

HOW TO BEST PREPARE FOR DIGITAL PATHOLOGY: A PRIMER ON TECHNOLOGIES, APPLICATIONS, AND CLINICAL CONTRIBUTIONS



Keith J. Kaplan, MD
Carolinas Pathology Group
Charlotte, NC



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Disclosures

- Clariant, Inc. – Consulting agreement
- Digital Pathology Blog – Educational sponsors
 - Aperio
 - Aurora MSC
 - BioImagene
 - Definiens
 - Digital Pathology Consultants
 - i-Path
 - MEDTING
 - Omnyx
 - SlidePath
 - Ventana

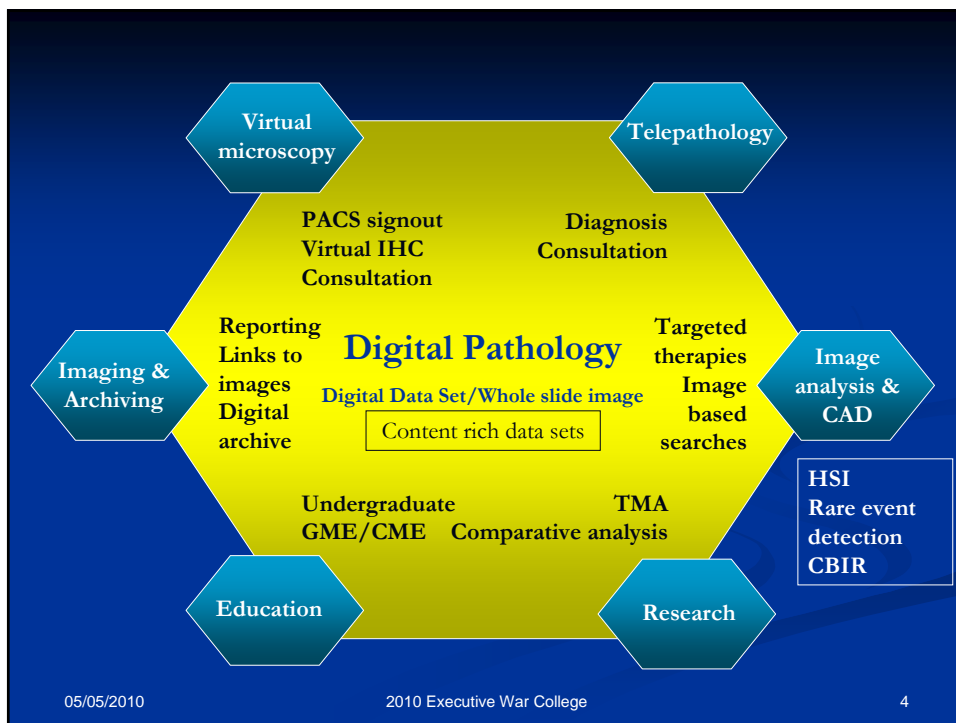
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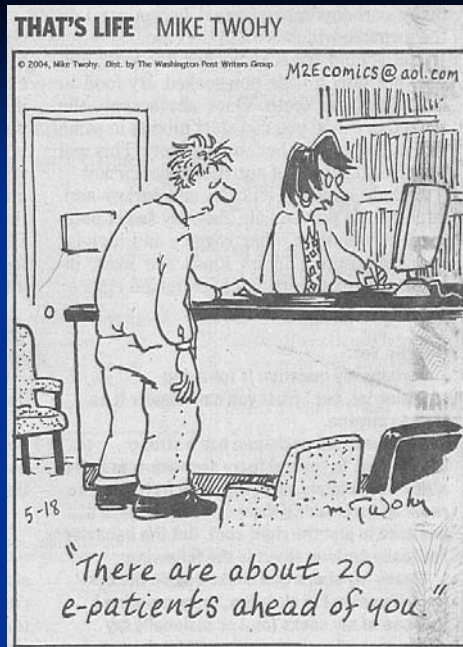
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Goals

- Digital pathology applications – defined and use
- ROI
- Cost-effectiveness
- Models





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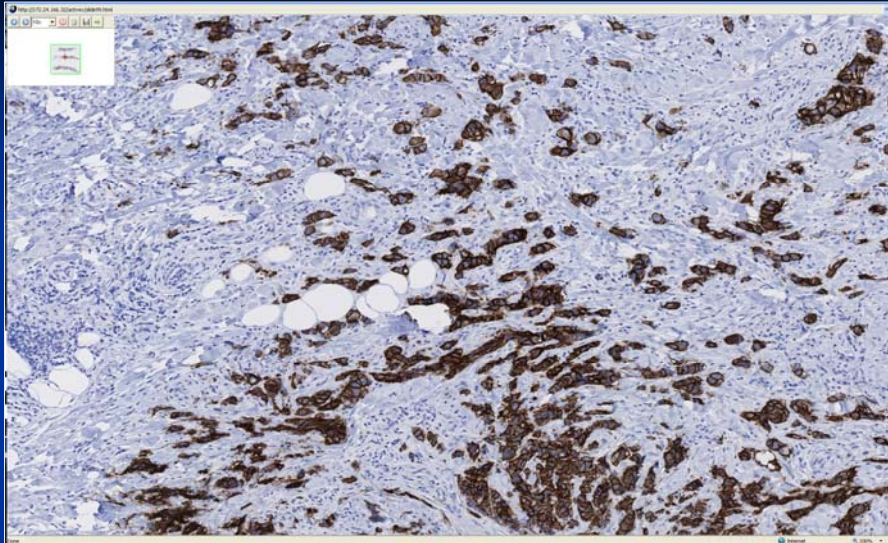
Digital Pathology is

- Direct patient care
- Education and clinical conferences at a distance
- Administrative/organizational meetings at a distance
- Image enhanced pathology
- Integration with LIS/EMR
- Part of Pathology 2.0

