Tele-pathology Evolution and Usage

Jared N Schwartz MD PhD
August 21, 2013
CLIAC Meeting
Atlanta, GA

Disclosures

All comments, opinions, and recommendations presented today are solely mine and not those of my employers or any other entity.

Disclosures

- Chief Medical Officer, Leica Biosystems
- Consulting Professor Pathology, Stanford School of Medicine
- Board of Directors, Personalized Medicine Coalition
- Board of Directors, American Pathology Foundation
- Advisory Board Cancer Commons
- Past-President College American Pathologists
- Past-Member of CLIAC

# Tele-Medicine and Digitization Not New in Medical Devices

- Digital Otoscopes
- Digital Stethoscopes
- Digital Cameras on Microscopes
- Digital Video on Microscopes
- Endoscopy and many more
- **Are Images Good Enough to Make DX? Yes**

Digital Microscopes (Whole Slide Imaging: WSI)
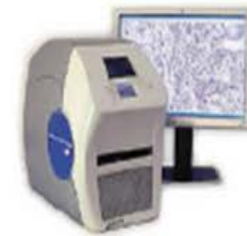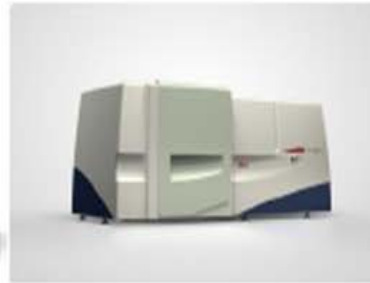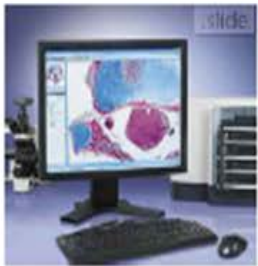
Hamamatsu Olympus Claro…
Aperio Omnyx Phillips Ventana Leica Zeiss …
and more

Different Tools - Same Image

Pathology 2.0
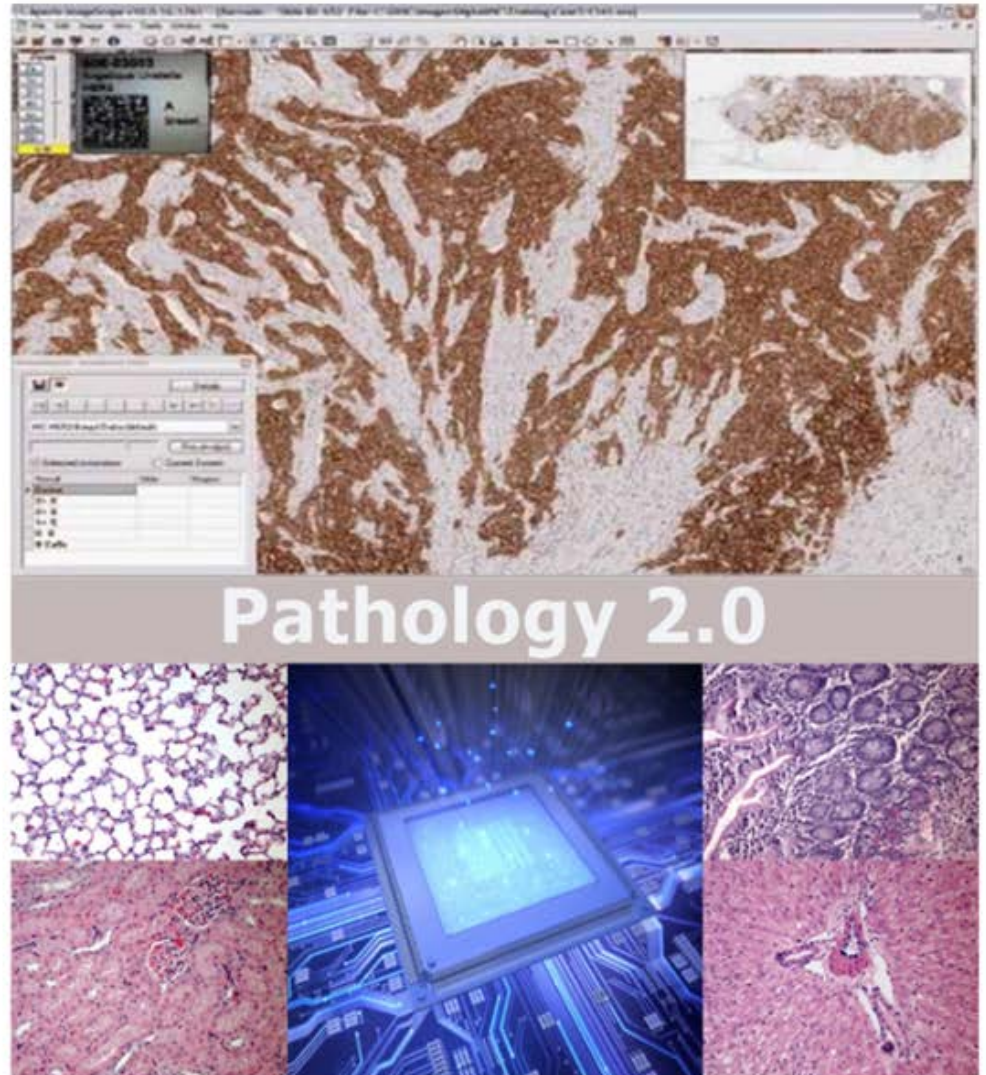
"Whenever science makes a discovery, the devil grabs it while the angels are debating the best way to use it."

