3rd European Conference
on Whole Slide Imaging and Analysis
29th – 30th November 2013 | Hamamatsu TIGA Center
BioQuant, Heidelberg University
Program Online

Whole Slide Imaging in Diagnostic Pathology

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IPH
Institute of Pathology Heidelberg

TIGA
HAMAMATSU
TISSUE IMAGING & ANALYSIS CENTER

VM in Pathology

- Teaching and training
    - Courses on site and remote
    - Examinations
    - collections
- Research
    - Basic research
    - Biobanking/TMA/consortional logistics
- Diagnostic translation
    - Consensus/reference cases
    - Quality assessment/roll out/
    - Parameters for diagnostic imaging/assay evaluation
- **<u>Clinical diagnostic application</u>**

Institute of Pathology University of Heidelberg

- Largest German Academic Pathology
  - ~300 Employees
  - >8 Mio € Third Party Funding p.a.
  - Leading Molecular Diagnostics
- >6000 m2 Clinical and Research Space
- >20 separately funded Research Groups
- Part of >20 funded Research Programs
- > 1500 Impact Points (2012)
- Leading German Tissue Bank (>1300 Projects)
- Biomarker Development and Translational Diagnostics Program
- Diagnostic Trial Center
- Virtual Microscopy Center

Clinical Service

- Largest University Pathology in Germany (>70.000 entries; serving 20 hospitals)
- 32 MDs, 17 Board certified
- Dedicated Specialists for all entities
- Structured Training Programs
- QM, Accreditation (since 2007)
- Specific Administration (Clinical, Research)
- >20 tumor boards/CPC per week
- Reference/2nd Opinion Center

Evo – Revo in Diagnostic Pathology

Evolution (evidence based)

- Identify areas of obvious benefit
- Evaluate and test impact
- Specific (sectoral) implementation

Revolution (dogmatic)

- Throw away microscopes
- No more physical archiving
- Complete electronic workflow (reporting, training)
- Comprehensive implementation

Special thanks to J. Shwartz and O. Eichhorn, Pathology Vision 2010

Revolution I

The anti-innovation enemy *or* throw off your chains discussion

It has taken us 500 years to get to this point!!

1595: 1st Compound Microscope

Mid-1700s: Cuff-style microscope; 1st to provide ease of use and accurate focusing mechanisms

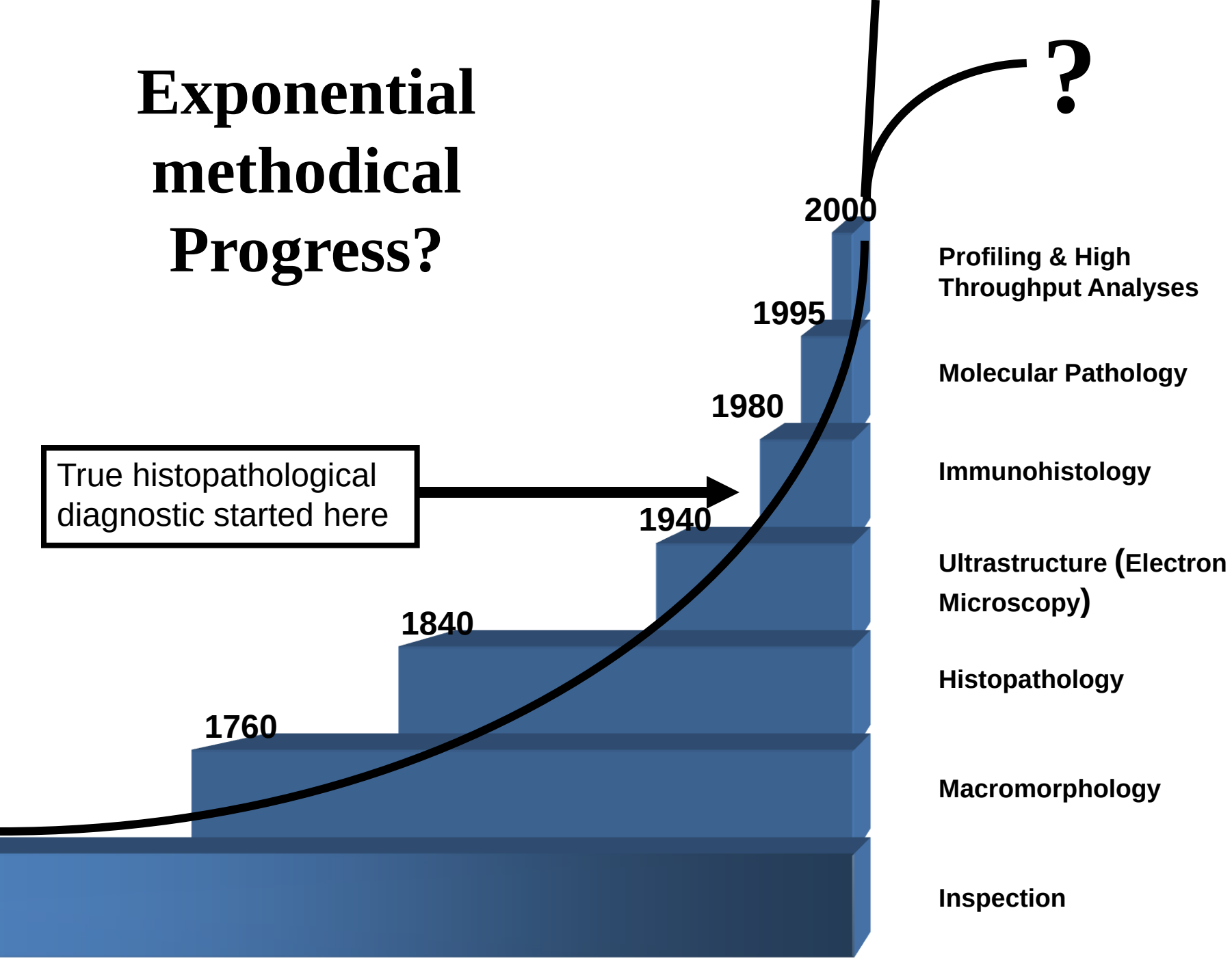
1998: State of the art contains accessories for DIC, fluorescence, polarized light, phase contrast, and photomicrography

1680s: English Tripod Microscope

1899: Ernst Leitz Compound Binocular Microscope

Pathologists need a bias for action

Exponential methodical Progress?



Some will always see the glass as half full

- Slower than current microscopy
- Adds a step to the process
- Pathologists resist change
- Has not been fully vetted in the literature
- Capital investment barrier is high
- Operating costs may exceed current practice
- Lack of stands; non-interoperable solutions
- No integration with existing AP systems

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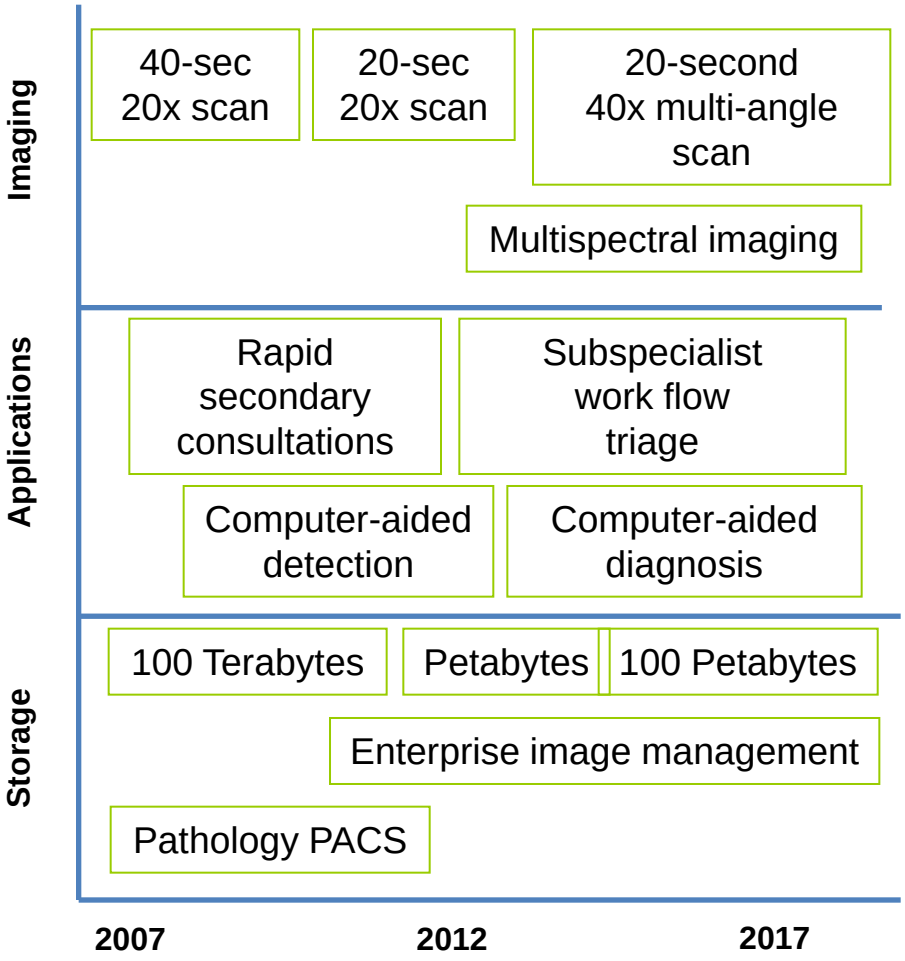
What is wrong with that ? *or*