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Consistent

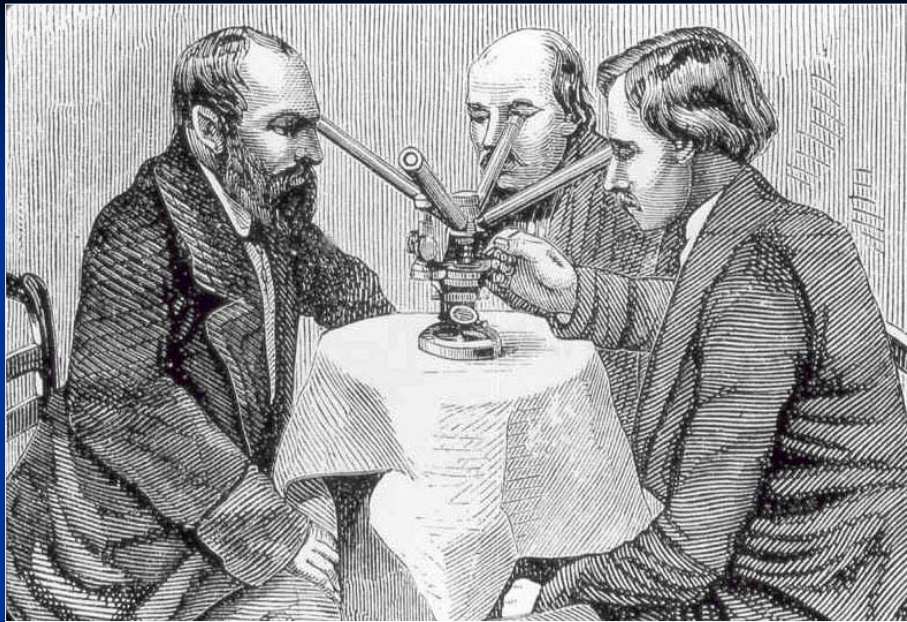
Persistent

Efficient

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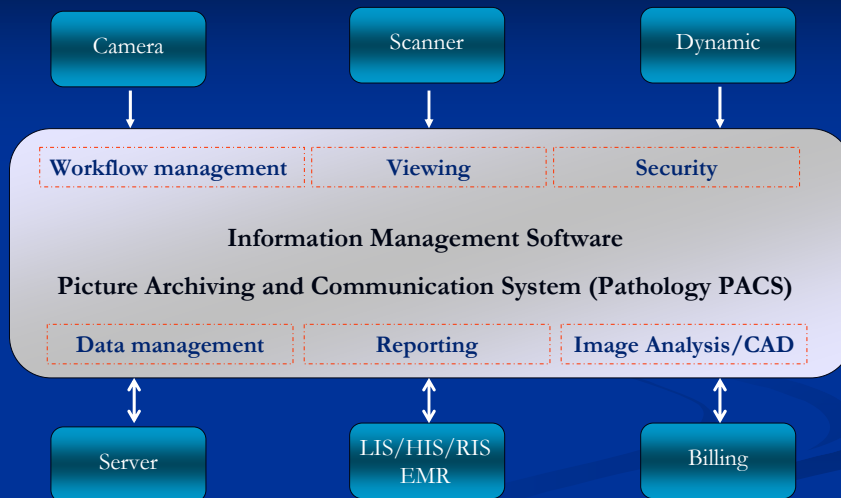
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Projected Whole-Slide Scan Times with Evolving Platforms

- 2009:
 - Best Possible: 1:30 (minutes)
 - Typical: 5:00-8:00
 - 2012
 - Best Possible: 0:12
 - Typical: 2:00
 - 2018
 - Best Possible: 0:03
 - Typical: 0:20
 - Worst Case: 4:00
- With high compression algorithms for clinical use

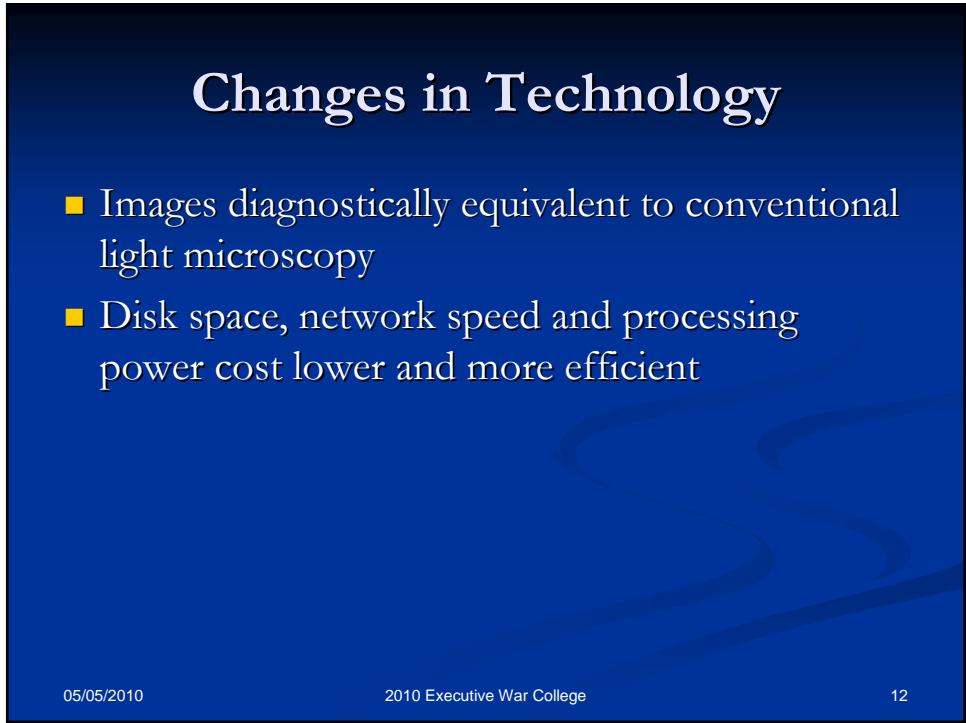
Applications





Changes in Technology

- Images diagnostically equivalent to conventional light microscopy
- Disk space, network speed and processing power cost lower and more efficient



Why telepathology?

- Rapid consultation on cases
- Provide capability to have subspecialty experts review challenging cases (added value)
- Provide a peer review capability for single/isolated pathologist
- Distance independent diagnoses
- Manpower shortages and wide spread geography
- Pathology 2.0

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Established Practices

- Frozen section
- Routine surgical pathology
- Consultation (second, expert, QA/QC)
- GME/CME (ABP, USCAP, CAP, ASC)

Provisional Practices

- Cytopathology (Z-stack focusing)
- Clinical microscopy

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Special Section on Telepathology

Primary frozen section diagnosis by robotic microscopy and virtual slide telepathology: the University Health Network experience

Andrew J. Evans MD, PhD*, Runjan Chetty MB, BCh, DPhil, Blaise A. Clarke MB, ChB, Sidney Croul MD, Danny M. Ghazarian MD, PhD, Tim-Rasmus Kiehl MD, Bayardo Perez Ordonez MD, Suganthi Ilaalagan BSc, MLT, Sylvia L. Asa MD, PhD

Department of Pathology Laboratory Medicine Program, University Health Network, Toronto, Ontario, Canada M5G 2C4

University Health Network – Toronto, Canada



Princess Margaret



Toronto Western



~ 1.5 miles



Toronto General

Why Telepathology at UHN?