~Alan Valentine

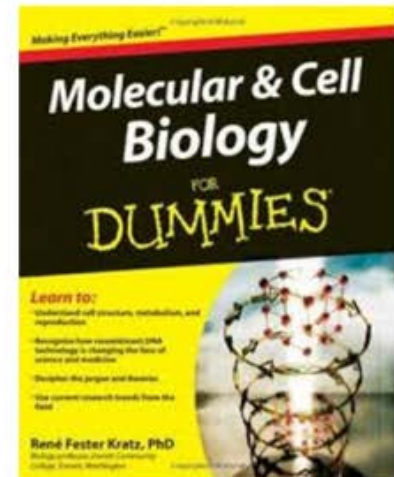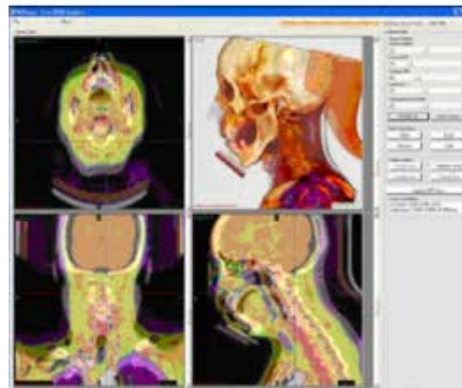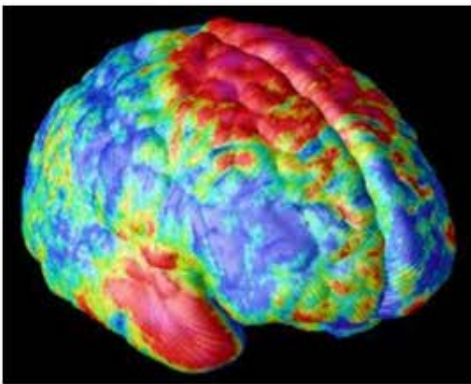… it's not about the tools, it is about the PEOPLE

Minimally Invasive Robotic Surgery eSurgery / In Vivo Imaging/ Sequencing on a Chip

The specimens we receive are getting smaller and smaller, yet expected to obtain so much more usable information

Does Viewing Pathology Images Place Patient in Harms Way

- Pathologists have 1:1 relationship with image be it glass or digital

- Not True for Chemistry/Hematology/Cytology Analyzers

- Glass Slide **Always** Available (Nearby, Courier Service)

- **Pathologists Can Always Go Back To Original Source of Image**

Why do Something Now?

Why paper isn't the answer

This is a top Pathologist's office

Glass slides are a challenge

I want to compare this to the last specimen?
Where is the patient's past biopsy?

I need an expert, opinion, fast?

Cases ready to ship

Collaboration is essential

Where are the results?

Patients are worried

Waiting times are too long

Digital Pathology Can Make a Difference

What is WSI DIGITAL PATHOLOGY ePathology?

- **ePathology** is a complete scan of a microscopic glass slide (eSlide) and the viewing of the eSlide on a computer monitor through a software system

- **ePathology** is the process by which a patient's pathology results, **including images**, are available in their electronic medical record

- ePathology **Means Much More** to Pathology Research and **Patient Care**
  - **Engage** Pathology more easily to support patient care
  - **Ease** of access limited specialty resources
  - **Efficiently** manage of turn-around time
  - **Effectively** communicate critical information across care settings with different providers and patients
  - **Expand** Quality Assurance Tools
  - **Enable** use of Mobile Technologies for Sharing & Education
  - **EXCITE** and **ENTICE** Medical Students, Graduate Students, Histology Staff, and Residents to an ever **EVOLVING** Specialty Career in Pathology Research and Clinical
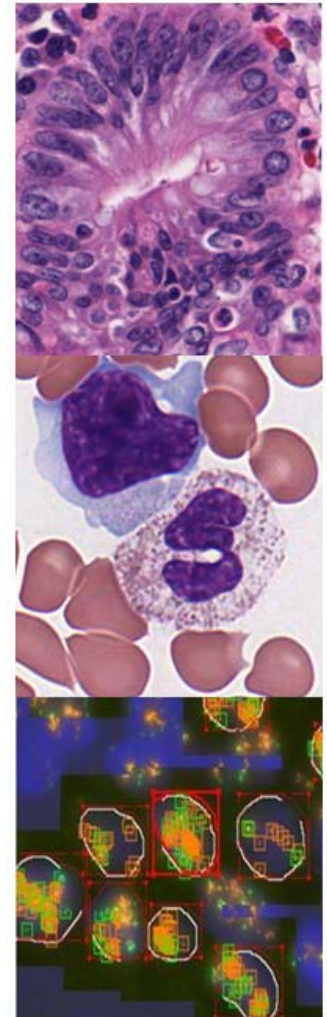
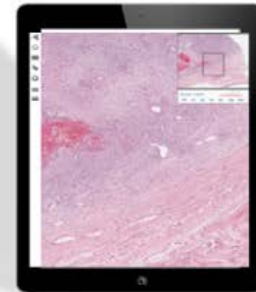# All Pathology Images...