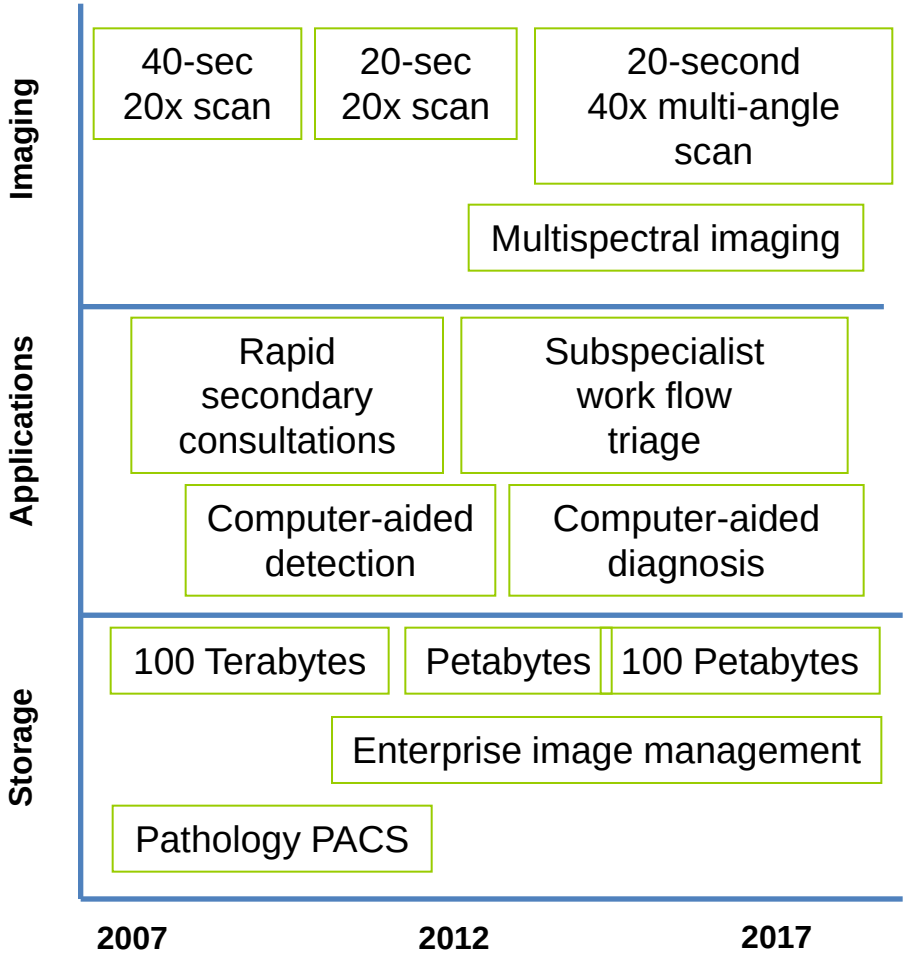
Do you believe your budget comes out of the money machine?

It’s just a matter of time



* Source: Sg2 T3 Virtual Slide Imaging

It's just a matter of time

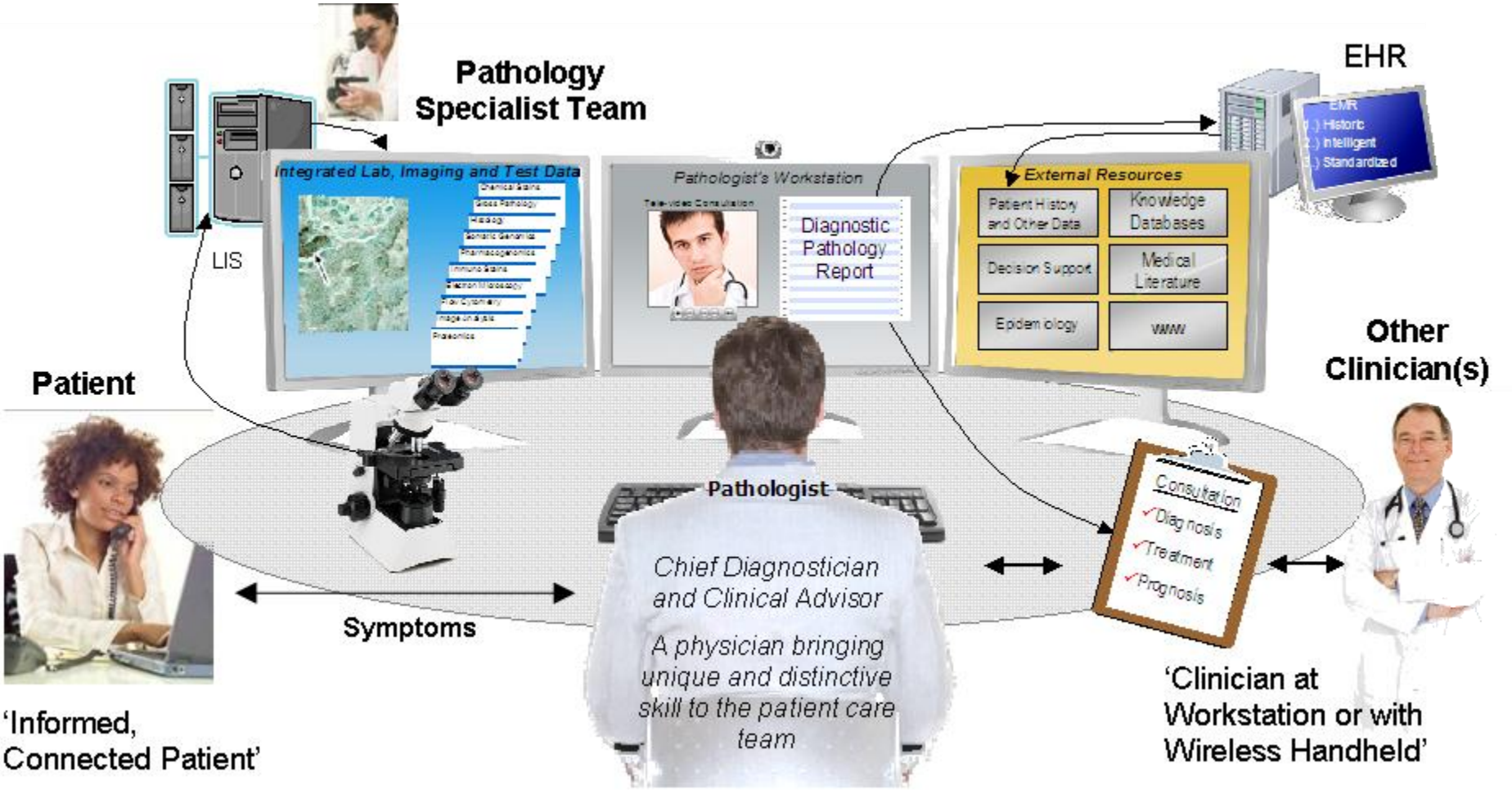


Do you calculate your travel time from Munich to Hamburg by the maximal speed of a Ferrari?

It’s time to bust out

..and maximize use of all tools available to us to assume new and expanded roles

Our Vision

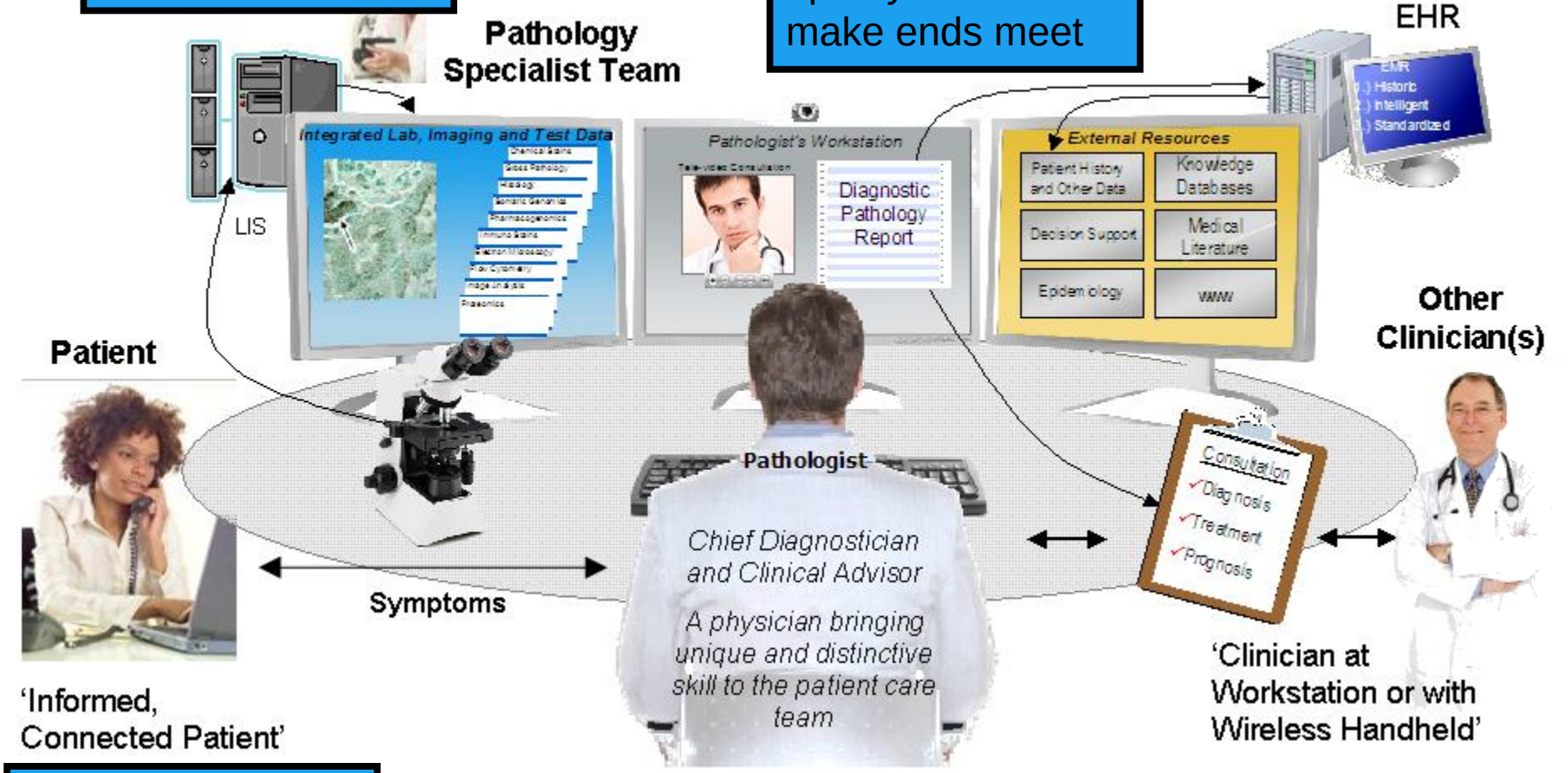

Pathology Specialist Team
EHR
LIS
Integrated Lab, Imaging and Test Data
Pathologist's Workstation
Diagnostic Pathology Report
External Resources
Patient History and Other Data
Knowledge Databases
Decision Support
Medical Literature
Epidemiology
www
Other Clinician(s)
Patient
Pathologist
Chief Diagnostician and Clinical Advisor
A physician bringing unique and distinctive skill to the patient care team
Consultation
Diagnosis
Treatment
Prognosis
Symptoms
'Informed, Connected Patient'
'Clinician at Workstation or with Wireless Handheld'

Wake up!

