Integrated Diagnostics Emerges as Key Element in Healthcare

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- Member of Medical Advisory Board, Siemens Diagnostics
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Preface: The Role of My Blog, *Lab Soft News*, in Developing These Ideas

- Will be presenting a number of new ideas about clinical lab & pathology; want to give credit to my blog for many of them

- Have been blogging for 2½ years; *Lab Soft News* focuses on lab software, clinical lab industry, and healthcare in general

- Number of current readers per day averages 400; about ¼ enter directly & ¾ of them are email or RSS subscribers

- I use the blog as a tool for testing new ideas; restrict blog notes to ~300 words; link together to create complex ideas

- We are just beginning to understand value of “professional blogs” in communicating new knowledge on global basis
Moving Resources from the Therapeutic to the Diagnostic Silo

I moderated a panel discussion at the recently completed Pathology Futurescope conference sponsored by the CAP Foundation. The panel members spoke to the topic of Corporate Innovation as an Engine for Change and included the following corporate representatives: Gene Cartwright (GE), David Oksong (Siemens), Dirk Soenkien (Aperio), and Mark Newburger (Apollo PACS). During the course of the discussion about the future of integrated diagnostics, Gene Cartwright suggested that we need to move resources from the therapeutic to the diagnostic silo in order to achieve the promise of pre-symptomatic/pre-clinical diagnoses for patients. This basic idea is incorporated in the concept of the early health model being championed by both GE and Siemens and about which I have posted a number of previous notes. There was insufficient time during the panel discussion to discuss any of the practical details about how to achieve such a reallocation, but I would now like to speculate.

I have come to believe that the process of increasing available resources for diagnostics is embedded in the concept of therapeutic silos being broken down in order to begin to organize a broad diagnostic effort to detect disease. This includes the use of substances, being prescribed and administered to patients, part of the therapeutic process, and determining the results. Put simply, the process of determining the therapeutic efficacy can be measured by means of biomarker monitoring and medical imaging.

The necessary first step in this process will be to determine criteria for measuring therapeutic efficacy by drug by disease and recommending the diagnostic tests and procedures used to measure efficacy. After these criteria have been developed, the program can proceed. A number of possible drug treatments will never be initiated because of negative results obtained from companion diagnostics. Other drugs will be discontinued at some point during therapy because of lack of measurable efficacy. A portion of the dollar savings achieved by the termination of drugs can be reallocated to offset the increased cost of the diagnostics used to assess drug efficacy on a much broader basis.

Needless to say, broader scrutiny of the therapeutic efficacy of drug therapy and...
Internal and external Google search

Implications of the Kaiser-Microsoft PHR Deal

A report of a new partnership between Kaiser Permanente and Microsoft regarding personal health records (PHRs) (see: Kaiser Backs Microsoft Patient-Dates Plan) raises a set of interesting issues. Below is an excerpt from the article (boldface emphasis mine):

Kaiser Permanente, the nation’s largest nonprofit health maintenance organization, is planning a deal with Microsoft. The partnership would be executed upon Kaiser's 156,000

employees, a majority of whom are covered by the

organization. The deal, if successful, would

linking Kaiser's patients to Microsoft's Health Vault personal

health records (PHRs), allowing patients to

Kaiser’s 8.7 million members in

nine states to access their records online.

...There are several companies

offering personal PHRs on the Web, but the big new players

last October, and Google, which

came in late last October, and Google, which

and Google health offerings give

individuals control of their own health records, as well as responsibility for them. Today, most electronic health records are maintained by health providers and insurers, allowing individuals access to their records through the Web. But those records are typically controlled by the

provider and insurer. The Kaiser-Microsoft deal would give patients control over their own health records.
Subscription options

I have posted a number of previous notes about the Kaiser Health System, including its prolonged roll-out of the Epic EMR system, called HealthConnect, across its entire chain of hospitals. Kaiser usually hides the cost of the project (see the most recent of the notes: HealthConnect Project). Kaiser admits to a cost increase thus far for the planned 36 hospital EMR system. Only 13 of the 36 Kaiser hospitals have had the EMR deployed so far. For a typical hospital, the tethered personal health records (PHRs) of both patients and employees (HIMSS, PHRs, Microsoft’s Health Vault, and Google Health (see: HIMSS President Slams PHRs: I Wonder Why)):

