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

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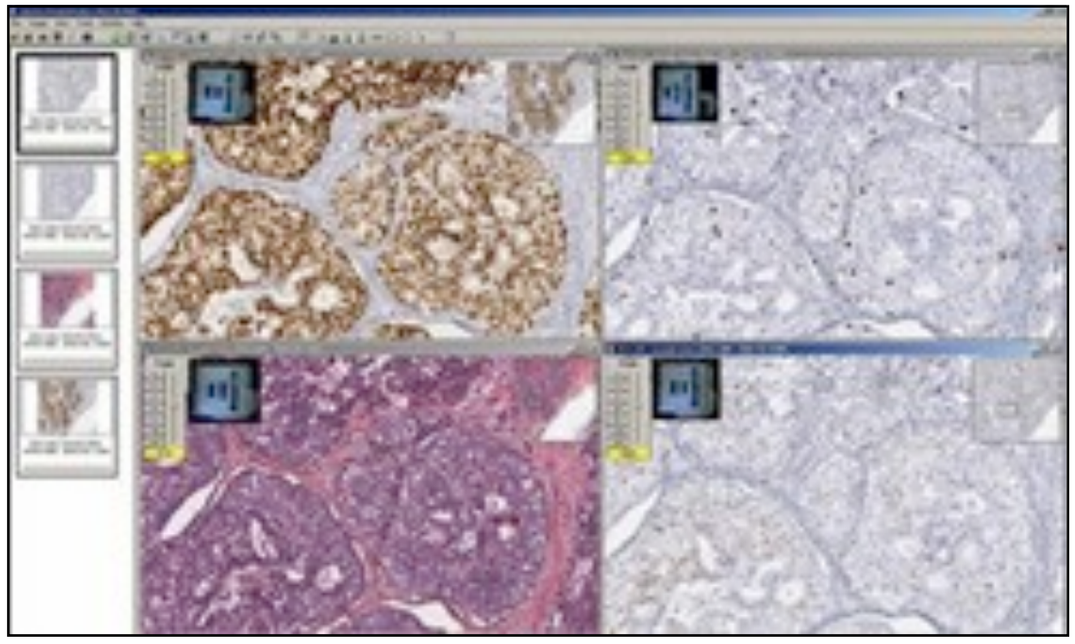


Topical Outline for This Presentation

- 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

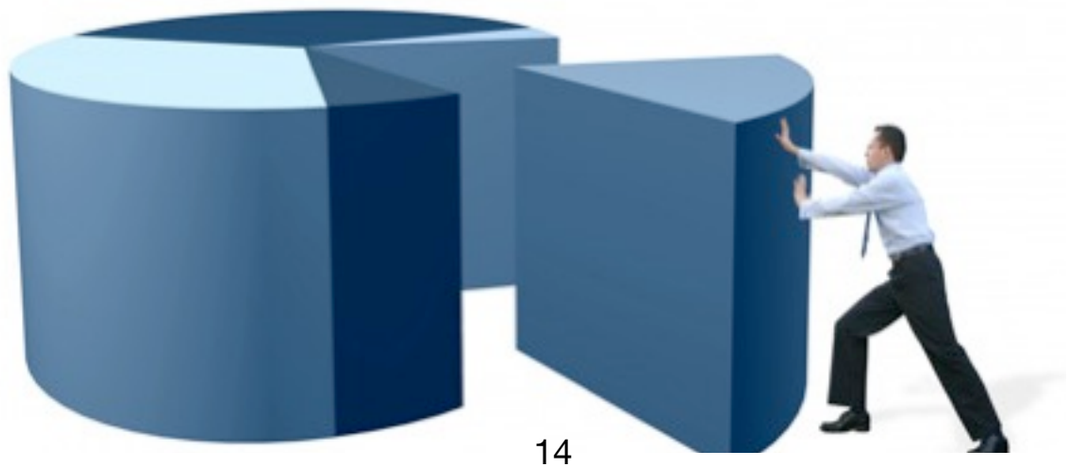
- Medical silos can also lead to polypharmacy with geriatric patients, for example, on multiple drugs; each specialist adds to the mix