They are sitting and waiting for you? Get real!

If you need that open you will not make ends meet

Show me a CIS able to perform like this



You wanna keep contact with 50.000 patients?

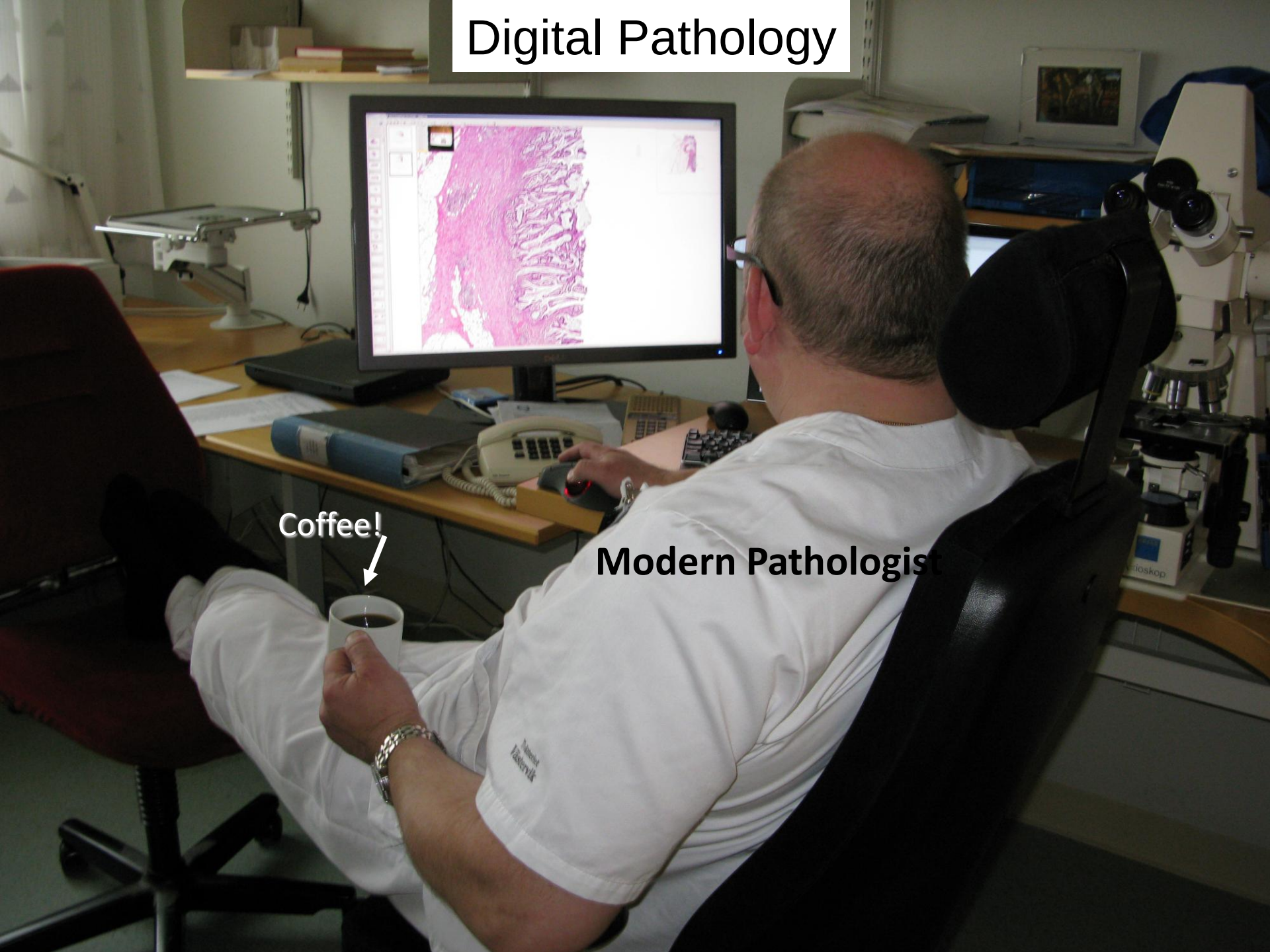
And the diagnosis rained down on him……

Revolution II

The life style argument

REAL MEN DO PATHOLOGY

Digital Pathology



Its a Question of Attitude but..

- ..the diagnostic workload is still the same
- ..the way to the coffee machine has still the same distance
- ..have you seen the microscope at the right side?

Marketing but not realistic

Revolution III

The raisin-picking extrapolation argument

Pathologist T&M Study Goal

Hypothesis: Inefficiencies exist in the pathologists' workflow that can be improved by an all digital workflow.

A before-and-after study of actual impact in pathology is in-progress, therefore the first study goal was to identify the potential opportunity.

Pathologist T&M Study Context
Experience from Radiology

Radiology realized significant improvements in productivity as the most significant value-add from PACS implementation.

"Since the introduction of PACS, reporting times have decreased by 25% and the productivity improved by 18%."

Mackinnon AD, Billington RA, Adam EJ, et al. Picture archiving and communication systems lead to sustained improvements in reporting times and productivity: results of a 5-year audit. *Clinical Radiology* 2008; 63; 796-804.

"…overall Radiology Department productivity increased by 12%, TAT improved by more than 60%. Timelier patient care resulted in decreased lengths of stay.... A well-planned PACS deployment simplifies imaging workflow and improves patient care throughout the hospital while delivering substantial financial benefits."

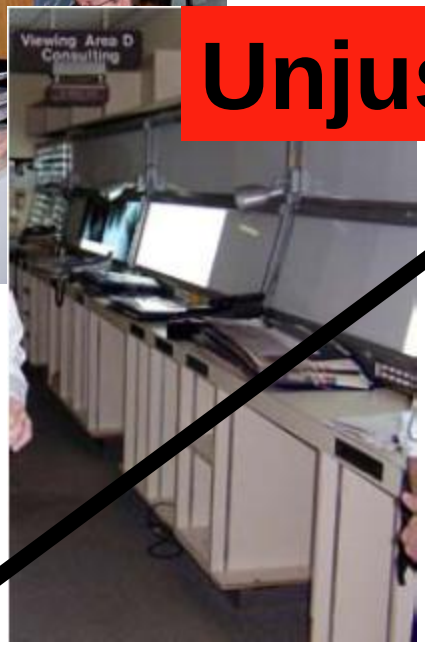
Nitrosi A, Borasi G, Nicoli F, et al. A filmless radiology department in a full digital regional hospital: quantitative evaluation of the increased quality and efficiency. *Journal of Digital Imaging* 2007; 20(2); 140-148.

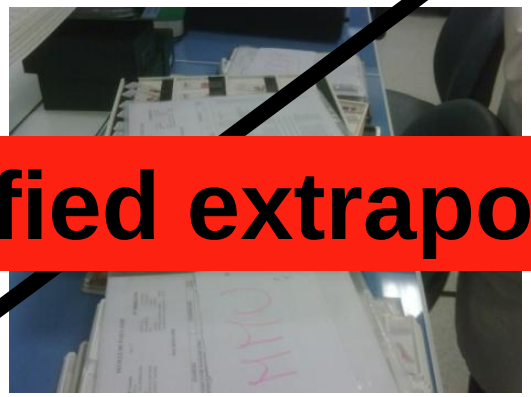
Differences to Radiology PACS

- Complete production of intermediate required – add on procedure
- Less interdisciplinary use of specific imaging product;
    - exclusive use by pathologist; no clinician interprets path slides; the report matters
    - no need to store in electronic file
- More storage space required (10x)

Pathologist T&M Study Context
Similarity of Pathology and Radiology

The challenges pathologist experience from managing slides is similar to the challenges radiologists experienced with film.





Unjustified extrapolation

Histology Lab T&M Study Context
Digital Workflow – APLIS & Barcode Integrated

Accessioning / Grossing / Histology

Slide Creation

Enter Patient
Enter Case
Enter Slides

Stain and coverslip slides

Case Assembly

Quality Check

Sort slides to Cases

Review slide quality
Review case quality

Transport

Pathologist

Case Entry

Eliminate

Imaging

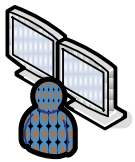
Load slides
Generate images
Unload slides

Case Assembly **Quality Check**

Eliminate

Review slide quality
Review image quality
Review case quality

Pathologist



DUP TASKS **NEW TASKS** **EQUIVALENT TASKS**

Pathologist T&M Study Results
Identified Opportunities for Time Savings

Matching:
- Matching paperwork to case
- Matching new stains ordered upon arrival
- Tracking receipt of ordered slides
- Re-checking slide to case match

Reduced Error Correction:
- Transporting case to correct pathologist
- Obtaining correct or missing paperwork
- Reducing duplicate slides ordered
- Picking up wrong slides / missing slides

Retrieving Prior Cases:
- Sending request for prior case
- Context switch away from current case
- Tracking receipt of requested prior cases

Transporting Cases:
- Giving for Pre-Signout Q/A
- Packaging cases for consult

Organizing Cases:
- Prioritizing cases for review
- Dividing with residents and fellows
- Tracking which cases are ready for review
- Tracking cases for conferences

Querying for Cases:
- Checking mailbox for new cases
- Checking if STAT cases have arrived
- Checking if Frozen Section cases are ready
- Visibility of overdue cases

Searching for Cases:
- Searching for cases when receiving phone call
- Searching for “orphan” slides
- Pulling cases for re-review at final sign-out
- Passing cases between residents and fellows

Communication:
- Sending ROI images vs. co-scheduling time at scope

T&M Study Conclusions

Routine use of an all-digital workflow shows…

Opportunity to **increase available pathologist time** from workflow savings

Observed average **13.4% per pathologist** in addition to savings from secondary effects, frozen sections, tumor boards, consults, slide review

- Quality, Profitability, Lifestyle

Opportunity to **eliminate case assembly tasks** in the lab

Observed average **18.5% FTE per lab**

- Offset some of the additional time required for new Imaging tasks

Efficiency of pathology department has **downstream effects**

Clinician Efficiency and Patient Care

- Patient satisfaction, timely treatment, reduced length of stay

Does this relate to REAL Diagnostic Situation?