What’s really worries [HIMSS CEO Steve] Leiber and the EMR vendors, from whom he takes his orders, is the likes of Microsoft’s HealthVault and Google Health. Note that the latter company has recently created a partnership with the Cleveland Clinic (see: Google CEO Discusses New Partnership with Cleveland Clinic). What Leiber and the EMR companies fear is that Microsoft and Google will launch a fully-featured EMR/PHR combo that will deliver both value and functionality.

The recent Kaiser/Microsoft announcement brings into play three critical questions that I will summarize below:

1. Who owns/controls patient clinical information: (1) the health system that creates the information; (2) the vendor of the electronic medical record deployed within a health system such as Kaiser; or (3) the patients on whose behalf electronic medical records are generated and who pay for them, either directly or indirectly through health insurance plans? My personal vote on this question is the patients.

2. To what extent is a health system like Kaiser limited in its ability to replicate clinical information managed by an EMR supplied by a vendor such as Epic to a free tethered PHR like HealthVault? Epic has its own tethered PHR product called MyChart that it sells to its hospital clients such as Kaiser (see: The Revolution Will not be Televised). Kaiser currently provides a tethered PHR to its patients, My Health Manager, which is based on the MyChart patient portal (see: HealthVault Signs on Kaiser). I personally think that PHRs should be free,
Brazil as the leading contributor of out-of-country blog readers.
Readership of Lab Soft News in Brazil: Speculation About Popularity

- Intrigued by the interest in *Lab Soft News* in Brazil; readership exceeds all English speaking countries + all countries in Europe

- Readership from Brazil also far exceeds three other BRIC countries with large populations: Russia, India, China

- Possible reasons for this interest in my blog in Brazil:
  - Large population compared to many other countries
  - Large number of clinical labs & lab professionals
  - Energized & entrepreneurial lab professionals
  - Lab professionals seeking new perspectives on field
  - Lack of rigid governmental control of healthcare
For 26 years, I have sponsored a yearly conference devoted primarily clinical lab software; called AIMCL for first 21 years

All lectures posted on conference web site and blog; opportunity for all to review current thinking in the field

Pathology/lab informatics has experienced little growth in last three decades despite important role in lab practice

Specialists located largely at large medical centers where fulfill important roles in patient care, technology, & research

Will highlight in this lecture the critical role of information technology (IT) in the evolution of the clinical lab industry
Lab InfoTech Summit 2008
Laboratory Information Management

The fifth annual Lab InfoTech Summit will be held on April 9-11, 2008, at the Venetian Resort Hotel Casino, Las Vegas, Nevada. Lab InfoTech Summit is a unique three-day conference designed for all clinical laboratory professionals, including pathologists, medical technologists LIS managers, and lab business managers. Health system executives, particularly those with responsibility for the clinical laboratories, will also find the conference to be valuable. Now approaching its fifth year in Las Vegas, Lab InfoTech Summit is a continuation of the AIMCL conference that was held in Ann Arbor, Michigan, at the University of Michigan Medical School for 21 years beginning in 1983. Click here to view a PDF file of the conference brochure. Another link to the conference brochure is provided in the left hand column of this home page as well as a link to on-line registration for the conference.

It is anticipated that about 44 exhibitors will participate in Lab InfoTech Summit 2008 including most of the major lab software vendors and most major in-vitro diagnostic companies with software products. Two pre-conference workshops will be offered, the first of which will focus on case studies relating to the use of middleware to increase lab efficiency and productivity. The second will address training and teaching issues in pathology informatics. The fifteen lectures in the plenary sessions by faculty of national prominence will highlight all of the current major initiatives in pathology informatics. To help you decide if you would like to attend Lab InfoTech Summit 2008, you can review all of the lectures presented at the 2004, 2005, 2006, and 2007 summits by clicking on the links to the left under Past Conferences.