- No on-site at AP frozen section service at TWH for ~10 years
- Tissue sent to TGH – up 1 hour TAT
- Lack of timely intraoperative frozen section support.
- Small volume frozen section requirement

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Telepathology QS Procedure

- Only when the result will directly influence intraoperative management
- The pathologist can give the surgeon the answer they are looking for
- The information sought at frozen section cannot be obtained by other means

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Telepathology QS Procedure

- *Single pieces of tissue EIT*
 - Tissue Identification
 - Tissue for Intraoperative Staging
 - Resection Margins
- *> 3 separate specimens or complicated dissection/orientation*

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UHN Telepathology Experience/Outcomes

- 674 primary FS diagnoses (350 by RM and 314 by WSI)
- 95% of which were for neurosurgical cases.
- Average of 9.98 minutes RM decreased to 2.71 minutes with WSI
 - 26% of cases requiring < 1 minute/slide and
 - 43% of cases < 2 minutes/slide.
 - Smears were examined in addition to FS slides in 30% of the WSI cases.
- Diagnostic accuracy was 98% for both WSI and RM, however the use of WSI has markedly improved pathologist satisfaction.

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UHN Telepathology: Due Diligence Before Going Live

- Medical Malpractice Insurance Provider
 - Canadian Medical Protective Association (CMPA)
 - Telepathology will not affect coverage
- UHN Medical Advisory Committee
 - SOP presented for approval
- Federal Health Protection Branch - Ottawa
 - Telepathology does not involve “medical devices” (no direct contact between instrument and patient) – no HPB approval required
- Surgeon Education
 - Demonstrating the robotic microscope/slide scanner
 - Essential to get surgeon buy-in!

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From the conventional microscope to the digital slide scanner in routine diagnostic histopathology

Sten Thorstenson, MD
Medical Director
Department of Pathology and Cytology
Kalmar County Hospital
Kalmar, Sweden

Presented @ Pathology Visions 2009, San Diego

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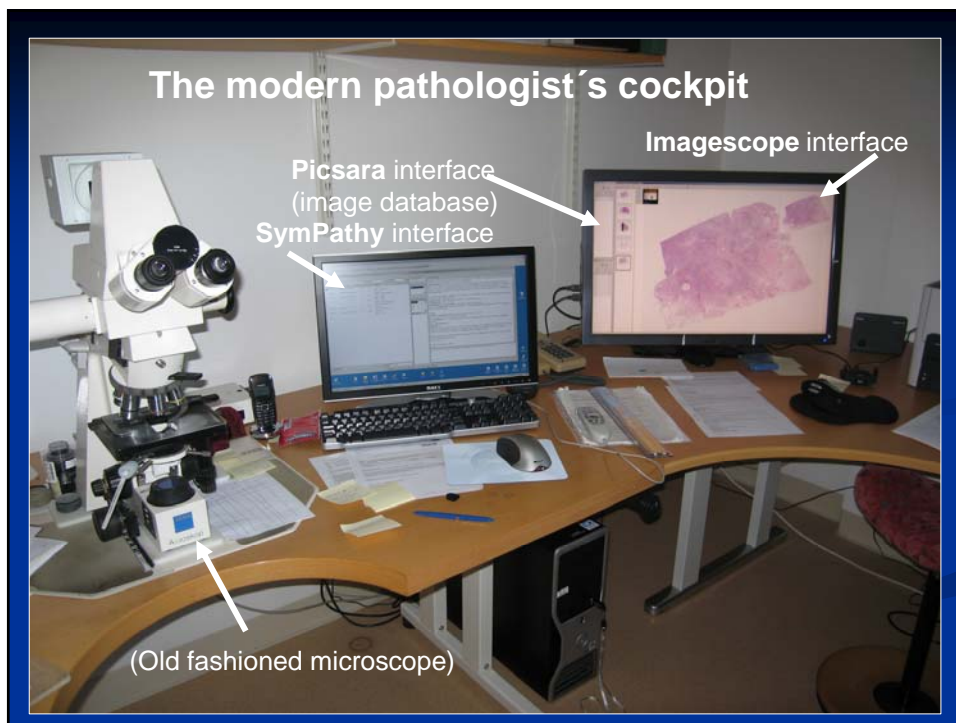
Kalmar today

- >60000 histopathology slides have been scanned
- 24 hr scanning (2 Aperio Scanscope XT)
- 1.5 years of routine histopathology diagnostics
- >75% of the routine histopathology is diagnosed digitally
- 10 years experience of digital telepathology frozen section service.
- Some clinicopathological conferences digitally
- Individual digital slide conferencing (on demand from clinicians)