- Improvement potential of 13-18 % under ideal workflow conditions is useless under practical conditions; minimum required would be 50%
- Improvement potential only existing under supervised, ideal and streamlined workflow condition; this is not the real situation
- Requires coevolution of automated workflow procedures (barcode tracing; completely automated slide labelling etc.), thus complete new lab investment and restructuring
- Asymmetric workload reduction (doctor vs. tech) – personel structure?
- Add on procedure which extends waiting time in high throughput centers; postpones case management
- Increases problems with low quality slides, recurrent procedures, necessary special case management. Huge problem for error management
- Investment in instruments (scanners), space, and personel

Disadvantages by far outweight benefit of general implementation and necessary prerequisites do not exist

The Revolutionary Approach

It is nice to have visions, but the revolutionary approach is

- Dogmatic
- Neglects reality and imperfectness
- Not amenable to real world financing, staffing, and personalities

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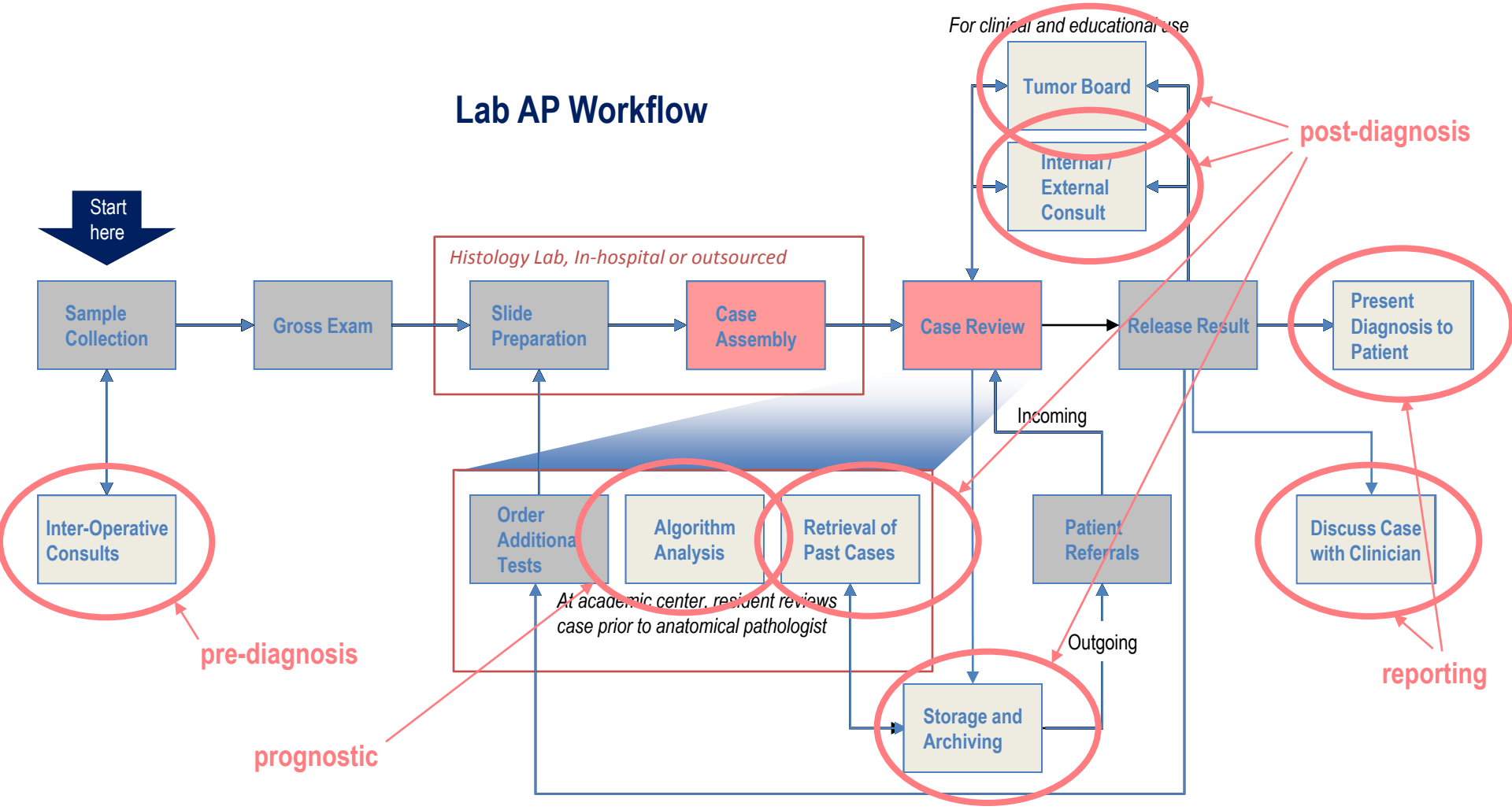
My Dogmas

- Only intimate knowledge of a field and its situative context generates optimized solutions
- The better is the enemy of the good *but* theoretical (‚obvious') improvements very rarely translate in true objective situative improvements
- Diagnostic pathology is true life and not a test lab
  - optimized medical results with high efficiency
  - Cope with all possible problems (QM, trouble shooting)
- Pathologies are up and running and adjusted to current needs
- But future needs are foreseeable
- Pathologists are in principle conservative (guardians of medical knowledge and treatment) but receptive
- First generation solutions are never good

Lab Anatomic Pathology Workflow



Agenda

- Archiving, Documentation
- Remote Cryosection Service
- Tumor boards/clinico-pathological conference
- Teleconsulting
- Quantitative diagnostic image analysis (Immunohistology, FISH)
- VM in clinical trials

Archival / Retrieval
Store by VM but not Glass Slides!

- no significant reduction of physical archive
    - blocks
    - old cases
- mixed storage (VM/physical)
- storage capacity >>10 pByte
- storage costs are manageable and are much lower than VM full costs
- saved storage space is of little use
- some legal restrictions

Positive:

- Potential to simplify and speed up archiving to some extent and reduce storage space and archiving material

Incentive: low but not negligeable

Archival / Retrieval

save consult cases – risk management

Here is the problem

- organisational not methodical problem
- IT **increases** but not reduces personal organisational problems
    - lack of traceability
    - lack of physical attachment
    - more space to hide

Supports archiving of structured persons but dramatically increases problems with poorly structured personel

Incentive: low (principally high but danger outscores advantage)

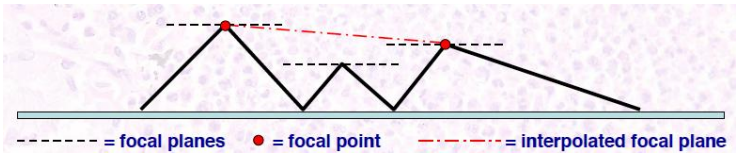
Remote intraoperative Cryosection Service for outside Hospital

- Pilot: Sentinel-LN in Mammary Carcinoma (Bruchsal; 30-40‘ by car)
- Requirements: Cryo-Histo-Lab, TA
- Sampling/Macro by Surgeon
- 3 cryo sections + Cytology
- Scanning by TA
- Lab time ~ 10‘
- Since 2 years
- Now service for 2nd outside hospital

Intra-Operative Consults

Value of Digital Pathology

- Enables remote interpretation
- Reduces travel / simplifies logistics
- **Reduces OR-time/costs**



- More time consuming for analysing pathologist
- Availability and speed of central and decentral IT
- Quality of sections; reduced feedback and correction potential
- Potential focussing problems
- Dependency from remote macropreparation
- Additional potential for discordant histo-diagnoses
- Many formal problems (refunding, certification, liability)

Applicability only under specific restricted conditions

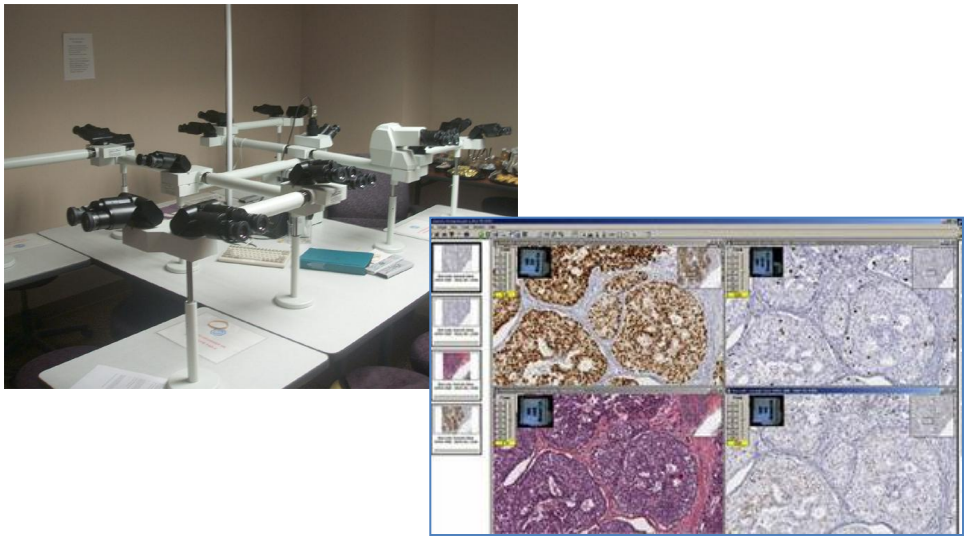
Not compliant with official certification rules (institute, breast crenter)

Tumor Boards/Clinico-pathological Conferences

remote access / participation

- Reduce time / simplify process for preparation
- Enable remote access / participation
- Improve presentation of case information
- No requirement for decentral projection microscope
- No slide transport

- Infrequent case presentation at tumor boards; cpc is not generally part of patient management
- Slides used for this purpose are less than 0.5%



Suitable, but limited application

Consultations
shipping and handling

1. Help in low level health services (any help welcome)
2. Service for remote, developed health service areas (just the distance)
3. Practical advice (what to do)
4. True teleconsultation

1-3: VM helpful but highly context dependent

How about 4?