Bruce Friedman, the director of Lab InfoTech Summit, has developed a blog devoted to clinical lab software, the clinical lab industry, and the entire healthcare industry called Lab Soft News. The link for this blog is www.LabSoftNews.com You may want to visit the blog or subscribe to it using RSS and a blog reader. The blog will also provide periodic announcements and updates about Lab InfoTech Summit.
"Dave, stop. Stop, will you? Stop, Dave. Will you stop, Dave?" So the supercomputer HAL pleads with the implacable astronaut Dave Bowman in a famous and weirdly poignant scene toward the end of Stanley Kubrick’s 2001: A Space Odyssey. Bowman, having nearly been sent to a deep-space death by the malfunctioning machine, is calmly, coldly disconnecting the memory circuits that control its artificial
Is Web and Web Searching Making Us Stupid?

- Active discussion on blogs currently about the effect of instant access to huge amounts of information on web

- Question of whether web produces short attention spans and lack of ability to concentrate on long articles and books

- No question that Google can cause new (improved?) style of acquiring information; can quickly scan multiple references

- My own belief is that all new technologies change behaviors; change from previous behavior not necessarily bad for us

- Can’t point finger solely at web; modern life faster & more complex; “multitasking” not good excuse for lack of attention
Overarching Goal of This Lecture

- Primary goal today is to present set of strategic ideas about how the role of diagnostics in healthcare is rapidly changing.

- Diagnostics defined as *lab medicine* + *pathology* + *medical imaging*, may eventually form specialty of *diagnostic medicine*.

- I propose that we adopt and use term *integrated diagnostics*, collaborative effort to quickly arrive at correct diagnosis.

- Will also present concept of *integrated diagnostic centers (IDCs)*; will serve as home for these new diagnostic activities.

- Will then describe some paths for change; one important example will be the transformation of our training programs.
High Level View of Healthcare; Focus in Lecture on Complex Disease

Routine Medical Care and Clinic/Office Visits

Diagnosis and Treatment of Complex Disease

Wellness and Preventative Medicine

Domain of Primary Care Physicians and Nurses

Domain of Diagnostics & Special Focus of Lecture

Emerging Specialized Field for Physicians
Key Elements of the Genomics/Proteomics Revolution

- Lab medicine moving from measurement of non-specific analytes to broad panels of serum and tissue biomarkers

- These complex panels frequently require use of computerized algorithms running on LISs for interpretation

- These panels will enable both earlier diagnosis (see later: early health model) & greater specificity of diagnoses

- Smaller labs will be challenged by this change; may need to collaborate with esoteric reference labs in networks

- Lab reports will be more integrated and routinely provide diagnoses, prognosis, and therapeutic recommendations
Reasons Why Changes Required in Diagnosis of Complex Disease

- Current diagnostic processes often uncoordinated & inefficient; better managed in specialized diagnostic centers

- These inefficiencies result in wasted time & resources; cannot afford today with need for greater access to services

- Molecular diagnostic reports often too complicated for non-experts to understand; specialists want to focus on proper rx

- Large capital investment required in imaging and laboratory equipment; process better managed in specialized centers

- Integrated diagnostic approach will result in higher quality reports and higher quality clinical outcomes for patients
Integrated Diagnostics: What Is It and How Will It Come About?

- *Integrated diagnostics* refers to the blending of all the tests and procedures used to diagnose disease & predict prognosis.

- Pathology, lab medicine, and radiology deeply embedded in specialty silos; need to stimulate a broader view of disease.

- Surgical pathology becoming more quantitative like clinical pathology; stimulated by research in tissue biomarkers.

- Step one will be closer integration of clinical pathology & anatomic pathology; hematopathology provides a good model.