- 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 specialities
- 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



Fragmentation; dx team as sol'n

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

Integrated
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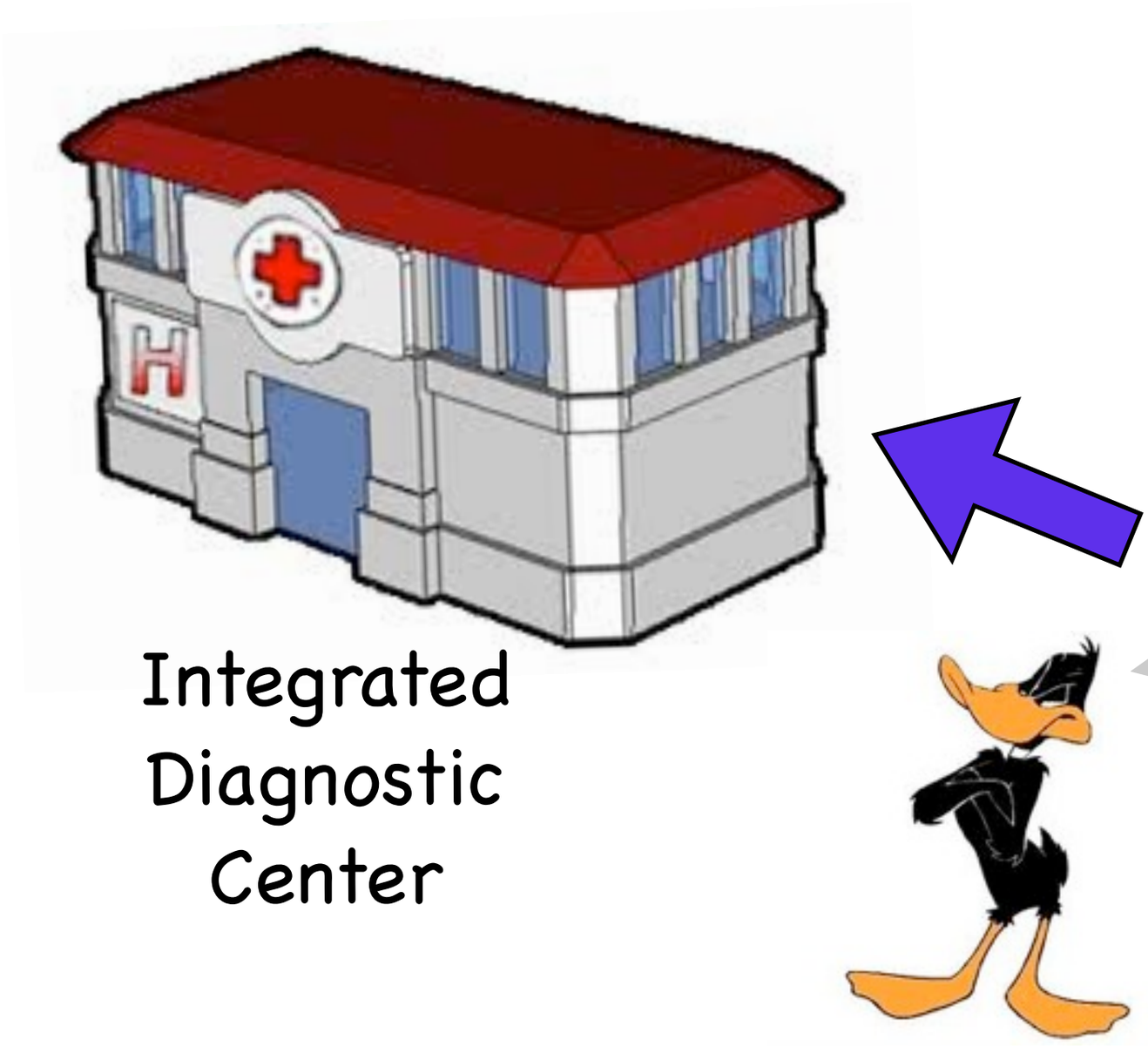