From Procedure Room –
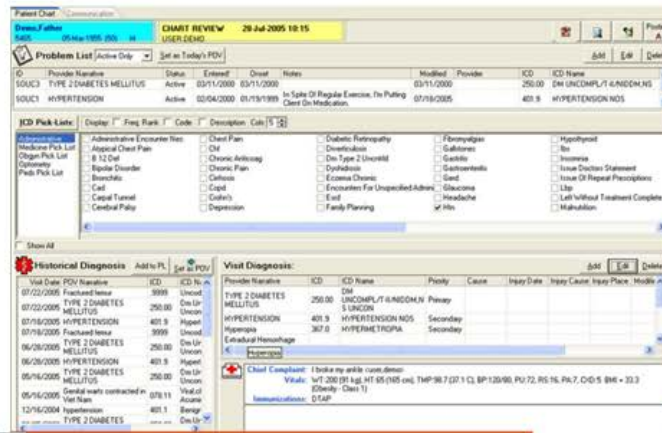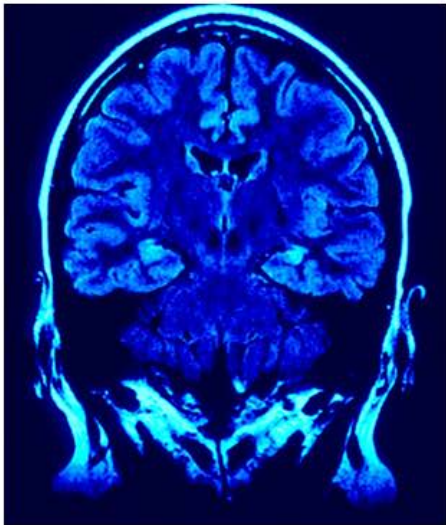

to Pathologist –

to Patient's EMR –

WSI Scanner

to Your Mobile Device!

eSlides Means All Pathology can be Integrated into the LIS and Ultimately the EHR and/or What Else?