- Movement now toward integration of *in-vivo* diagnostics (medical imaging) & *in-vitro* diagnostics (lab + pathology).
Recent Siemens Diagnostic Solutions Brochure

Next generation of healthcare

Integrated diagnostics

Personalized medicine

Convergence of lab diagnostics, medical imaging, and IT solutions
Current Model for Diagnosis and Treatment of Complex Disease

- Current model most frequently involves patient presenting to MD/nurse with signs & symptoms of disease, often advanced

- Physician examines patient and orders lab tests/imaging procedures; confirms diagnosis on basis of these reports

- Physician then selects therapy based on various factors such as diagnosis, age/sex of patient, available drugs, cost of rx

- Physician functions as the diagnostician, prognostician, and therapist with limited input from lab/pathology personnel

- Drug selection and drug dosage often based on trial and error; observations about efficacy of current drug regimen
Proposed Model for Diagnosis and Treatment of Complex Disease

- Symptom-free consumer or symptomatic pt. referred to specialized integrated-diagnostic-center (IDC) by MD/nurse

- IDC staffed by lab medicine physicians, pathologists, and radiologists who will take control over entire dx. process

- Hand-offs & referrals within the IDC (imaging vs. serum/tissue biomarkers) managed by computerized rules

- Diagnosed patient leaves the IDC with diagnosis, calculated prognosis, & even some therapeutic suggestions

- Treatment then initiated by clinicians with occasional referrals back to IDC to monitor the efficacy of treatment
Top Level View of Progression Through Integrated Diagnostic Center (IDC)

Symptom-Free Consumer or Symptomatic Patient

Integrated Diagnostics Center

Diagnosed Patient Ready for Therapy
The Integrated Team Approach to the Diagnosis/Treatment of Complex Disease

- Specialized cancer hospitals provide integrated team approach; emerging new model for dx of complex disease

- Advantages of team approach is that tunnel vision of various medical specialists minimized; checks and balances in place

- For example, checks placed on surgeons whose instinct is to operate or on radiotherapists who favor this form of therapy

- Proposed integrated diagnostic centers are yet another example of such a team approach in healthcare delivery

- Cancer hospitals are one logical site for launching the formal IDC model; need for rapid diagnosis of complex diseases
Scenarios for the Evolution of Integrated Diagnostic Centers

- Centers already exist in Brazil and emerging in the U.S. focusing on specialized diseases such as breast cancer

- IDCs offer convenience and quality for patients so will continue to gain market share wherever established

- Likely that may offer greater efficiency and arrive at diagnoses more quickly than current less organized process

- For-profit enterprises more in tune with the needs of patient consumers & less insulated from market forces

- Academic centers more removed from market forces; will hold more closely to classic medical specialty boundaries
Distinction Between Wellness & Diagnosis in Integrated Diagnostic Centers (IDCs)

- **Wellness** defined as state of optimal well being, not simply the absence of illness, but an improved quality of life.

- **Preventive medicine** involves the prevention of disease rather than curing it; can be contrasted with therapeutic medicine.

- IDCs will detect early disease and predisposition to disease and lifestyle issues with its multiplex test panels & imaging.

- Inevitable that IDC will begin to focus on both wellness and preventive medicine; essential parts of health continuum.

- Should not be viewed as a problem but rather an opportunity to provide services to patients not currently addressed.

- Slide 24 -
Relationship Between Personalized Medicine and Integrated Diagnostics

- You have all heard of **personalized medicine**: defined as finding the right drug for the right patient at the right time.

- I prefer term **targeted therapy**: treatment that identifies & attacks specific cancer cells without harming normal cells.

- Biotech drugs evolving with **companion diagnostics**: molecular tests & imaging to match patients with best drugs.

- Targeted therapy is the future of healthcare delivery and cannot proceed without sophisticated companion diagnostics.

- Biotech drugs & integrated diagnostics **developing in parallel**; diagnostic methods help choose drug & monitor therapy.
More Details About the Growth of Companion Diagnostics

- Pharmaceutical companies not enthusiastic about companion diagnostics in past; belief that such test would reduce sales

- This view changing with decline in sales of blockbuster drugs; now viewing as important in proper subject/patient selection

- Leading supporter of this trend has been Roche with major position in both diagnostics and manufacture of pharmaceuticals

- Diagnostics now being developed in tandem with drugs; test commercialized alongside the drug for both dx and rx purposes

- This new model important for diagnostics companies; would not take risk of developing test without seeing drug “on other side”
Defining the Early Health Model: Pre-Symptomatic & Pre-Clinical Diagnosis