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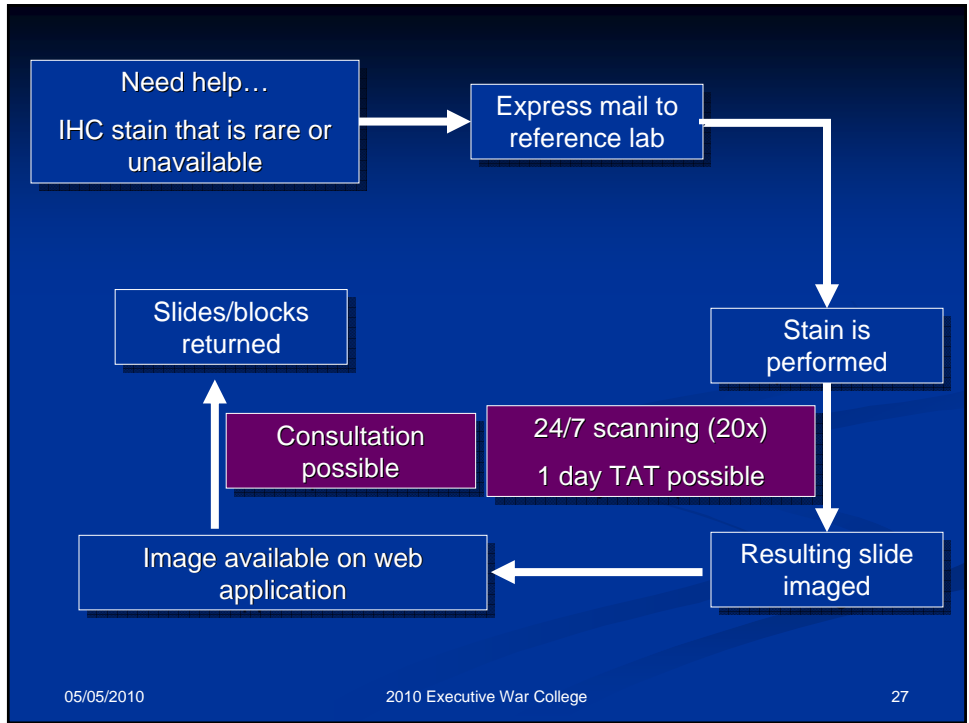
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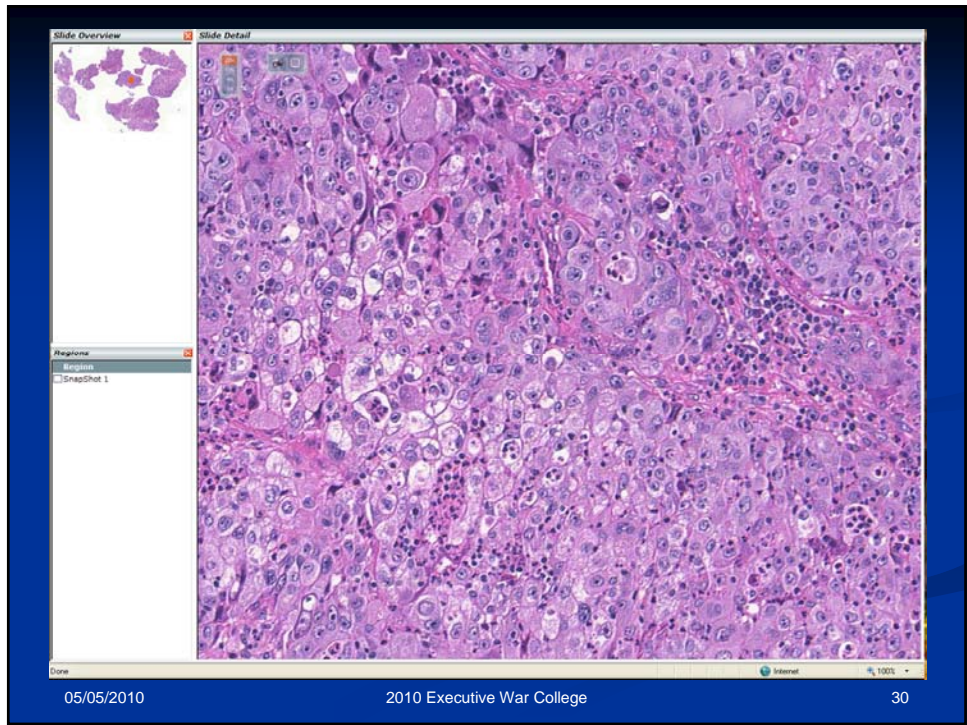
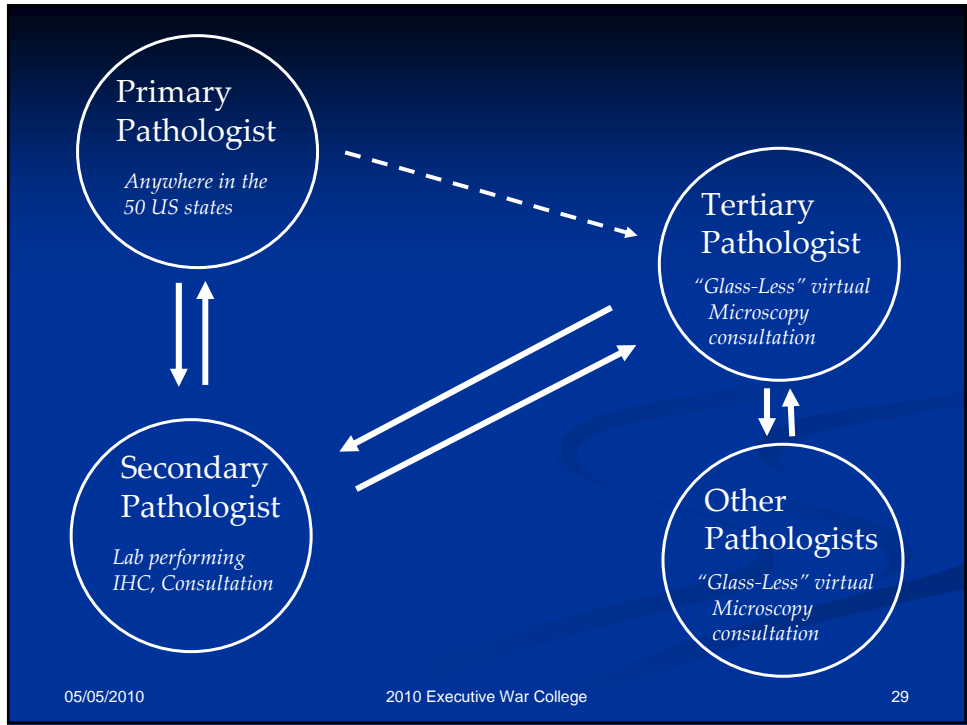
Virtual IHC Business Model

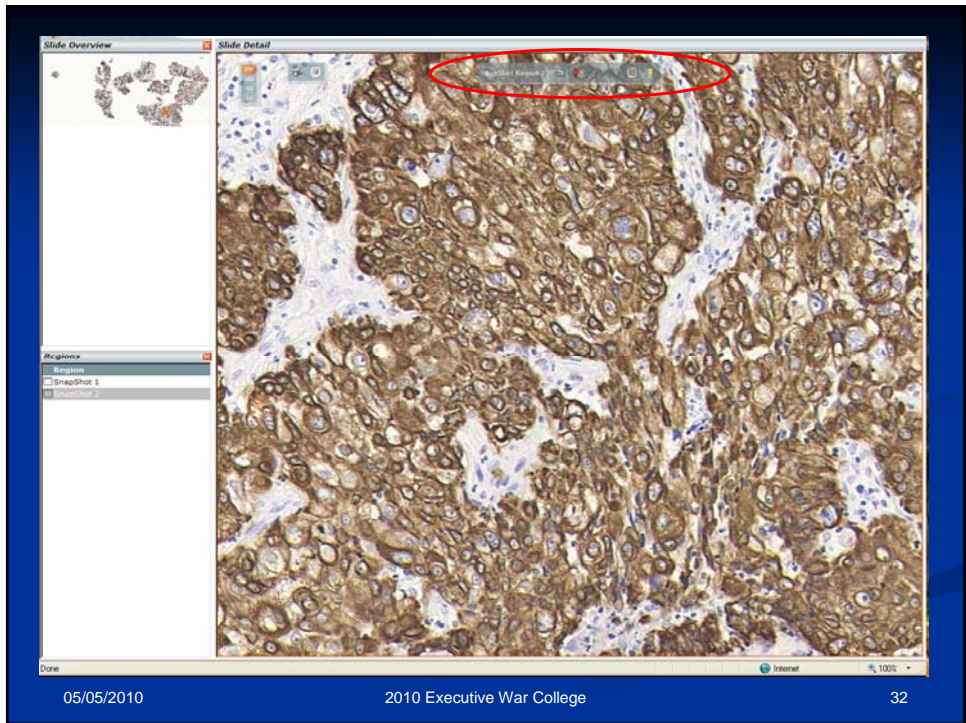
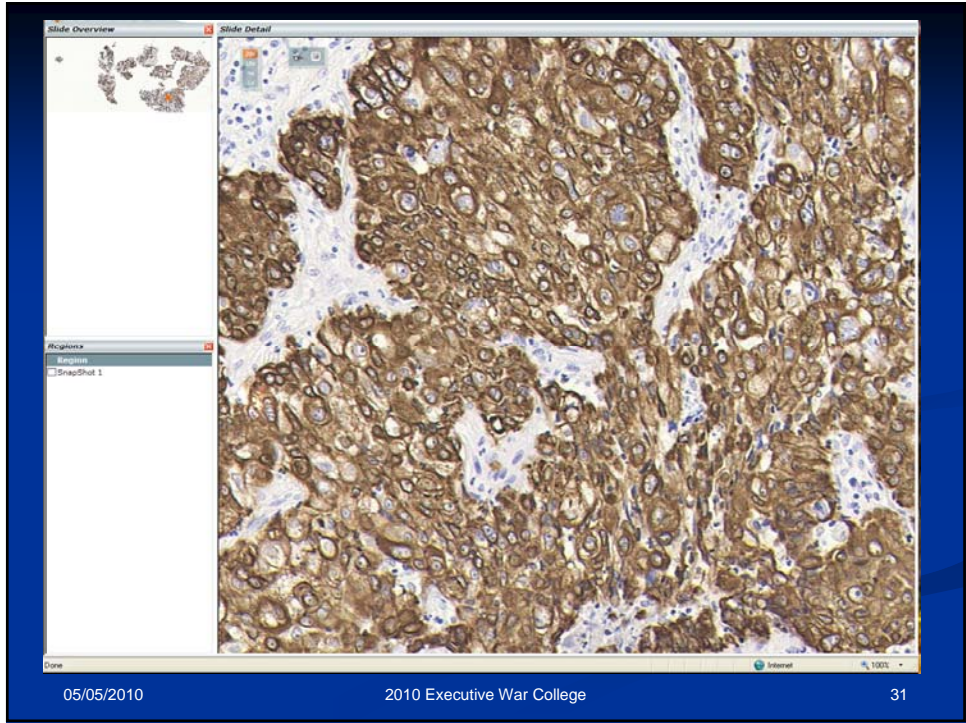
- Large laboratories partnering with pathologists or pathology groups
- Large laboratory performs technical component
- Pathologists performs professional component