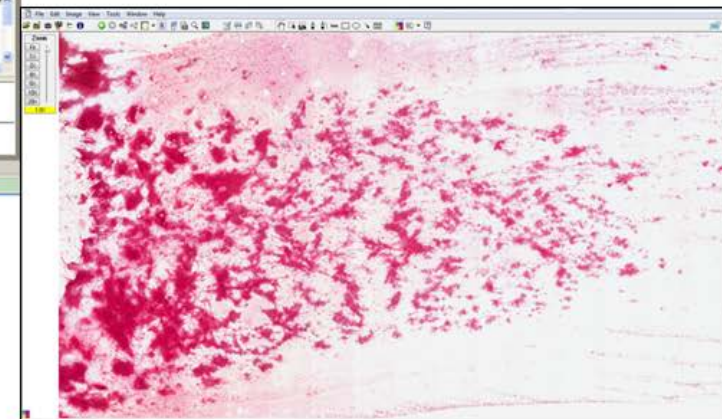Radiology

Pathology
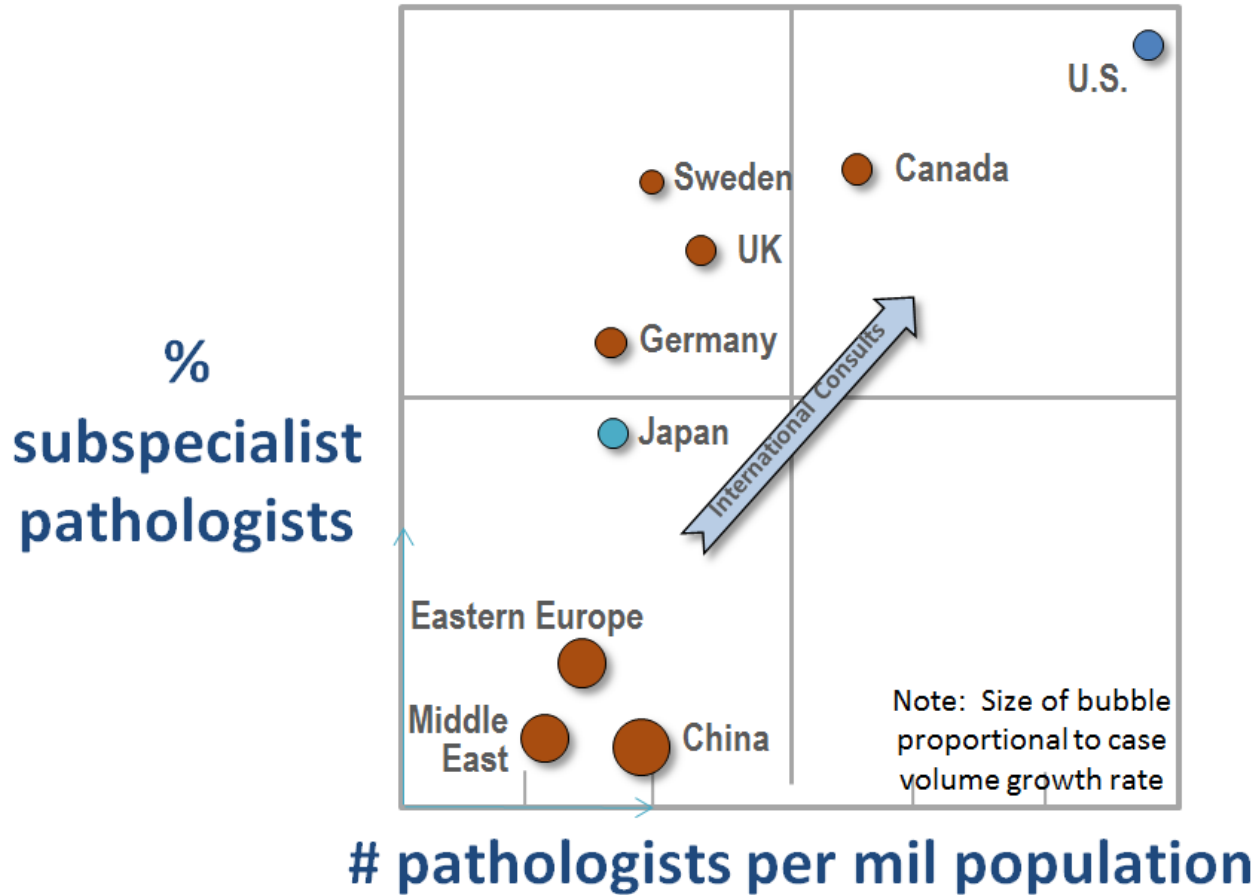
digitize

OMICS
A Journal of Integrative Biology

eSlides Integrated into LIS

EMR

Severe Shortage of Pathologists and Especially Subspecialists

HHS Digital Priorities


STRATEGIC GOAL 1:
HEALTH CARE

Strategic Objective 1.1:
Broaden health insurance and
long-term care coverage

Strategic Objective 1.2:
Increase health care service
availability and accessibility

Strategic Objective 1.3:
Improve health care quality,
safety, cost, and value

Strategic Objective 1.4:
Recruit, develop, and retain a
competent health care
workforce

Pathologists Can and Are Providing Help to Hospitals/Communities with No Pathologists
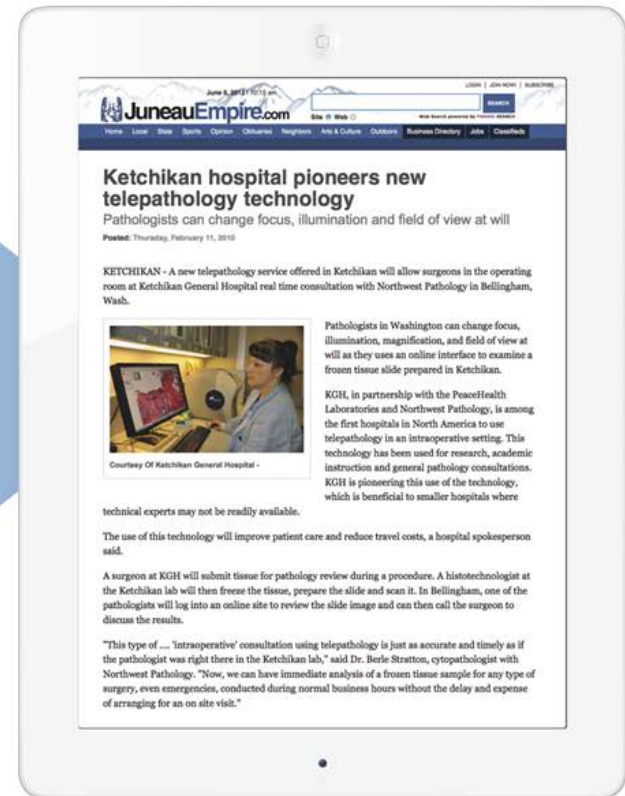
Networks Using WSI are Enabling Regional Centers to Provide Access and Assistance

Major technological advance improves cancer treatment at Kuwait Cancer Control Center

Kuwait: Monday, July 09 - 2012 at 13:38 | PRESS RELEASE

The University Health Network (UHN) in partnership with the Kuwait Cancer Control Center (KCCC) and the support of the Ministry of Health, have installed cutting-edge telepathology equipment in the KCCC laboratories

Telepathology is defined as the "practice of pathology at a distance using telecommunications technology to make it possible to transfer image-rich pathology data between distant locations for the purposes of diagnosis, education, and research." UHN is a leader in the field of telepathology.

The Chief Pathologist at the Kuwait Cancer Control Centre (KCCC), Dr Salah Al-Waheeb, was asked by a colleague from a nearby hospital to look at microscope slides of a tissue specimen from a Kuwait citizen that he thought had a rare type of cancer.

Usually, when this type of situation arises; a biopsy is done to get a specimen from a mass found in the body. This specimen is then placed on microscope slides to be reviewed by a pathologist to confirm the type of cancer and its changes of malignancy. Specialists would then be able to prescribe the correct treatment for the diagnosed cancer.

Dr Salah Al-Waheeb looked at the microscope slides and requested that they be sent for review by his Canadian colleague, a specialist pathologist located at UHN in Toronto, Canada.
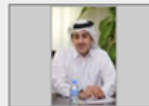
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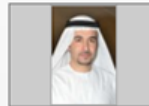
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HULT

Global brand leaders to share best practices to... »

- Easy and intuitive way for Pathologists to share cases with Pathologists for expert opinions

- Seamless workflow for requesting internal or external sharing

- Easily identify collaboration requests

# Use of eSlides Enabling Us to Do More Without Traveling: A Sample

UCLA

May 06, 2010

Live tele-consultation of complex cases, professional pathological diagnosis, regular packaged delivery---these are steps to guarantee the double check of diagnosis of every patient's pathology by experts of both the Second Affiliated Hospital Zhejiang University and UCLA Medical Center. This is the perspective on joint pathology consultation by the Second Affiliated Hospital and UCLA stated by Prof. Rao Jianyu, tenured professor of pathology and epidemiology at UCLA Medical Center, Director of gynecologic pathology and cytopathology