- Ideas being promoted by GE Medical and Siemens; aligns with their large investments/integration of IVD and imaging

- Basic concept is pre-symptomatic, pre-clinical diagnosis based on biomarker panels & new imaging techniques

- EHM changes the rules of the game for MDs, healthcare insurance companies, and pharmaceutical companies

- Suggestion that EHM results in lower cost for healthcare but may not be correct; need to wait and see whether true

- EHM moves diagnostics to center of healthcare delivery process; critical first step because patients symptom-free
Who Most Nervous and Who Supports the Early Health Model?

- **Opposed**: Health insurance companies and government payors who can’t keep up with current financial demands

- **Nervous**: Pharmaceutical companies with all of current drugs having been tested only on symptomatic research subjects

- **Nervous**: Physicians who have only trained with current disease model that is based on overt signs and symptoms

- **Nervous**: Governmental regulatory agencies who have trouble understanding current healthcare environment

- **Enthusiastic**: Healthcare consumers who want to know what will happen to them before they get sick & need intervention
Boundary Between Preventive Medicine and the Early Health Model

- Historically, we have always diagnosed disease on basis of signs and symptoms of disease; basis for diagnostic medicine

- Major challenge: distinguish between gene/biomarkers that define disease & those indicating predisposition to disease

- Will assume that preventive medicine will continue to focus on discovery of pre-disease & ways to prevent emergence

- Current example of a pre-disease: metabolic syndrome; now know that weight loss/lipid control can prevent diabetes

- Easy solution: incorporate idea of preventive medicine into definition of early health model; logical evolution of term
Motivation for GE & Siemens to Pursue Integrated Diagnostics Business Model

- Assumption that radiology with molecular imaging & IVD with molecular diagnostics are now starting to converge

- Profit margins from medical imaging equipment are being squeezed by insurance payors who want to reduce costs

- Pressure to reduce healthcare costs; suggestion that early and efficient diagnosis can eventually result in cost savings

- Belief that integrated diagnostics provides efficient pathway for reaching personalized medicine (i.e., targeted therapy)

- Companies can influence practice of medicine globally by large size and ability to provide package deals to customers
Molecular imaging uses biomarker probes to identify various targets/pathways; technology overlaps with molecular dx

Biomarkers interact chemically with tissue & alter image based on molecular changes occurring in area of interest

Medical imaging research centers around world operated by GE/Siemens mainly focusing mainly on biomarker research

Molecular imaging has potential for radiologists to deliver specific diagnoses and compete with surgical pathology

Makes sense to collaborate now rather than later when will view each other as competitors rather than collaborators
Ten Reasons Why Pathology & Lab Medicine Should Merge with Radiology

1. Substantial overlap already exists between the mission of the two specialties; merger would recognize current realities

2. Enhanced clinical/research value of the merged LIS, RIS, and PACS systems & databases; value of DICOM & SNOMED

3. Integrated imaging & molecular dx reports would achieve higher levels of quality and provide benefits to patients

4. Merger already taking place in multinational companies through their integrated approach to research & sales

5. Scientific & research agendas of molecular imaging & molecular diagnostics already shows extensive overlap
Ten Reasons Why Pathology & Lab Medicine Should Merge with Radiology (cont.)

6. Radiologists experiencing leakage of their procedures to other specialists; merger would enhance their specialty

7. Merger would breathe new life into the combined training programs; attract young physicians due to larger mission

8. Merged specialties would achieve greater influence and political power within large integrated health systems

9. Pathology & lab medicine badly need new capital in the form of corporate R&D funding for expanded biomarker research

10. Radiology, pathology, & lab medicine all dependent on information technology, molecular dx, & imaging technology
Molecular Summit launched on February 5-6, 2008. First conference focusing on the merger of Pathology, Lab Medicine, and Radiology.
Can the Classic Autopsy Be Improved by Addition of Medical Imaging

- During discussion of merger of pathology/radiology, also need to discuss integration of CT scans into all autopsies

- Autopsy rate falling rapidly in the U.S.; expensive, labor-intensive, & uncompensated; reports may take many weeks

- **Catopsy (autopsy + CT scan)** would consist of total body CT scan; followed by endoscopy or biopsies to obtain tissues

- Goal of 2-4 hours for **final catopsy report** back to clinicians; also ability to salvage fresh tissue for **biorepositories**

- Most important advantage is for trainees; will learn medical of imaging plus histopathology in first year of training
Merging LIS, RIS, and PACS Information Systems to Create a DIS

- My primary interest is lab computing so should speculate on how emergence of IDCs will affect lab computing in future.