Teleconsultation

Transfer of slides and blocks

Advantages

- Identical conditions; liability
- Additional stains and tests
- Improvement of quality possible; adjustment to own artifacts
- Archiving (Compliance with CP archiving system and case documentation)
- Billing (no category; partial service)
- Integration in own case collection possible (incentive)
- Selectivity barrier (no ‚Email contamination‘)

Disadvantages

- Higher TAT
- Higher logistic effort
- Transport costs, double lab costs
- Possible loss or destruction

Expert Teleconsulting

- VM helps in advising
  - Possible diagnoses
  - Possible solutions
- VM currently unable to replace expert teleconsulting
  - Lack of incentive (blocks retaining/research pay-off, billing)
  - Lack of owns laboratory performance
  - Logistic drawbacks (registration, compliant archiving/ documentation)
  - Liability problems

The more of the open questions are solved, the more cases may be amenable; total replacement is unlikely

Routine Consultation in Territorial State: U of Arizona Medical Center 2008

Havasu Regional Medical Center

316 Miles

University Medical Center Tucson, AZ

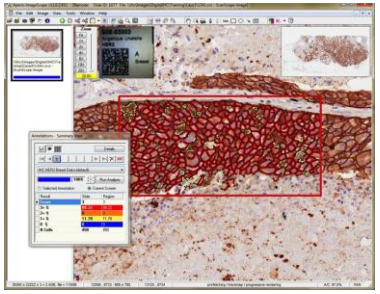
Telepathology-refractory Diagnoses

Pathologists	Total cases in general	Deferred cases	Total cases excluding the pathologist's subspecialty	Total deferred cases excluding the pathologist's subspecialty	Deferral rate in general	Deferral rate excluding pathologist's subspecialty
Gastro Intestinal	501	24	344	17	4.79%	4.94%
Heart and Lung	369	30	321	25	8.13%	7.78%
Renal	188	24	150	22	14.79%	14.67%
Soft Tissue	174	37	165	36	21.26%	21.81%
GYN	166	12	161	12	7.23%	7.45%
Renal	139	12	109	10	8.63%	9.17%
Endocrine	85	9	83	9	10.59%	10.84%
ENT Path	84	6	76	6	7.14%	7.89%
Dermatology	58	7	50	5	12.07%	10%
Breast	51	4	50	4	7.84%	8%

IHC/ISH automated Assessment

- Specified technology, work flow, and collective
- Work flows are up to it
- High pressure to provide quantitative data
- Reliable quantitative data can be produced
- Marriage of VM and image analysis
- Parallel processing

- Requires highly elaborate segmentation programs
- Needs tedious adjustment to every single test
- Additional standard incubation
- Only stepwise (testwise) implementation possible



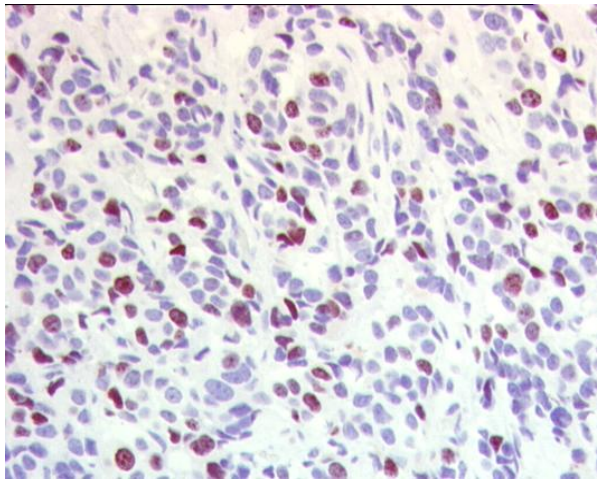
Nevertheless, this is the proof of principle!

Applications

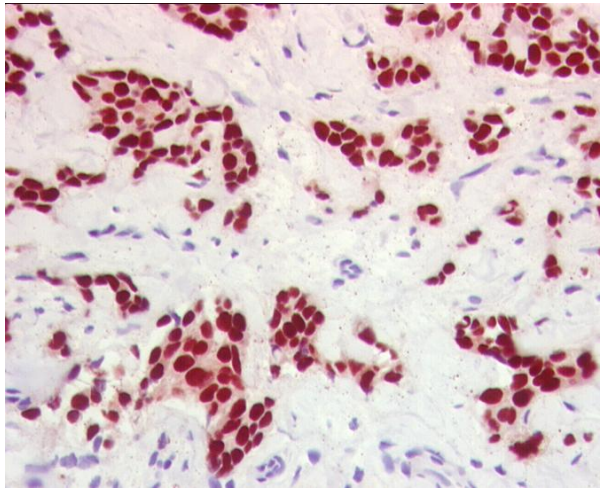
- Proliferation index (endocrine/mammary)
- Receptor expression (ER, PR, Her2)
- Novel markers
- Trial associated analyses!
- Cytology
- Histology parameters

- Tumor entity adjusted tumor-stroma segmentation
- Technology (IHC, FISH, CISH)
- Signal type (yes/no, intensity, subcellular compartment, distance etc.)
- Area selection
- Standard
- Artifact recognition

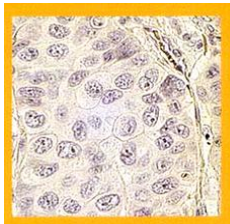
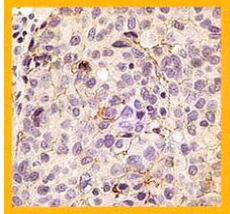
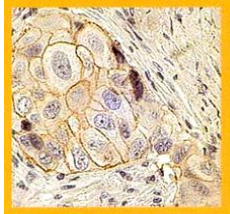
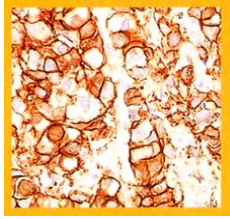
Immuno-Tests Breast Cancer



Ki67: yes/no



ER/PR: yes/no; intensity

	Keine Färbung zu sehen oder **weniger als 10%** der Tumorzellen zeigen eine membranständige Anfärbung.	0	Negativ
	Eine schwache oder kaum sichtbare Membranfärbung ist in **mehr als 10%** der Tumorzellen zu sehen. Die Zellen zeigen eine nur **unvollständige** Membranfärbung.	1+	Negativ
	Eine schwache bis moderate **komplette** Membranfärbung wird in **mehr als 10%** aller Tumorzellen festgestellt.	2+	Schwach Positiv
	Eine **starke**, die komplette Membran umfassende Färbung wird in **mehr als 10%** aller Tumorzellen beobachtet.	3+	Stark Positiv

Her-2:intensity and continuity of membranous signal, # of positive cells

Conclusion

- Diagnostic pathology offers many useful applications for VM
- Pathology is an innovative discipline open for REAL improvement
- Comprehensive implementation of VM into diagnostic pathology is not useful and would require enormous surplus resources with unpredictable consequences. Benefits are vague and uncertain even on long run.
- Implementation has to be focussed for well defined application areas
- Potential users without impact in other areas (research, training, tech dev) other applications should wait for better solutions (hardware, software, data storage)
- Implementation requires coevolution in many different areas (refunding, lab workflow, legislation, hospital and personel management etc.) for positive development

Thank you

- Institute of Pathology, University of Heidelberg
- TIGA Center Heidelberg

Vor- und Nachteile

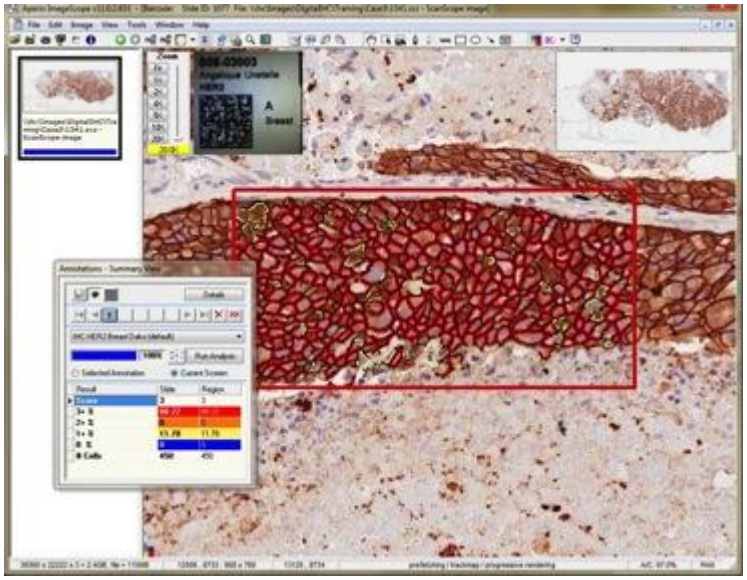
- VM für Schnellschnitte:
  - Anwendbar, wenn keine makroskopische Beurteilung erforderlich
  - Zeitaufwand vergleichbar mit konventioneller Technik
  - Beurteilung zeitaufwendiger
- VM für Telekonsultation
  - Vorteile:
    - Asynchrone Bearbeitung
    - Wesentlich bessere Bildqualität als klassische Telepathologie
  - Nachteile: Subjektiv unterschiedlich im Vergleich mit klassischer Mikroskopie