The medical diagnostic center at the Second Affiliated Hospital Zhejiang University is the first one UCLA Medical Center is involved in, and it is an exploratory pattern expected to benefit not only people of Zhejiang Province, but also of a wider area in near future. This is regarded as one step toward the goal of medical reform

It's learned that UCLA Medical Center has a reservoir of more than 30 experts in pathology to provide remote medical consultation service. Most of these specialists in cell pathology, urinary pathology, etc., have rich clinical experiences with solid academic background and patients with complex cases or special requests can have their pathological images transmitted to UCLA for diagnosis

Cleveland Clinic
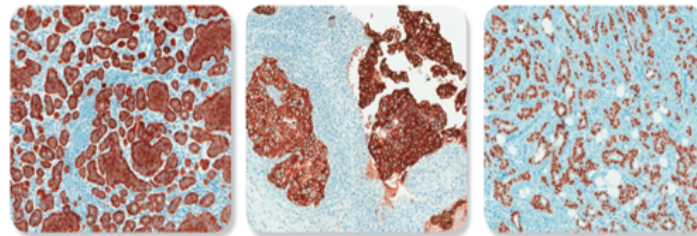
eIHC
Leveraging Digital Image Technology for Rapid Interpretation of Immunohistochemical (IHC) Stained Slides

Incorporating technological advances in digital imaging (eSlides) enhances research, education, and patient care across the street and around the world. Cleveland Clinic Laboratories now offers web-based eSlides of IHC-stained slides to help optimize clinical workflow for IHC.

In collaboration with Aperio, a provider and global leader of ePathology Solutions, a secure internet site provides access for clients to read immunohistochemically stained eSlides on a computer monitor anytime, anywhere. When a case is opened, all case, specimen and slide information, as well as controls are conveniently at your fingertips.

The service provides access to eSlide conferencing and secure messaging allowing the pathology community to engage in dialog and exchange information.

The opportunity to view stained eSlides within 24 hours after the blocks arrive at Cleveland Clinic may help clients follow a staining algorithm rather than requesting batches of stains, some of which may ultimately be unnecessary.

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DIGITAL

UPMC Digital Pathology Consultation Portal

Now it's easier than ever to send your slides electronically and let UPMC Pathology experts be your second set of eyes for diagnosis and treatment.

The UPMC Digital Pathology Consultation Portal gives you a valuable second opinion necessary to be accurate and efficient in both diagnosis and treatment.

Enter the UPMC Digital Pathology Consultation Portal

Our pathologists, who are physicians at UPMC and faculty of the University of Pittsburgh, deliver their expertise and high-quality consultation directly to your practice, hospital, or lab. Now you can get rapid consultations with no mail, courier, or inconvenience required.

Through this exclusive technology, you overcome geographic, time, social, and cultural barriers by connecting to the set of second subspecialty eyes needed to speed diagnosis and treatment of your patients.

A Gateway to Better Health Care

We will set up infrastructure on your terms and make it easy to open unsurpassed access to our team of pathology experts.

Your slide image systems and whole-slide scanners are an easy gateway to real-time telepathology, consulting, and second opinions.

Access Top Experts

UPMC has one of the largest academic pathology departments in the country, with more than 100 diagnostic anatomic pathologists,

CHINA-UCLA WSI Telepathology

TELEPATHOLOGY CLINICAL CARE AND MEDICAL EDUCATION SPANNING THE GLOBE

• Major Medical Centers Providing Increased Access and Education To China and Other Countries with Shortage of Pathologists

• The department also continues to develop a successful telepathology exchange with a prestigious health center in China

• The prestigious Second Affiliated Hospital Zhejiang University (SAHZU) currently sends an increasing number of challenging digitized slides/cases to UCLA Pathology for diagnostic purposes

• The goal is to collaborate even more closely over the next few years, and the result of this collaboration may be a new joint diagnostic center using the advanced technologies of telepathology, molecular pathology and genomics to create the most advanced cancer diagnostic center in China, under the leadership of both UCLA and SAHZU pathologists

Improving Access To Care in USA Using WSI?

- Under the leadership of Scott Binder, MD, senior vice chair for Clinical Services, the department continues to expand its pathology expertise via telepathology

- **Binder is leading work, in conjunction with the University of California (UC) Office of the President, on a UC system-wide initiative to implement this new technology to a network of 8–10 remote hospitals throughout the state of California. These sites would have the ability to send high quality images of pathology slides to UCLA pathologists over a secure Internet connection, which would enable a group of pathologists without subspecialty expertise to consult with the department's expert team of pathologists for advanced diagnostic purposes**

- This technology also produces a windfall of educational opportunities for medical students, residents, and fellows in the David Geffen School of Medicine. It enhances clinical training by providing greater exposure to some of the world's most complex pathological cases. It also benefits the UCLA scientific community by providing material for research

Major Medical Centers Enabling WSI
to be Received by Their Subspecialist Experts

International Academy of Digital Pathology
Congress 2011

iadp

Digital Pathology in Asia

Robert Y. Osamura,MD
International University of Health and Welfare(IUHW)
IUHW Mita Hospital Tokyo Japan
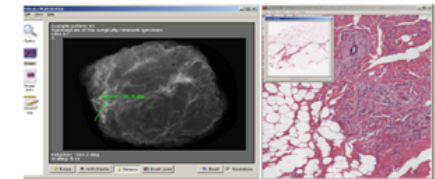

August 4, 2011

Quebec city

Digital pathology:

Pathology diagnosis & Telepathology
  Daily surgical pathology
    CAP validation of digital pathology
  Image Analysis
  Frozen section diagnosis
  Consultation

Teaching
Archiving the cases

Vilppu J. Tuominen and Jorma Isola:
Journal of Digital Imaging, 2010

Telepathology by satellite July 2010

Satellite "Kizuna"

IUHW Mita Hospital

Japan Aerospace Exploration Agency
(JAXA).