- I predict that LIS/RIS/PACS vendors will begin to experiment with integrated diagnostic information systems (DISs).

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

- As pathology moves to virtual microscopy (whole slide imaging), can make better use of PACS for image storage.

- Integrated DIS will also increase efficiency/effectiveness of diagnostic work-ups in the integrated diagnostic centers.
Increased Need for Computerized Rules to Manage the Mission of IDCs

- As noted previously, hand-offs & referrals within the proposed IDC need to be managed by computerized rules.

- Such software does not exist today; will need to be developed & will be an important tool for use in the IDCs.

- These rules will make a major contribution to the ability of the IDCs to arrive at diagnoses faster than current system.

- Example: positive test for biomarker A+B+C requires imaging study A which then prompts biomarker D+E etc.

- Rules will need to be modified constantly because biomarker research is constantly updated; also changes in imaging studies.
Information Technology Strengths of Pathologists vs. Radiologists

- Pathology/lab medicine deployed LISs about 5-10 years prior to RISs & PACS came later; fields now about equal in IT

- Advantage of radiology is invention/adoption of DICOM standard; governs management/storage of images in PACS

- Advantage of pathology is that it invented the SNOMED standard for the coding of surgical pathology reports

- Surgical pathology a decade behind radiology in the adoption of digital technology; merger would accelerate this process

- Little return-on-investment for digital pathology; new imaging procedures provide high margins for radiology
Some Additional Thoughts About Conversion to Digital Pathology

- Conversion to digital pathology will take some prodding because of challenging technology & limited financial return

- Will also introduce need for radically altered workflow in surgical pathology; new patents being developed in area

- GE has just announced new digital pathology company, Omnyx, formed in collaboration with major medical center

- Evolution of digital pathology department will be required for merger of pathology/radiology to take place efficiently

- Major incentive for merger: search image databases for matches using fields from difficult surgical pathology cases
Responding to the Challenge of Integration of Lab Data into Hospital EMRs

- Major LIS problem currently is notion that the electronic medical record (EMR) is sole reporting system for clinicians

- In U.S., EMR technology decades old; EMRs cannot adequately report complex genomic/proteomic data

- Solution is to “dumb down” or truncate lab data so that it can be reported to clinicians via the inadequate EMRs

- Reasonable solution is to report out the top-level lab data via the EMR; retain the LIS databases as the source of truth

- Favorite solution is federated architecture for EMRs; labs given “white space” in EMRs to format at time of request
Creating a Lab Network of Hospital Labs and Esoteric Reference Labs

- In genomic/proteomic era, likely that many smaller labs will not be able to perform many of the newer esoteric tests.

- As before, serum and tissue samples will be referred from these smaller labs to esoteric labs for performance/advice.

- In addition to emergence of IDCs, also suggesting the need for national or regional integrated clinical lab networks.

- Such networks will be seamless; receiving labs can divide serum samples or pre-process samples prior to handoff.

- Commercial radiology network already exist (e.g. Nighthawk Radiology) with image interpretation available 7/24.
Possible Evolutionary Sequence for IDCs, DISs, and Diagnostic Lab Network

Current Model

- Esoteric Reference Lab
  - Reference LIS
  - Hospital LIS
  - Pathology and Lab Medicine
- Nighthawk Radiology
  - Nighthawk RIS
  - Hospital RIS
  - Radiology

Evolved Model

- Esoteric Reference Lab
- Nighthawk Radiology
- Reference LIS
- Nighthawk RIS
- Diagnostic Information System (DIS)
- Integrated Diagnostic Center (IDC)