	Central Lab	Referring Pathologist
Capital investment	Yes	
Large menu		Yes
Research and Development	Yes	

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Work List - Windows Internet Explorer

Drag a column header here to group by that column

Case No	Synopsis	Patient Name	Client	Priority	Case Type	Received	Pathologist
10452500				Eastern	Consult		Kaplan, Keith
10449912				Eastern	Consult		Kaplan, Keith
10452455				Eastern	Consult		Kaplan, Keith
10443275				Central	Consult		Kaplan, Keith
10453275				Central	Consult		Kaplan, Keith
10449411				Pacific	Consult		Kaplan, Keith
10452002				Pacific	Consult		Kaplan, Keith

Report to XLS Report to PDF Number per Page: 30

Done Internet 100%

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Entry Screens - Windows Internet Explorer

Users: Kaplan, Keith
Roles: Pathologist

Work List Setup Test Information Billing Security

Case No: No of Blocks:
Patient Name: No of Unpaired Slides:
Gender (DOB): No of Containers:
Accession ID:

Body: -- Select Macro -- Spell Check

Save Changes Launch VIGS Remove Slan Table from Report
INC Consult 4

Client Name:
Client Phone:
Ordering Phys

Concurrent Cases: 3M 4/22/09

Patient History: Controls Order Date Comp. Report Info

Test Add-On View Images

Slan Name	Block #	Result	Case
Acqs - Smooth Muscle	1		
Calcitonin	1		
Calcitonin	1		

Done Internet 100%

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Image Analysis

- Image analysis for quantitative immunohistochemical stains
 - Machines are good at counting
 - They are not very good at thinking
 - Good reproducibility
 - Better information
 - Associated increase in billing codes relative to manual IHC

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Inconsistency of HER2 Test Raises Questions

J Natl Cancer Inst 2007;99(14)1064-1065.



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American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer

Antonio C. Wolff, M. Elizabeth H. Hammond, Jared N. Schwartz, Karen L. Hagerty, D. Craig Allred, Richard J. Cote, Mitchell Dowsett, Patrick L. Fitzgibbons, Wedad M. Hanna, Amy Langer, Lisa M. McShane, Soonmyung Paik, Mark D. Pegram, Edith A. Perez, Michael F. Press, Anthony Rhodes, Catharine Sturgeon, Sheila E. Taube, Raymond Tubbs, Gail H. Vance, Marc van de Vijver, Thomas M. Wheeler, Daniel F. Hayes

Archives of Pathology and Laboratory Medicine: Vol. 131, No. 1, pp. 18–43.

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Preanalytic

- Time to fixation
- Method of tissue processing
- Time of fixation
- Type of fixation

Analytic

- Assay validation
- Equipment calibration
- Use of standardized laboratory procedures
- Training and competency assessment of staff
- Type of antigen retrieval
- Test reagents
- Use of standardized control materials
- Use of automated laboratory methods

Postanalytic

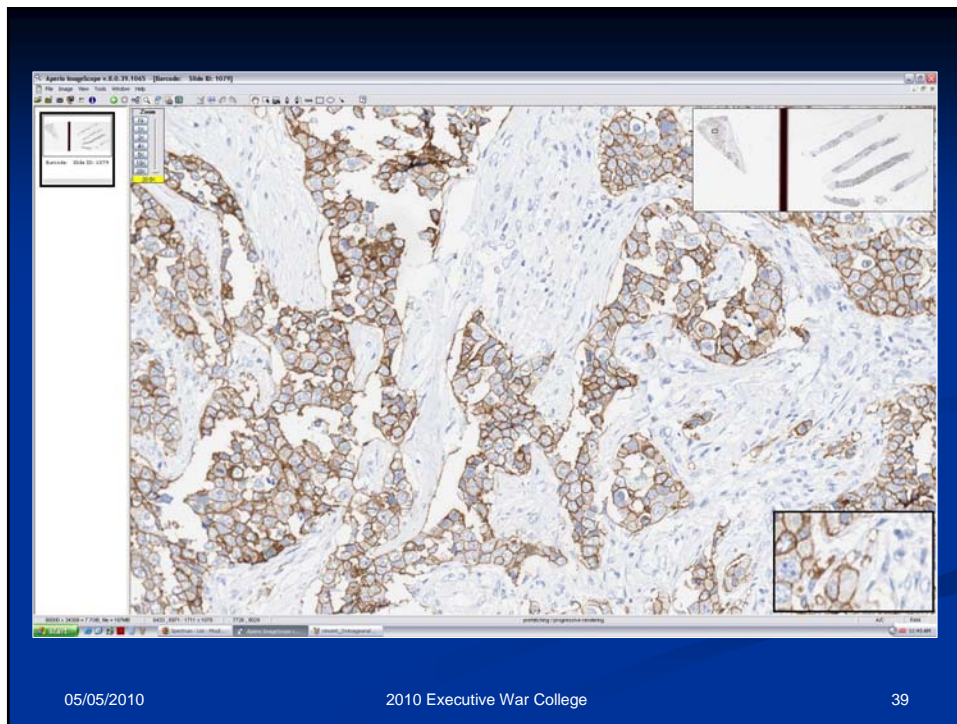
- Interpretation criteria
- Use of image analysis
- Reporting elements
- Quality assurance procedures
 - Laboratory accreditation
 - Proficiency testing
 - Pathologist competency assessment

Abbreviation: HER2, human epidermal growth factor receptor 2.