Iwate University

**Ryukyu University
Okinawa**

Its function in the Asia
is expected.

Digital Pathology in Canada

Toronto Ontario

Quebec project

*When we think about DP in Asia,
we refer to the networks in Canada.*

Digital telepathology using Satellite Kizuna JAXA

Adenocarcinoma
Lung Cytology

FV papillary thyroid carcinoma
Intrannuclear
inclusions

BC HER2 3+

Virtual microscope:Aperio
Image:acceptable
Interobserver variation:minimal
Time lag: when we change the
 fields or magnification

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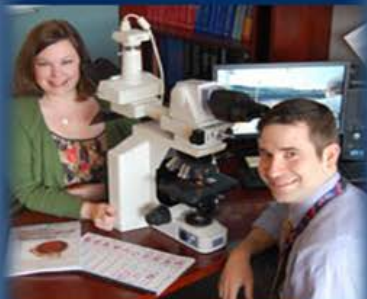
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The Juan Rosai Collection
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(1945- Present)
A comprehensive historical collection
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aperio

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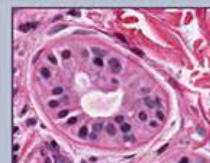Meeting Online - photos, videos and
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Important CME Changes to Enduring Materials

Diagnostic Pathology Update 2012
Secure Online Registration 🔒
Registration Information
Course Faculty, Topics & Schedule

2013 Annual Meeting
Preliminary Meeting Announcement
Online Abstract Submission NEW!
Currently Scheduled Short Courses

2014 Annual Meeting
Short Course Proposals 📝

Practical Pathology Seminars 2012
CME Claim/Evaluations/SAM Tests

2012 Annual Meeting

USCAP-TV

CME Claim/Evaluations/SAM Tests
Online Program Book
Virtual Meeting
Specialty Conference Handouts
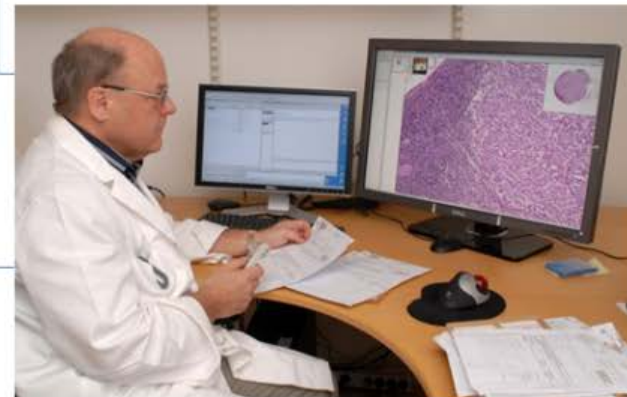Companion Meeting Handouts
Meeting Photos
Meeting Summary
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View Abstracts Online

First Full Adoption Hospital

ADVANCE, February, 2010

First hospital in the world to adopt digital pathology for 100% of their histology work (over 60,000 slides / yr.)