Clinical

applications for Digital Pathology

- Archival / Retrieval
  - Risk Management
  - Decision Support
  - Quality Control
  - CAP / CLIA Compliance
  - Clinician Communication
  - Education
- Intra-Operative Consults
- Tumor Boards
- Consultations
- IHC Quantification

Digital Signout



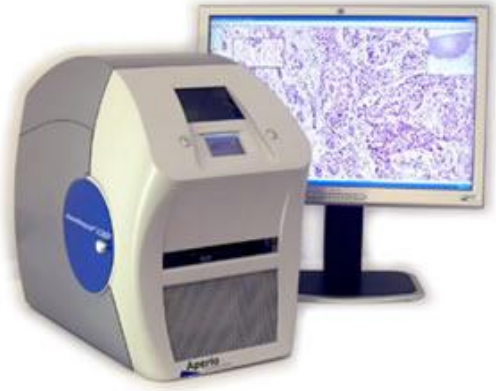
IHC Quantification
value of Digital Pathology

Digital IHC quantification is U.S. FDA approved

Vorgehen bei Telekonsultation einzelner Fälle

Lokaler Pathologe (Sender, Institut A)

1) Selektieren der Objektträger



2) Einscannen der Objektträger

3) Übertragen auf Webserver

4) Anforderung der Konsultatin

Vorgehen bei Telekonsultation einzelner Fälle

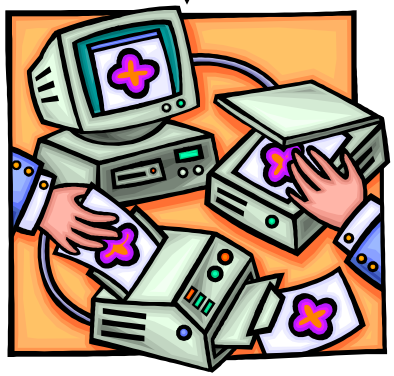
1) E-mail Benachrichtigung

2) Fallreview im Webbrowser

3) Erstellung von Referenzdiagnose und Bericht

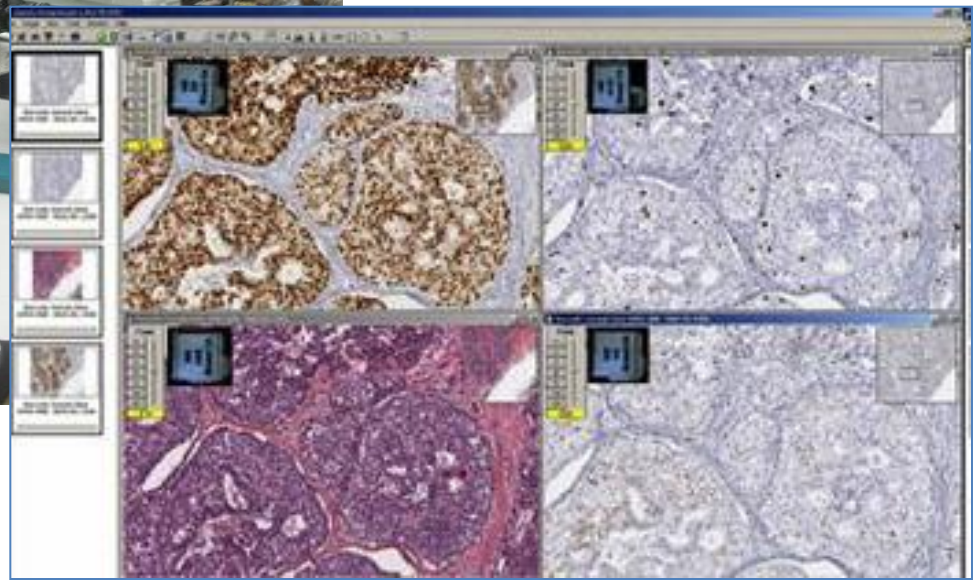
Anfordeerung zusätzlicher Daten

7) Übermittlung der Referenzdiagnose an den anfragenden Patholoen (Institut A)



Tumor Boards/Clinico-pathological Conferences

remote access / participation



- **Tumor Boards**
- **Clinico-Pathological Conferences**

Archival / Retrieval

save consult cases – risk management

Archival / Retrieval

case archives – decision support

Pathologist T&M Study Results
Additional Opportunities for Time Savings

Common current uses:

- Tumor boards
- Frozen sections
- Consultations

Secondary effects caused by delays from noted opportunities:

- Time re-orienting to case after waiting for prior case
- Phone-tag with ordering clinician after retrieving case

Level-loading work:

- Continuous flow of cases from lab to pathologist
- Distribute workload across locations

Surrounding personnel:

- Resident matching (observed 1:26:11)
- Administrator preparing cases (observed 1:35:43)
- Prior case retrieval and re-storage
- Slide transportation

Pathologist T&M Study Summary

13.4% opportunity for increase in available pathologists' time from **Workflow** is a significant value-add opportunity for implementing digital pathology in routine use

Example options for utilizing this time:

- Increase volumes without additional staff
- Increase utilization of patient history
- Increase rate of quality assurance review
- Improve recruiting and retention

Impact of **secondary effects** has opportunity to show significant additional opportunity
Reducing dependence on **surrounding personnel** drives efficiency across department

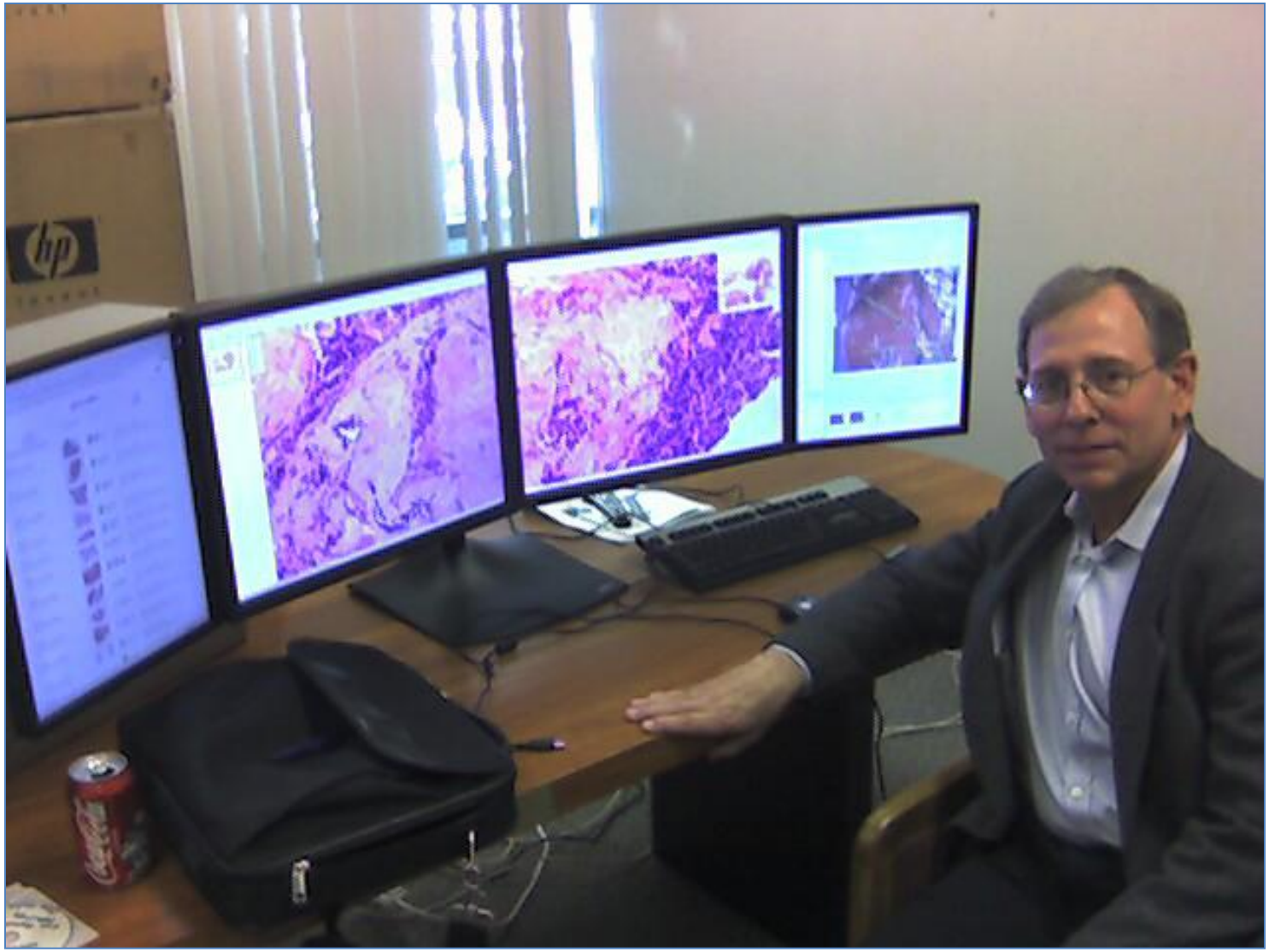
Scoped for analysis in before-and-after study

Additional analysis of **Slide Review** efficiency opportunities is suggested from radiology

"Time-motion analysis showed a reduction of 16.2% in the overall time required for soft-copy interpretation of CT compared with that of film."

Reiner BI, Siegel EL, Hooper FJ, et al. Radiologists' Productivity in the Interpretation of CT Scans: A Comparison of PACS with Conventional Film. *AJR* 2001; 176; 861-864.