Introducing the Integrated Diagnostic Center

Results in 48-72 hours

Integrated Diagnostic Center

Successful Reporting of the Dx for Our Friend

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

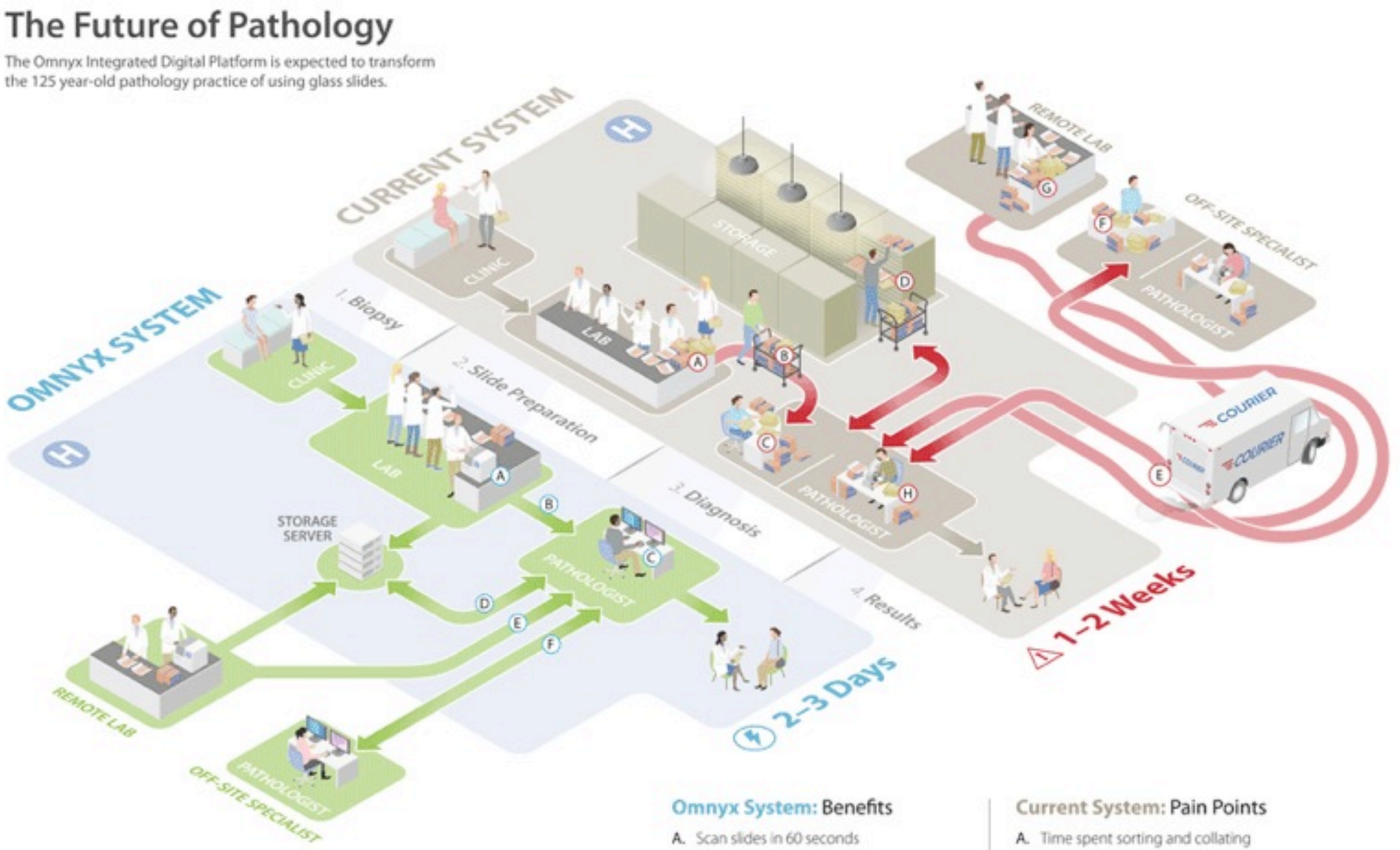
- Currently well established are breast screening/mammography clinics managed by radiologists; process highly regulated by government

- 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



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