Pathology RE-imagined
GE’s Perspective of the Future of Anatomical Pathology

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Pathology is Fundamentally Similar to Radiology

Imaging Device

- Whole Organ Anatomy
- Cellular Anatomy (morphology)
- Molecular: not quantitative.
- Molecular: not quantitative.
Image Data is a *Huge* Aspect of Dig Path

- Ave. Size of Radiology Exam: 0.1 Gb
- Annual Volume of Exams: 200,000
- Ave. Size per slide: 2.0 Gb
- Annual Volume of Slides: 200,000

- 20 Tb/yr
- 400 Tb/yr

- Acquiring
- Storing
- Retrieving
- Streaming
- Analyzing

Handling Large Volumes of Large Images is Key to Enabling Digital Pathology
Workflow Can Be Improved by Digital

- time to collate
- cross reference to requisition
- queued cases
- physical sign-out

- package for shipping/receiving
- post-review collection and sending to storage
- wait time to send/receive case for consultation or re-review
- time to gather cases/images/patient data for presentations

Reference Lab

Primary review

Surgical

Camera on scope

Patient data

Lis

Consult

Satellite Sites

Tumor Board

Presentations
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There are some things **only** digital can do

**Volume Analysis**
- 3D CT MR/X-RAY
- MPR/MPVR and MIP Protocol Engine

**Multi-channel Histochemistry**
- 3D co registration of 6 post-synaptic proteins in neuronal cells
Digital Improves Quality of Care in Radiology

1895 - Present

X-Ray

2005

Multislice CT

Lung cancer revealed by CT Lung Screening

http://www.cshs.org/images/LungScreen/PACSweb-28720.jpg

31,567 asymptomatic persons at risk for lung cancer using low-dose CT identified 484 with Stage I Lung Cancer. Surgery on these patients improved outcome.

Survival of Patients with Stage I Lung Cancer Detected on CT Screening

The International Early Lung Cancer Action Program Investigators

Survival (%)

100 - Resected clinical stage I cancer, 92% (95% CI, 88-95)

All lung cancers, 80% (95% CI, 74-85)

0 12 24 36 48 60 72 84 96 108 120

Months
Digital Can Improve Quality of Care in Pathology

1850 - Present
H&E

2003
Automated IHC
AQUA™

DNA Synthesis and Repair Genes RRM1 and ERCCI in Lung Cancer
Zhong Zheng, M.D., Ph.D., Tingan Chen, M.D., Ph.D., Xueling Li, M.D., Eric Haura, M.D., Anupama Sharma, M.D., and Gerald Bepler, M.D., Ph.D.

Automated subcellular localization of RRM1 in 187 stage I NSCLC Lung Cancer patients, stratifies patients following surgical treatment.
The Future of Anatomical Pathology

From Glass
To Digital

From Quasi-quantitative
To Dynamic Range

From Single Biomarker
To Multiplexing

From Dx
To enabling Rx
Let’s Dispel Some Myths About “Why Digital Pathology Will Not Happen”
The ‘technology’ myth

The technology of digital microscopy will never be good enough to make Dx…

The Perception

Throughput of scan not fast enough
Can’t browse the slide fast
Quality of image not good enough for Dx
Data storage too great/expensive

The Reality

30s for 15mm² @ 0.5μM/pixel
- The is equal to > 800 slides/day (<20% of all labs have greater volumes)
- Going faster is still within laws of physics and will happen.

Browsing has Virtually no Latency
- Current graphics cards and computational processing power has reached acceptable levels.

Diagnostic Equivalence is Validated
- Several 510K Approvals for Digital Tests
- Studies show equivalence of Dx accuracy from H&E slides

Data storage ~ 1000/TB
- Cost today for average whole digital specimen ~ 25 cents
The ‘cost’ myth

Compared to glass, digital imaging will be too expensive...

How expensive is glass?

- Colating glass for case sign-out: $XX,000/yr
- Preparing glass for shipping: $XX,000/yr
- Receiving and preparing glass for consultations: $XX,000/yr
- Retrieving glass for re-review: $XX,000/yr
- Finding ‘lost cases’: $XX,000/yr
- Preparing cases for tumor boards: $XX,000/yr
- Finding and preparing cases for education: $XX,000/yr
- Waiting for reference lab results: $XX,000/yr
- Lost revenue to competitors with digital: $XX,000/yr
- Opportunity Costs to Increase Throughput: $XX,000/yr

Total for getting glass and people to be in same place: > $XXX,000/yr

“Getting a case anytime, anywhere… priceless”
The ‘no value’ myth

There is no real value provided by using digital slides?

