnover evidence of interest of financial community in business

- Radlinx Group pioneered expansion of teleradiology services beyond night coverage to rural coverage; provided vital service

- Industry consolidation with more than 500 of these firms operating in the U.S.; industry shakeout may be coming
What Are Some Reasons That Teleradiology Has Prospered in the U.S.?

• CT imaging has become essential tool in trauma cases in ERs throughout country; new set of radiologist skills to interpret

• Technology allowed “insertion” of expertise of sub-specialists (pediatric, neuroradiology, musculoskeletal) into rural hospitals

• Teleradiology fulfilled an urgent business need; hospital radiology groups had been required to provide off-shift diagnostic services

• Firms only hired radiology applicants with good training; most of the Indian radiologists trained in either the U.S. or England

• Lifestyle issues were important for some of teleradiology new hires; some were allowed to work at home or with reduced hours
The Major Downside Risks of “Nighthawk Radiology” for the Radiologists Themselves

- Traditionally, strong link between radiology groups & their imaging equipment; teleradiology provides option for severing this link

- Hospital executives can now discharge hospital radiology group & turn the contract over to a remote teleradiology company

- Facet of changing relationship between hospitals & MDs; latter becoming employees & not members of independent groups

- Digital radiology spawning on-line auctions for radiologist services; places market pressure on radiologists’ compensation

- Relationships changing among the physicians on hospital staff; success of clinicians dependent on quality of pathology/radiology
Steep Learning Curve of Digital Radiology & Digital Path; Pathologists May Seek to Avoid

- Newer radiology modalities “digital from birth”; this caused acceleration of mass conversion of radiology depts. to digital

- Younger radiologists favored because new modalities generated higher margins for hospitals; placed pressure on older cohorts

- Many rank-and-file pathologists see little gain in converting to digital pathology as opposed to continuing with analog approach:
  - No additional revenue from analog to digital conversion
  - Digital conversion require high capital investment
  - Conversion places pathologist at job-risk for outsourcing
  - Conversion also requires major reeducation to interpret images
Normal Procedure for Diagnosing a Lesion Discovered in an Organ Like the Lung

• Mass usually first discovered by a physical exam or screening X-ray; this search may have been prompted by a sign or symptom

• Responsibility of the PCP to pursue the dx; accomplished by ordering a series of imaging procedures & often subsequent biopsy

• This process can often take 2-3 weeks or more; burden on the PCP office staff of ordering and coordination of dx procedures

• Few tools for the optimization of these dx process by PCP office staff; frequently time-consuming and uncompensated service

• Meanwhile, the patient is anxious because acutely aware of the seriousness of the problem; need to accelerate this dx process
Overview of the Integrated Diagnostic Center (IDC)

• Physical, or potentially virtual), clinic to which a patient is referred by his/her PCP with an undiagnosed mass; goal is firm tissue diagnosis

• Such lesions are common in breast, lung, liver, thyroid, ovary, pancreas; colonic lesions detected during colonoscopy & biopsied

• Center staffed by diagnosticians (pathologists & radiologists) + internists; goal is to establish a final tissue diagnosis in 48-72 hours

• Efficiency gained by integrated team approach & wringing “down-time” or wasted time out of all of the diagnostic procedures

• Assume that sequencing of tests/procedures will be managed by IDC computer algorithms based on protocols and positive results
Introducing the Integrated Diagnostic Center
Introducing the Integrated Diagnostic Center

I have an undiagnosed mass in my lung.
Introducing the Integrated Diagnostic Center

I have a diagnosed mass in my lung

I have an undiagnosed mass in my lung

Results in 48-72 hours

Integrated Diagnostic Center
Successful Reporting of the Dx for Our Friend

No need to worry. The lesion was benign.
Will Referring Clinicians Such as Oncologists Object to the Creation of IDCs?

• At least in the U.S., 100% of patients accepted for care by oncologists have a diagnosed malignant lesion ready to treat

• It is the responsibility of the referring primary care physician (PCP) to have taken necessary steps to dx the mass prompting the referral

• Coordinating this diagnostic process in the U.S. is a tedious and unremunerative process, synchronizing/coordinating tests/apts.

• In the U.S., oncologists earn bulk of their income from the oncology/chemotherapy concession; percentage of drug costs

• Bottom line is that most U.S. oncologists and patients would welcome the services of the efficient diagnostic process by an IDC
Case Study: Grafting Pathology Services on to Current Breast Screening Radiology Clinics

• The diagnosis of an unknown mass such as in the breast can often take 2-3 weeks; complex process with multiple steps/organizations

• Currently well established are breast screening/mammography clinics managed by radiologists; process highly regulated by government

• Women with suspicious lesions shunted to special workflow for fine needle biopsy (FNA), core biopsy, or excisional biopsy by surgeon

• Graft onto this latter process the rapid transportation of specimen to histopathology lab for processing and whole-slide-imaging

• Digital image can be interpreted by pathologist quickly in the U.S. or even abroad; this enables final dx of the biopsied lesion 24-48 hours
Digital Pathology Workflow; Relationship to Integrated Diagnostic Center

The Future of Pathology

The Omnyx Integrated Digital Platform is expected to transform the 125 year-old pathology practice of using glass slides.

Omnyx products are not cleared or approved by FDA for diagnostic use.

Omnyx System: Benefits
A. Scan slides in 60 seconds
B. Continuous case flow
C. Digital workstation
D. Retrieve archived files instantly
E. Collaborate with remote facilities at the click of a button
F. Immediate consults with sub-specialists

Current System: Pain Points
A. Time spent sorting and collating
B. Cases hand-delivered in batches
C. Slow process of sorting, collating and filing paperwork
D. Time-consuming, error-prone retrieval of past files
E. Packing and shipping slides severely delays collaboration with remote facilities and specialists
F. Shipping and manual packing, unpacking and sorting
G. Time spent sorting, collating
H. Re-check cases for accuracy
Capitalizing on the Golden Era of Diagnostics

• We are now entering the era of personalized medicine; picking the right drug for the right patient at the right time

• Bedside diagnostic skills have atrophied at the same time that the diagnostic menu of tests/procedures has exploded

• Clinicians have gown highly dependent on radiology/pathology to deliver diagnoses to them; they then proceed to treat patient

• Now entering the golden era of dx; most complex part of the process is the diagnosis; treatment often based on protocols

• For historical reasons & patient comfort, diagnosticians tend to be out of limelight; now opportunity to reexamine their status
Summary of Key Take Home Points from Lecture

• Digital pathology key enabler for integrated diagnostics

• Digital radiology has spawned teleradiology & strategic changes

• Health care training/processes highly/annoyingly fragmented

• Integrated dx can help to repair this care delivery problem

• Multidisciplinary dx teams would staff Integrated Dx Centers

• Integrated dx moves process upstream to the diagnosticians

• Overarching goal: generate super-dx’s quickly & improve quality