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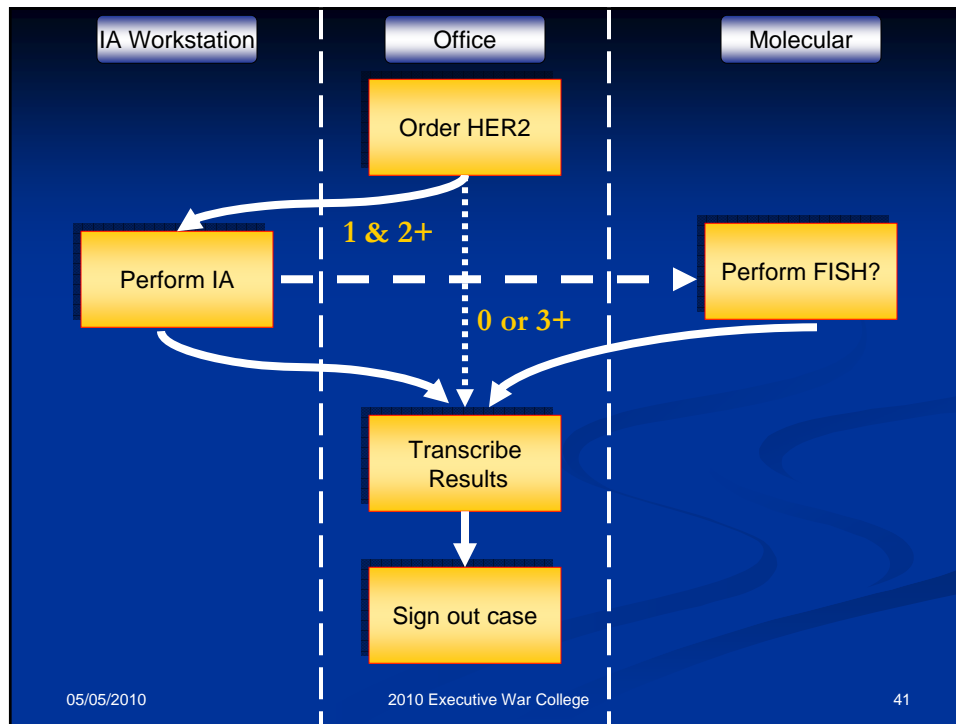
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Conclusions

- IA appears to be more accurate than MA in HER2 IHC, particularly for 2+ cases (FISH non-amplified)
- Algorithms appeared to overscore or underscore a minority of cases, particularly 1+ IHC cases (FISH non-amplified)
- Pilot study suggests a role for IA in 2+ cases to avoid unnecessary FISH testing in overscored cases
- Cost and time required for WSI analysis may still be prohibitive for routine clinical use without added resources in the laboratory for IA.



Reimbursement

- CPT 88360 – Morphometric analysis, tumor immunohistochemistry (e.g., Her2/neu, estrogen/progesterone receptor), quantitative, **semiquantitative**, each antibody; manual
 - PC+TC=\$147.95
- CPT 88361 – Morphometric analysis, tumor immunohistochemistry (e.g., Her2/neu, estrogen/progesterone receptor), **quantitative**, semiquantitative, each antibody; using computer assisted technology
 - 88361 PC+TC=\$229.16 $\Delta(TC+PC)=$81.21$
- HER2 FISH
 - 88368 PC+TC=\$710.00

Technology: For Nations That Lack the Expertise, an Automated System for Detecting TB



<http://www.nytimes.com/2010/04/13/health/13glob.html>

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Is it worth it?

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Sacred Heart Pathology, LLC

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The 'Stage'

- Pathology practice
 - 5 pathologists
 - Sacred Heart Hospital
 - 300 beds
 - Willmar, MN
 - Rural practice
 - Hospital and Outpatient Procedure Clinic
 - 20,000 surgicals/year
 - Bone marrows, pap smears, FNAs
 - Fully staffed histology lab (IHCs)
 - Pathology assistant



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The 'Scenario'

- Watertown, SD
 - Solo pathologist retiring
 - 110 miles away
 - Low frozen section volume
 - 5,000 surgicals/year
 - 20 frozen section slides/week
 - Histology lab fully staffed (No IHC)
 - Pathology assistant

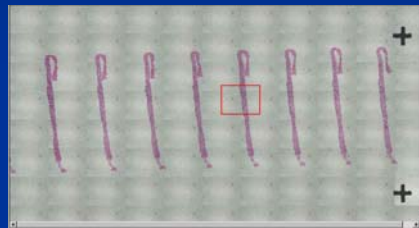
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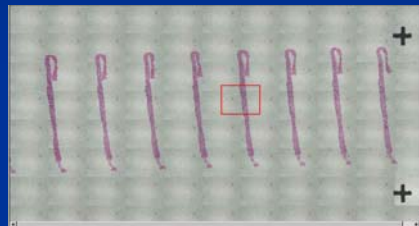
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Whole slide imaging scanner

■ Scanner

- \$120,000
- 1-yr warranty
- Expected use 5 yrs
- \$10,000 after 5 yrs
- \$2,000 maintenance/yr



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Cost Scenario 1: Hire Pathologist

■ Fixed cost

■ Pathologist	\$230,000
■ Pathology assistant	\$65,000
■ Histotech	\$36,000
■ Secretary	\$30,000
■ Courier service	\$6,000
■ Histology lab	\$8,000
■ Frozen section lab	\$1,000

■ Variable cost

■ Frozen section supp	\$5,000
■ Histology supplies	\$50,000

■ **Total** \$431,000

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Cost Scenario 2: Driving

■ Gas	\$9,000
■ Loss of productivity	\$115,000
■ Time lost	<i>priceless</i>

■ **Total** = #2 + (#1 – pathologist's salary)
= \$124,000 + \$201,000
= **\$325,000**

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Cost Scenario 3: Buy Scanner

■ Fixed cost	
■ Scanner	\$24,000
■ Pathologist assistant	\$65,000
■ Courier service	\$12,000
■ Frozen section lab	\$1,000
■ Variable cost	
■ Frozen section supplies	\$5,000
■ Total	\$107,000