<table>
<thead>
<tr>
<th>Workflow</th>
<th>Case Review</th>
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<tbody>
<tr>
<td>Read anywhere, anytime</td>
<td>Increase Dx accuracy with real-time consult</td>
</tr>
<tr>
<td>QA and consult at any time</td>
<td>Compare multiple slides directly</td>
</tr>
<tr>
<td>Load balance</td>
<td>Annotate</td>
</tr>
<tr>
<td>Retrieve secondary reads instantly</td>
<td>Localize</td>
</tr>
<tr>
<td>Eliminate case/slide collation, glass shipping/receiving</td>
<td>Computer assisted review</td>
</tr>
<tr>
<td>Permanent record of Dx ROI for future reads or admissions</td>
<td>Score intensity on dynamic range</td>
</tr>
</tbody>
</table>
“It is likely that a digital system will greatly improve our workflow”
- Director of Clinical Laboratory Medicine, (500,000 slides per year)

“The ability to consult with other physicians in real-time would be highly valuable, as well as being able to re-review cases without wait time for retrieval”
- Chair of Pathology, Academic Center, (300,000 slides per year)

“Ease of use and rapid desktop retrieval of images are highly valuable”
- Vice Chair of Pathology, Academic Center, (750,000 slides per year)

“It will be easier and faster to send difficult cases to Sloan or Mayo”
- Attending Pathologist, County Hospital (70,000 slides/yr)

“We spend an enormous amount of time searching out cases, collecting images and case information for tumor boards and grand rounds”
- Assistant Professor, Academic Center, 200,000 slides/year
(If) Adoption …
Why, When and How?
Selective Pressures Drive Change

Economic Pressures & Clinical Demands

Retiring Workforce & Specialist Shortage

Computational power growing, cost of storage decreasing

Post-genome Info. Leads to Molecular Dx

“Origin of the –ologies”

The Practice of Diagnostic Medicine
If it occurs, how will happen?

1. Camera on Scope
   - Current state solution enabling very basic digitization of specimen
   - Pathologist still performs diagnosis via slide & scope
   - Takes snap-shot of ROI for comparison, teaching & reports
   - Today’s Gap: basic image storage, image viewing and informatics

Adoption gateway

- Future state solution enabling full digitization
- Whole slides are scanned from case
- Pathologist performs diagnosis via digital image and monitor
- Need for sophisticated image storage, viewing and workflow
- Facilitates productivity gains & new analysis tools

1. Select whole slide imaging for secondary review
2. Selective slide/case for primary review
3. Total Digitization 100% Archiving
Don’t Forget the Impact of IHC Algorithms on Digital Adoption

Tsiambas et al.
JOP. J Pancreas (Online) 2006; 7(3):283-294

510k FDA approvals of digital pathology tests is growing
Slow Adoption is Forecasted
Adoption of Pathology will be similar to Radiology.
Slow, but steady

Comparison of the observed number of cumulative sales and the theoretical number of cumulative sales generated by the Bass model for Digital Radiography (DR system)

Take-off
When will adoption begin?

There are still critical missing pieces

... total workflow infrastructure will be foundation of change
Pathology could be integrated into imaging & workflow management systems

Clinician Optimized and Enterprise Scalable
Cost/Benefit Must Tip for Adoption

Enhanced Patient Management

Work Flow Efficiency

Infrastructure Changes

PACS

Analysis Software

Scanner

Needs to be built and validated

Needs to be outweighed by benefits

This is a critical balance
Caution: Some things are NOT like radiology

**Infrastructure**
- No real clinical infrastructure exists today for digital… workflow, reporting, standardization of image data

**Technology**
- Can not go “glass-less”. Primary data is not digital.
- Images are ten times that of radiology… special challenges in streaming, storing, etc

**Economics**
- Capital intensive and hospital economics will be huge barrier… Cost/benefit has NOT been established

**Customer Acceptance**
- Pathologists are NOT inherently technology savvy AND they love their microscopes
Summary

- There are glaring similarities between Radiology and Pathology

- There are great advantages to go digital including work flow efficiency and improved patient care

- Anatomical pathology lab is poised for digital revolution and pressures on the anatomical pathology space will drive change

- GE Healthcare understands the critical technology and market aspects to create value for the anatomical pathology space

- Adoption will be slow and dictated by benefits of total end to end solutions that include clinical workflow and connection to digital hospital infrastructure.