Medical Schools Not Waiting

Jamie Tsui/Stanford EdTech

Staff help students Aug. 19 to set up the iPads they just received.
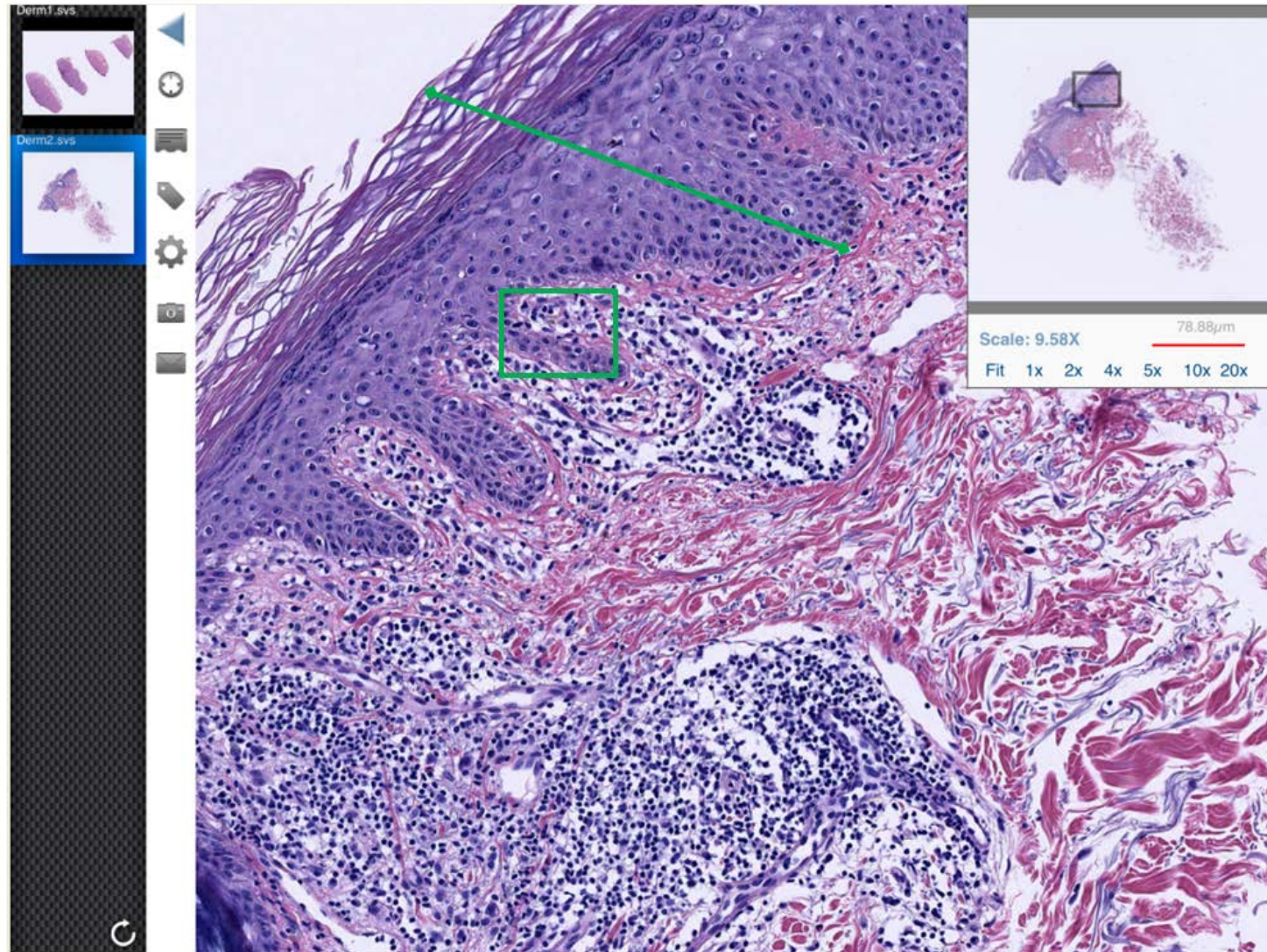
Stanford Medical Students

Yale Medical Students

Mobile Applications

Use of Annotations

Education Using WSI is Now Critical Part Training

Pathology Residents How to Diagnose
Prepare for Board Certification and in Board Testing

Development and use of a genitourinary pathology digital teaching set for trainee education

Li Li,[1] Bryan J. Dangott,[2] and Anil V. Parwani[2]

[1]Department of Pathology, Albany Medical Center, 43 New Scotland AveAlbany, NY, 12208, USA
[2]Center for Pathology Informatics, Department of Pathology, **University of Pittsburgh Medical Center**, Pittsburgh, PA 15232, USA
Anil V. Parwani: parwaniav@upmc.edu
April 5, 2010.

A teaching set of over 295 glass slides has been used for resident training at the Division of Genitourinary Pathology, Department of Pathology, University of Pittsburgh Medical Center (UPMC)

ePathology - eMobile - eLearning

Whole slide imaging technology and computer accessibility have advanced to the point that virtual microscopy can be integrated into a pathology residents' educational activities. The digital teaching set we developed provided additional benefits of using the glass slides

Education Using WSI is Now Critical Part Training

Pathology Residents How to Diagnose
Prepare for Board Certification and in Board Testing

- **Development and use of a genitourinary pathology digital teaching set for trainee education**
- Li Li,[1] Bryan J. Dangott,[2] and Anil V. Parwani[2]
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Does Color Make A Difference in Routine H&E Diagnosis

- Colorblindness in pathologists same as general population
- Can pathologists with cataracts make accurate diagnosis (color perception is impacted by cataracts)
- Image quality not color is what matters
- Wide variation in H&E recipes in different labs
- Individual pathologists have personal preferences for stain color
- Different tissues/cold ischemia time/fixation many other daily variables impact H&E slides

Pathologists are Trained for Slide Stain Variation

- Pathologists receive slides for consultation or patient referred to your institution and slides reviewed

- Some major cancer referral centers have half or more of all slides examined coming from outside histology labs with wide variation in staining color

- **Pathologists are trained to reject images that are not of sufficient quality to make a diagnosis be they glass or digital**

In terms of the lack of a significant difference in diagnostic accuracy, it simply may be that color, although a very important aspect of the pathology images, is not the only diagnostic feature that pathologists use during the interpretation process, so completely accurate rendering may not be as important as one would think.
There are many features that the pathologist processes visually when examining a typical specimen slide. The configuration of the cells and the cell structures are critical for example in determining whether a given specimen is benign or malignant, and although color may aid in visualizing these structures, **it is the basic configuration and relationship between the structures that matter rather than color.**