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Savings

Hire Pathologist

■ Fixed cost	
■ Pathologist	\$230,000
■ PA	\$65,000
■ Histotech	\$36,000
■ Secretary	\$30,000
■ Courier service	\$6,000
■ Histology lab	\$8,000
■ Frozen section lab	\$1,000
■ Variable cost	
■ Frozen section supp	\$5,000
■ Histology supplies	\$50,000

■ Total	\$431,000
---------	-----------

Buy Scanner

■ Fixed cost	
■ Scanner	\$24,000
■ PA	\$65,000
■ Courier service	\$12,000
■ Frozen section lab	\$1,000
■ Variable cost	
■ Frozen section supp	\$5,000

■ Total	\$107,000
---------	-----------

Savings: \$324,000

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Additional Benefits to Integrating Digital Pathology into Practice

- Tumor boards/Conferences/Teaching



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Additional Benefits to Integrating Digital Pathology into Practice

- Model for further expansion/acquisitions



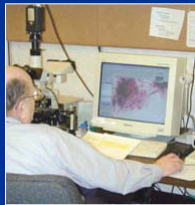
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Additional Benefits to Integrating Digital Pathology into Practice

- Consults
 - No slides sent through mail
 - Possibly faster TAT
 - However, additional stains = old way



Versus



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Quick Review of Groups Goals

- Provide excellent service to clinicians
 - Frozen section interpretation
 - Quick turn around time
- Harness combined knowledge of staff
- Use pathologists' time efficiently
- Use technology to improve service
 - Additional tests
 - Faster TAT
 - Expansion

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Limitations/Weaknesses

- Fewer (same) people doing more
- Technical cost considerations
- Use may not justify expense (# of FS)
- Back up plan
 - A difficult case is a difficult case
 - Technical problems
- Intangible benefits
 - Face on the lab/Morale
 - Clinical laboratory functions
 - Direct communication/interaction with clinicians

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Is it worth it?

- It depends – volume/cost & time of travel
- Utilize existing personnel to manage risk
 - Negate solo-pathologist/risk management
 - Consult with colleagues
 - Rapid subspecialty consultation
- Lose intangible benefits
 - PR – Face-to-face discussion with clinicians
 - Morale

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Is it worth it?

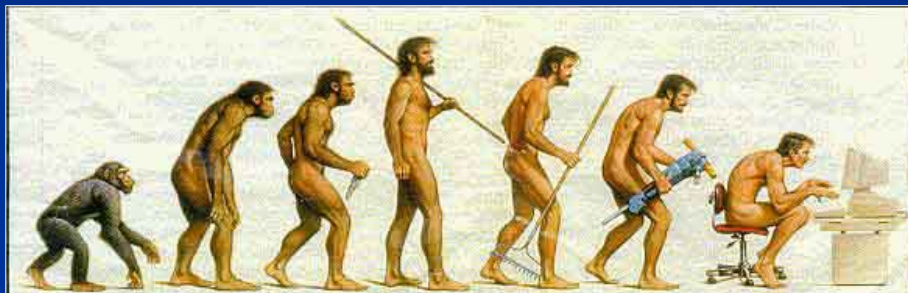
- Leverage technology into clinical business practice
- Transplant biopsy services
- Toronto General Hospital brain freezes
- Canadian provincial services networks
- DOD/VA
- Scandinavia/Europe
- Emerging markets – Asia/India

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Lessons learned



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General

- Technology diffusion & adaptation
 - “Technology is the easy part, changing hearts and minds is the hard part.”
- IT issues
- Human resources/personnel
- Sustainability
 - “Almost as good as light microscopy”
 - Not exactly the same – human user interface
 - As fast as glass

Insurance & Medicolegal Issues

- Check with local carriers and providers
- Telemedicine law and lawyers
- Nuances of clinical practice will dictate



It is agreed that no coverage is provided for liability arising out of the insured's activities performed for or in conjunction with Walter Reed Army Medical Center, telepathology, or the State of Pennsylvania.



Special Section on Telepathology

Medicolegal aspects of telepathology

Stanley T. Leung MD, JD*, Keith J. Kaplan MD

Received 10 November 2008; revised 14 January 2009; accepted 16 January 2009

3. Malpractice and liability

There is little case law that addresses the unique liability issues that could arise in telemedicine. Indeed, the state regulation of torts and medical malpractice usually leads to administrative remedies prior to adjudication by the courts. Thus, it is unlikely that a case would rise to the level of an appellate court in order to establish such case law.

The traditional tort or malpractice analysis should be performed in evaluating telemedicine liability:

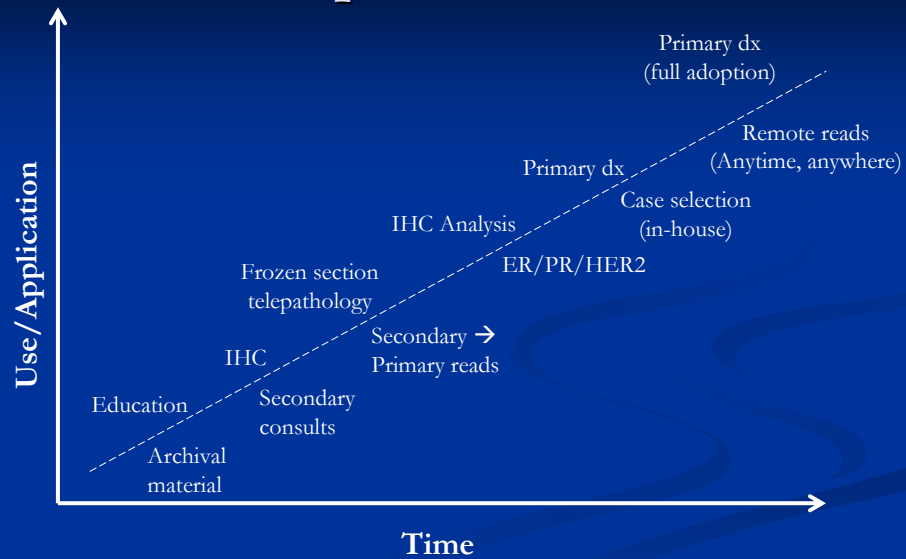
- Duty
 - (Is there a PPR? Foreseeable plaintiff?)
- Breach of the duty
 - (Has *standard of care* been met?)
- Damage caused by Breach
 - (Is there a remedy at law or equity?)
- Proximate Cause
 - (1. Actual “but for...”, substantial factor? 2. Foreseeable injury?)

Seven states have general exceptions to their state licensure laws that applied specifically to telemedicine. Alabama, Indiana, and Minnesota do not require out-of-state physicians to obtain a license to practice medicine from their home states if the physician does not practice in their state frequently. However, only Alabama provides a definition of “frequent” in its regulations:

if such practice occurs less than ten (10) times in a calendar year or involves fewer than ten (10) patients in a calendar year or comprises less than one percent (1%) of the physician’s diagnostic or therapeutic practice [11].