Super Evolved Model

- Diagnostic Information System (DIS)
- Integrated Diagnostic Center (IDC)
- Diagnostic reference network
Closer Look at Competition Between Cardiology and Radiology

- Useful to examine cardiology/radiology interactions in the U.S. for clues about how diagnostic enterprise may evolve
  - Cardiologists taking control over heart imaging from radiologists; integrating training into fellowship programs
  - Cardiologists also opening specialized cardiovascular centers/hospitals, taking business from general hospitals
  - Cardiologists also exercising political power in hospital politics because of ability to control their own patients
  - Strength of cardiologists as diagnosticians is that they are clinicians; can deal with clinical complications when occur
Sources of Referrals of Complex Disease to Integrated Diagnostic Centers

- Unlikely that patients with cardiovascular disease will be referred to IDCs because of dx expertise of the cardiologists

- Not a source of concern; clinicians in other specialties (e.g., oncology, endocrinology, immunology) will refer patients

- Predict that first examples of hospital-based IDCs will take place in cancer hospitals; familiar with team approach

- Because treatment of neoplastic disease now so complicated, oncologists would rather treat than diagnose their patients

- If early health model takes hold, possible that IDC physicians may be more familiar than other MDs with dx of pre-disease
Relevance of Therapeutic Efficacy to Integrated Diagnostics

- Need to move resources from the *therapeutic silo* to the *diagnostic silo* to cover increased cost of early health model

- This goal can be accomplished by measuring *therapeutic efficacy* of drugs, particularly expensive biopharmaceuticals

- Therapeutic efficacy will be measured by therapeutic drug monitoring, biomarker monitoring, & specializing imaging

- For oncology patients, some treatments never launched on basis of companion dx; other treatments will be terminated

- A small percentage of the cost of the drug savings will be reallocated to cover the cost of the therapeutic monitoring
Control of Proposed Integrated Diagnostic Centers Currently Up for Grabs

- Cannot assume that control over the IDCs will default to pathologists, lab medicine specialists, and radiologists

- Many current diagnostic specialists lack the hands-on experience of direct control for the diagnosis of patients

- Other specialty groups may mimic cardiologists and begin to introduce more diagnostic procedures into training programs

- Pathologists should study training and careers of our hematopathologists; come closest to the IDC model

- Before we can increase pipeline of diagnosticians with better clinical training, may need to integrate clinicians into IDCs
Need for Reform of Pathology and Lab Medicine Training Programs

- Urgent need for pathologists and lab medicine specialists to develop larger set of clinical skills to operate in IDCs

- Interventional radiologists facing same problem; losing patients to cardiologists who can respond to complications

- Radiology one of the most desirable specialties in the U.S. but leaders now expressing concerns about future of specialty

- Need fundamental reform of our teaching programs with recruitment of trainees with strong clinical backgrounds

- Greater clinical orientation of training programs will also help trainee recruitment programs; attracted by broader scope
Gradual Transition to Integrated Diagnostic Centers

- IDCs already exist in the Brazil; in U.S., such centers have also been started by radiologists focusing on breast cancer

- Close collaboration between radiologists/pathologists in fine-needle-aspiration (FNA) suites in tertiary-care hospitals

- Tightly integrated diagnostic protocols currently exist in cancer centers; these efforts will continue to evolve

- Both Siemens and GE continue to push idea of integrated diagnostics; may offer purchasing incentives for IDCs

- Pressure from healthcare consumers for efficiency in healthcare; farsighted organizations will rise to challenge
Summary and Take-Home Points for This Lecture

- Diagnostics sector of healthcare undergoing irreversible changes; science & technology enable earlier diagnosis
- For diagnosis & treatment of complex disease, integrated team approach offers quality & efficiency advantages
- New opportunity for development of integrated diagnostic centers staffed by pathologists, lab specialists, radiologists
- New software will be required for IDCs; blend of LIS, RIS, PACS plus rule-based software to manage hand-offs
- Control of IDCs may not extend to current diagnosticians by default; clinical specialists are extending diagnostic expertise
Questions and Discussion