Heterogeneity in Cancer

With Static Devices Person asking for Help is Selecting Area of Interest

Conjunctival Melanoma with orbital invasion

Staghorn pattern

Signet-ring cells

Rosettoid pattern
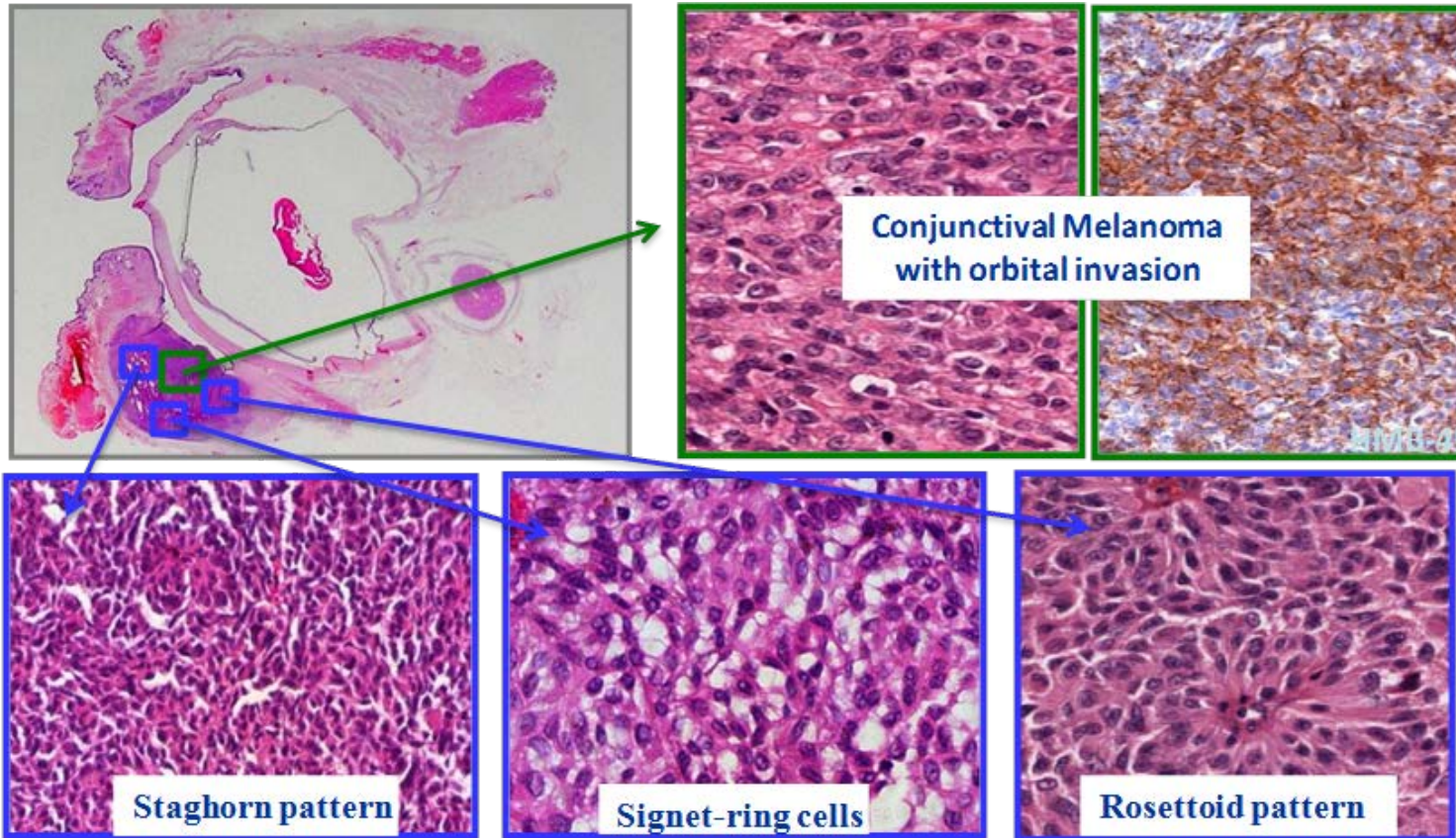
MN Burnier, AN Odashiro, BF Fernandes. Conjunctival Melanoma with orbital invasion. Ocular Pathology Course, IAP meeting, Sao Paulo 2010

WSI Enabler of Precision Medicine

FDA Class Determination

- **Device classification depends on the *intended use* of the device and also upon *indications for use*.** For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for making incisions in the cornea". Indications for use can be found in the device's labeling, but may also be conveyed orally during sale of the product. A discussion of the meaning of intended use is contained in <u>Premarket Notification Review Program K86-3</u>.

- **In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned.**

  Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

Sec. 892.2030 Medical image digitizer.

Identification. A medical image digitizer is a device intended to convert an analog medical image into a digital format. Examples include systems employing video frame grabbers, and scanners which use lasers or charge-coupled devices.

Classification. Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Standard, Joint Photographic Experts Group (JPEG) Standard

Class 2 Devices: Examples

- Cardiovascular diagnostic devices

  The arrhythmia detector and alarm device monitors an electrocardiogram

- Magnetic resonance diagnostic device

  A magnetic resonance diagnostic device is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance

- Gastroenterology-urology devices

  An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals

- Clinical chemistry and clinical toxicology devices

  A blood gases (PCO2, PO2) and blood pH test system is a device intended to measure certain gases in blood, serum, plasma or pH of blood, serum, and plasma

- Automated and semi-automated hematology devices

  An automated differential cell counter is a device used to identify one or more of the formed elements of the blood.

My Recommendations

- **WSI for primary diagnosis** should have a fast track for clearance, so all US patients can benefit from having access to same levels of pathology services as those available to patients anywhere else in the world

- The medical director should continue to use standard methods for validation and determine when and how to introduce WSI technology in the laboratory, as is the practice for other laboratory specialties under CLIA

- WSI should be treated as no more than a Class 2 device

In Conclusion
Digital Pathology (WSI) for primary diagnosis has been used around the world for many years with
no evidence of risk or harm to patients or user

"Everyone here has the sense that right now is one of those moments when we are influencing the future."

– *Steve Jobs*