Digital Signout

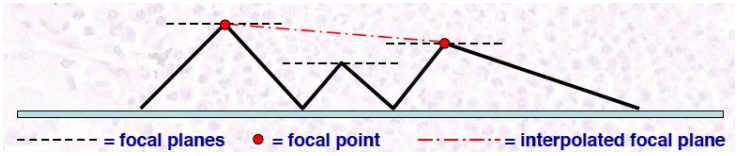


Consultations

VM in der Schnellschnittdiagnostik

Probleme

- Zeitaufwand bei multiplen Schnellschnitten
- Verfügbarkeit und Geschwindigkeit der Computernetze (zentral und peripher)
- Qualität der Schnittpräparate
- Beurteilung zeitaufwändiger als unter dem Mikroskop



Clinical

applications for Digital Pathology

- Archival / Retrieval
  - Risk Management
  - Decision Support
  - Quality Control
  - CAP / CLIA Compliance
  - Clinician Communication
  - Education
- Intra-Operative Consults
- Tumor Boards
- Consultations
- IHC Quantification

Digital Signout

Modern Healthcare
A Crain Communication Publication
THE ONLY HEALHCARE BUSINESS NEWS WEEKLY JANUARY 6, 2020

Pathologists take center stage in patient care

Necessity is the mother of all innovation…and adoption

NEWS FROM
REGIONAL/PROVINCIAL
Last updated at 8:03 AM on 24/06/08

Pathology labs first to be cut, inquiry told

- Telegram Photo

- Reduce time from biopsy to diagnosis
- Increase productivity
- Expand access to expertise and special stains

Digital Pathology Blog
A weblog for the digital pathology community and laboratory professionals

« HHS awards contracts to test e-health records exchange | Main | Aperio Announces European Digital Patholog Seminar Series »

February 18, 2008

Toronto's Michener Institute adding digital slide images to EHR

The Michener Institute is adding digital laboratory slide images to the EHR
By Jerry Zeidenberg

Toronto's Michener Institute, an educational centre for applied health sciences, has started integrating digitized mi ros Health Record system. It's one of the first sites in the country to do this.

"Typically, you do not see digital microscopy in the health record," commented Dr. Karim Bandali, vice provost of the Michen

Digital slide technology has the potential of becoming a very important tool for pathologists who analyze patient sam – of serious diseases, including cancer and blood disorders. "Digital microscopy is a major piece, and integrating development," said Dr. Bandali.

Digital Imaging expands our tool kit and extends our reach

- Broaden practice statewide, regionally, internationally
- Extend expertise with CAD
- Collaborate with peers; possibly increase demand for 2nd opinions
- Improve your value as the gatekeeper for subspecialty expertise and for patient information, and integration of diagnostic data from *any* source
- Better serve patients

Archival / Retrieval

Archival / Retrieval

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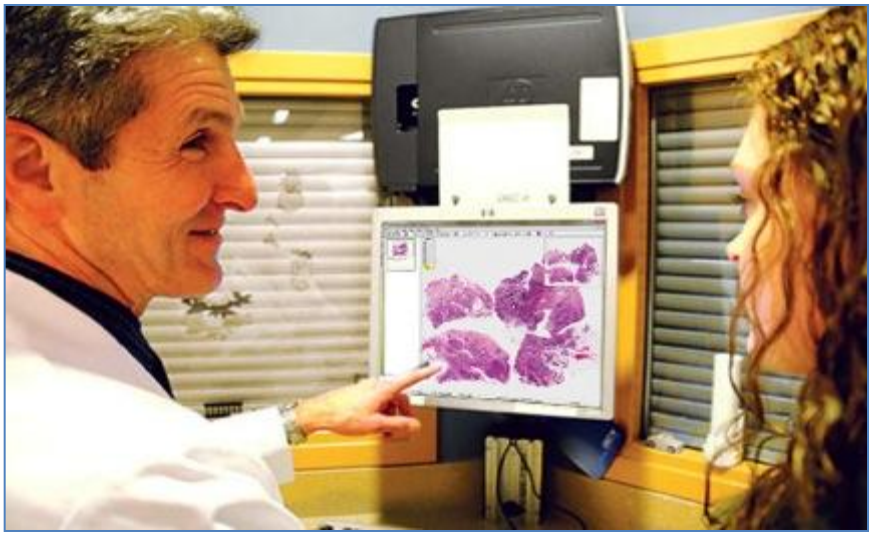

Digital Signout

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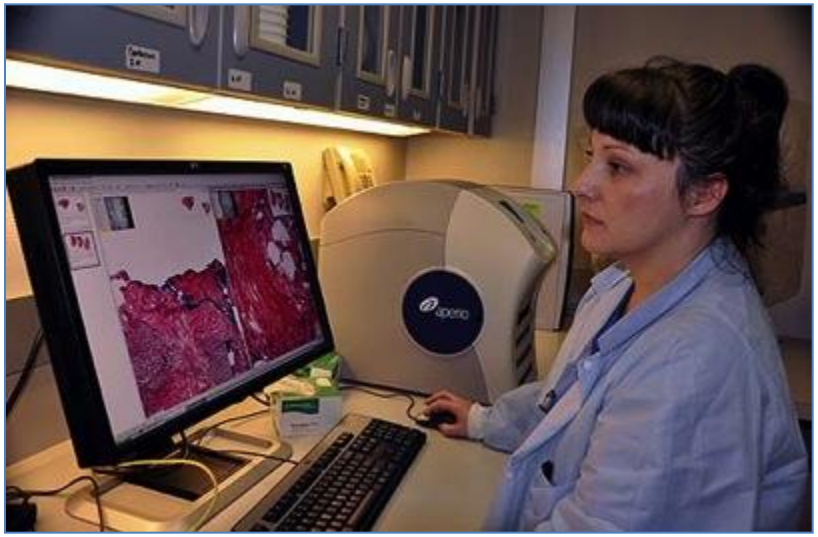


Tumor Boards

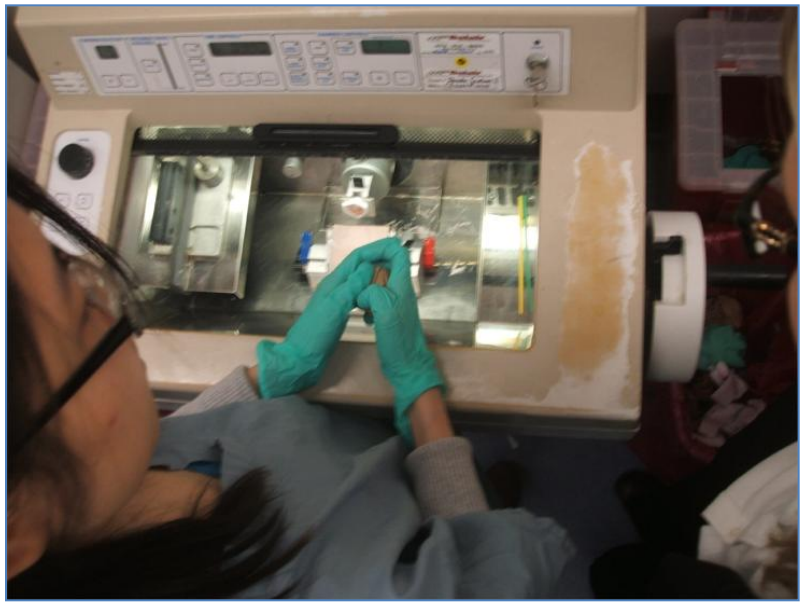
Archival / Retrieval
value of Digital Pathology

- Risk Management
  - Easily retrieve all case information
- Decision Support
  - Instantly retrieve / compare to previous cases for same patient
- Quality Control
  - Simplifies selection / routing of cas for internal overreads
- Clinician Communications
  - Improves turn around time for patients

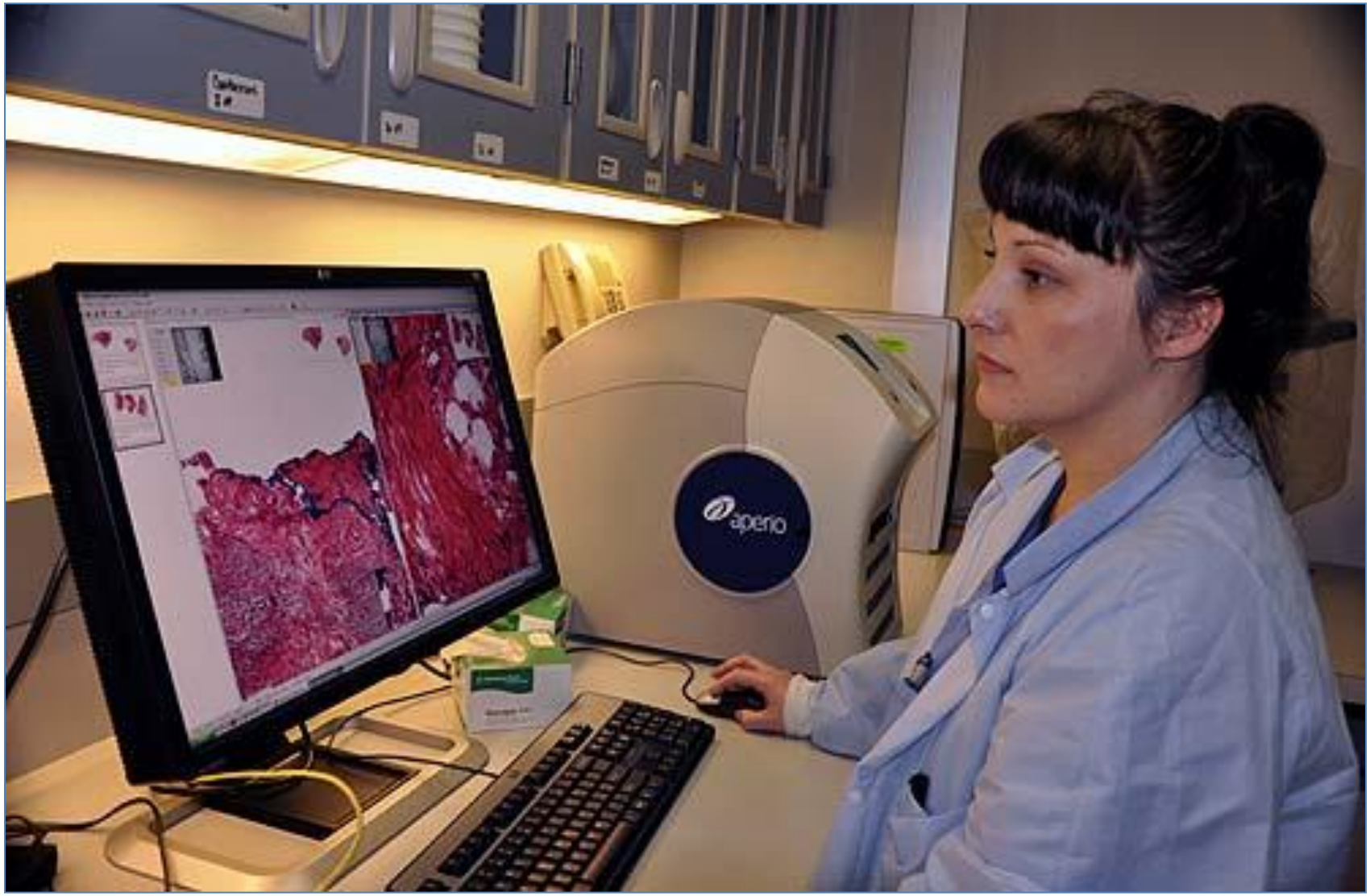
pathology reading lab, major medical center