Illinois and Tennessee do not require a license if the physician is merely providing a second opinion. New Jersey and Washington do not require a license if the physician does not open a physical practice in the state or accept calls in the state. Thus, it would seem that in Illinois, Tennessee, New Jersey, or Washington state, the practice of telepathology, in an exclusively consultative role as a pathologist providing a second opinion to another pathologist in the state where the patient resides, would fall under such exceptions. However, all 7 states require that the out-of-state physician has an unrestricted license to practice medicine in the location of the distant physician in order to qualify for these exceptions.

Niche Adoption – Whole Slide



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Resources

- VIC Telepathology & Whole Slide Imaging Course – Updated March 2010
- CAP Futurescape series
- Digital Pathology Association
- APIII-LITS

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Digital Pathology Blog - Whole Slide - Windows Internet Explorer

http://www.tissuepathology.com/wslblog/whole_slide/

NBR on PBS Blog Now on Digital Pathology

[The Big Deal about Digital Pathology](#)

posted by Jeff Yastine, Senior Correspondent at 5:47 PM on 07/10/08



When I first started researching tonight's story on "digital pathology" with my colleague Tess Patevskas, the first question I thought of was -- you hook up a digital camera to a pathologist's microscope, and you get "digital pathology." What's the big deal? Of course, the big deal is that a pathologist needs to zoom in and look at very small details on a microscope slide. How do you ever find zooming in to the finest elements on a digital family photograph? What happens? The resolution degrades and all the details in the picture disappear.

There are actually two major technological challenges in "digital pathology." One is getting enough detail. To examine just one microscope slide you need to render and store what amounts to 20 or 30 gigabytes of memory. The second challenge centers on the speed of the scanning process. In years past, the scan took many minutes to complete. If a hospital pathology lab is running out streams and even hundreds of slides every day and each slide takes minutes and minutes to digitally scan, the idea of "digital pathology" seems highly impractical. Today, both these challenges have been nearly overcome. And, the systems that make digital pathology possible are now available at a cost more hospitals can afford.

The industry leader in digital pathology is a California-based company named Aperio. Company representatives told me that we're still in the earliest phases of a revolutionary change in pathology. What's on the horizon? Computers and algorithmic software that actually "read" the slides, looking for multiple "bio-markers." This advancement will automate -- and further speed up -- the diagnosis process.

Posted at 04:30 AM in [tissue path](#) | [Permalink](#) | [Comments \(0\)](#) | [Trackback \(0\)](#) | [Share This](#)

July 11, 2008

'Bill of Health' - Digital Pathology

PBS Transcript of recent story on digital pathology

Thursday, July 10, 2008

SUSE GHARIB: In health care, digital X-rays and CT-scans have become commonplace. But the field of pathology is just beginning to enter the digital era. As Jeff Yastine reports in tonight's 'Bill of Health,' it's a change that promises faster diagnoses for patients and potential cost-savings for hospitals.

JEFF YASTINE, NIGHTLY BUSINESS REPORT CORRESPONDENT: For more than a century, this is how pathologists, specialists in identifying disease through the study of human tissue, do their job: a high-powered microscope, and glass slides embedded with tiny slices of tissue samples. But some pathologists, like Dr. Andres Morales, are beginning to embrace new digital pathology tools. The technology lets them rapidly scan and digitize dozens of glass slides at a time, then a pathologist can use a computer screen just like a microscope.

DR. ANDRES MORALES, PROFESSOR OF PATHOLOGY: I will have exactly what is in this slide. And then I could focus on a specific area there and bring that up and move the slide around. So I say, OK, I want to look at this in higher resolution.

www.tissuepathology.com

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Smith, Jane 09-9901 Cancel ADD-09-171 Send Slip

Pathologic Diagnosis: Skin, back, shave biopsy - Compound dysplastic nevus

Microscopic Description: There is lentiginous epidermal hyperplasia with bridging. Junctional nevi are present laterally for a distance of at least 2-3 ridges past the lateral limit of the population. Junctional nevi are present singly as well as in nests on the sides, as well as at the tips, and ridges. Nevus cells display moderate to severe cytologic atypia, with moderate to severe nuclear enlargement, hyperchromasia, a high mitotic rate, and abundant, dark cytoplasm. In the papillary dermis, there is chronic inflammation, neovascularization, and fibrosis. Margins of the shave specimen are uninvolved in the areas available for examination.

Specimen number: 09-9901

10:42

Back To Image Select Settings

Spectrum

(return from library images)	100% of immunofluorescence sample images	HgTTF sample images	CAP
Fluorescence	HP	3D Z-stack images	Print SR20s.tif
Print Hx2.tif	Print PR2.tif	Cell Area.tif	Print.tif
Print Hx2.tif	Print PR2.tif	Cell Area.tif	Print.tif
Print Hx2.tif	Print PR2.tif	Cell Area.tif	Print.tif
Print Hx2.tif	Print PR2.tif	Cell Area.tif	Print.tif
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Print Hx2.tif	Print PR2.tif	Cell Area.tif	Print.tif

Add from album Delete

1.8

Stop Play Rewind

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Found In Cache - Social Media resources for health care professionals from Ed Bennett

HOME FRIDAY FOLLOW ABOUT SEARCH TOOLS HOSPITAL SOCIAL NETWORK LIST SUBSCRIBE

Found In Cache

Social Media resources for health care professionals from Ed Bennett

Hospital List Update for April 2010

By ED BENNETT on APRIL 20, 2010

A big update this month, with 60 new hospitals added. Thanks to [Richard Harmon](#) for the VA listings, and [Tricia Wilkerson](#) for a large batch that I didn't have.

660 Hospitals total
 - 508 YouTube channels
 - 458 Facebook pages
 - 507 Twitter accounts
 - 89 Blogs

Full list after the break:
[More after the jump...](#)

Like Be the first of your friends to like this.

SEARCH THIS SITE
 To search, type and hit enter

SOCIAL MEDIA RESOURCES
 The Big List by State
 - Childrens Hospitals

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PathXchange Pathology 2.0 - Global Online Pathology Community

PathXchange | Pathology 2.0 - Global Online Pathology

PathXchange

Case of the Week

Membership is FREE!

SecondSlide - Digital Slide Sharing Services for Pathology

SecondSlide

SecondSlide improves turnaround time for consultations by eliminating glass slide logistics.

- Juan Rosai, MD

FREE SERVICE

Featured Collection

Free Digital Slide Sharing Service for Pathology

SecondSlide makes slide sharing easy:

- Share slides with anyone you choose, regardless of geographical location
- Improve turnaround time
- Eliminate glass slide logistics
- Provide pathology services to remote hospitals
- Gain access to subspecialty expertise

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Conclusions

- Digital pathology functional performance is adequate and improving
- Those who gain entry now are less likely to fall behind
- Gain a competitive advantage

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Thank You



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