Intra-Operative Consults

reduce travel, simplify logistics



Intra-Operative Consults

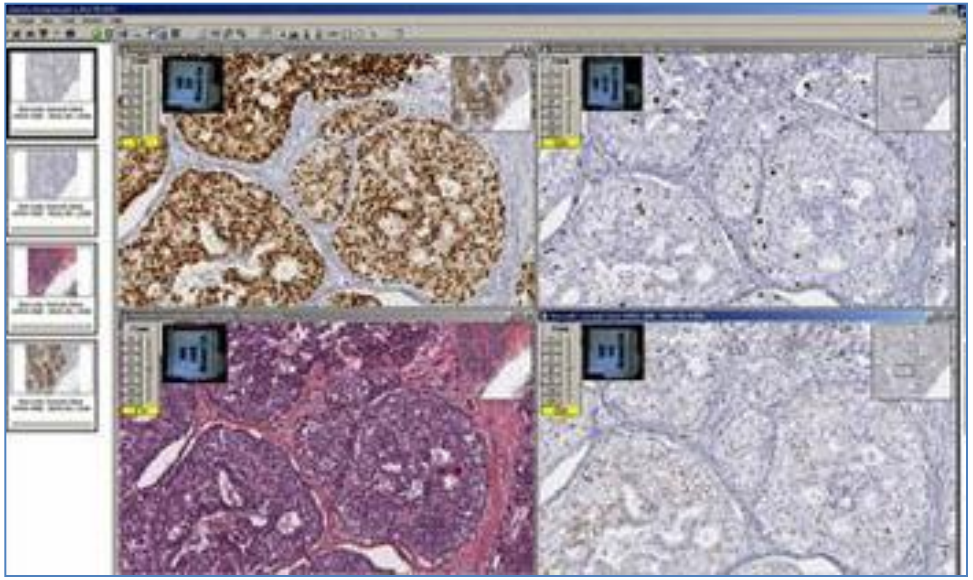


Consultations
value of Digital Pathology

- Faster turn around time, leads to competitive advantage
- Improved workflow
- Save cost / effort of mailing cases
- Permanent record of consul
- Physical slides never lost

Tumor Boards
Value of Digital Pathology

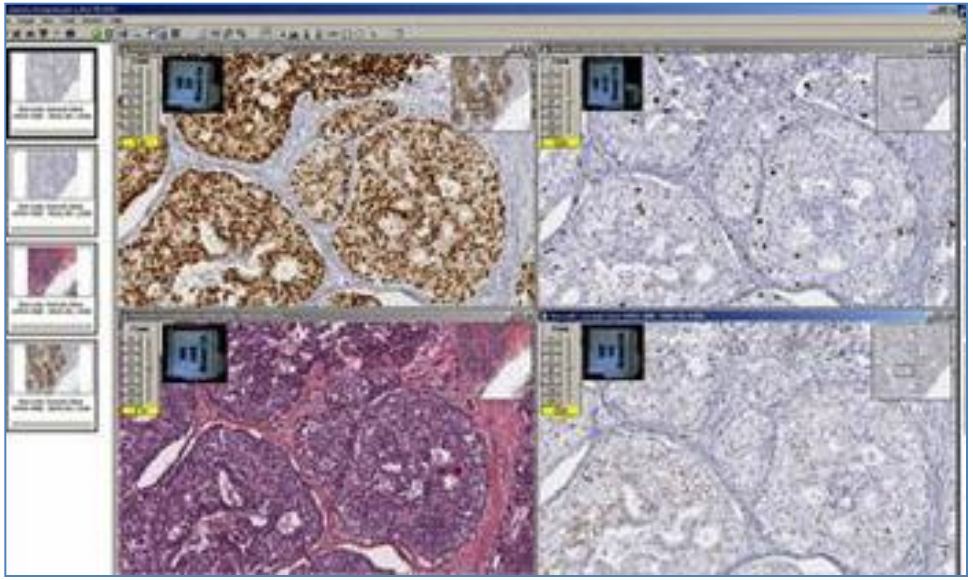
- Reduce time / simplify process for preparation
- Enable remote access / participation
- Improve presentation of case information



access all slides for case, display interactively

Tumor Boards

Value of Digital Pathology

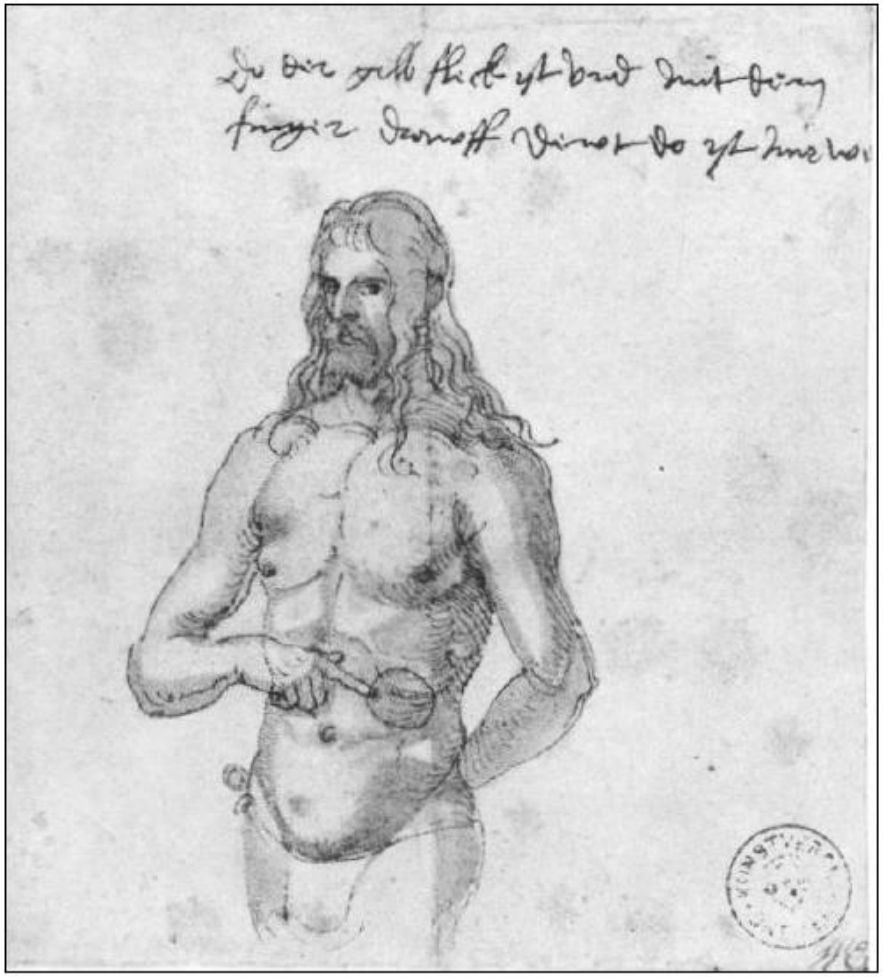


access all slides for case, display interactively

Telekonsultation

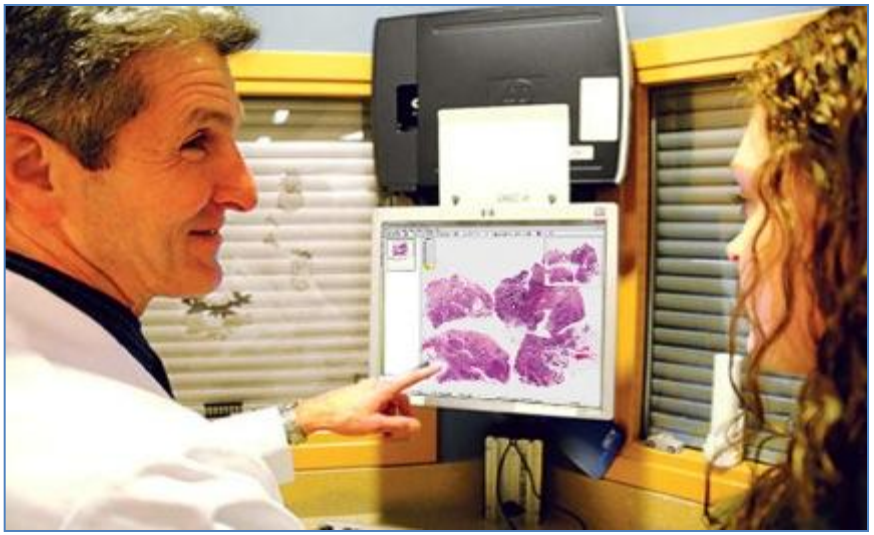
Sketch by Albrecht Dürer (1471-1528), depicting his Splenomegaly.

Hand geschrieben: *Do der gelb fleck ist vnd mit dem finger drawff dewt do ist mir we*, also "Da der gelbe Fleck ist und (ich) mit dem



Clinical

applications for Digital Pathology



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Digital Signout