Less is More

Real-World of Digital Pathology and AI

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Disclaimer

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Topics for Today’s Discussion

- Introduction
- CLIA updates
- Billing
- Real world applications of digital pathology
- Artificial intelligence
- Integrated sign-out dashboard
What is digital pathology?

- Acquiring and interpreting pathology information from a digitized glass slide
  - Diagnosis
  - Consultation
  - Teaching
  - Multi-disciplinary conference presentation
  - And so much more!
Artificial Intelligence (AI)

- Developing algorithms and models using digital analysis and machine learning
Is remote sign-out feasible post COVID?

Yes, you can sign out digital slides without a CLIA certificate for your house or other remote location!

As long as the primary lab meets updated guidelines

Primary site requirements

• Has CLIA certification and complies with all relevant Federal laws.
• Is certified to perform all the of work performed at the remote site and the laboratory director is responsible for all testing.
• Retains all documentation, including tests performed remotely and list of staff working remotely.
• Indicates remote site location on the reports (coding system ok).
Yes, you can code!

- Category III digital CPT codes now available
- Must use whole-slide imaging
- No codes for
  - Education/research
  - Tumor boards/clinical conferences
  - Archiving
  - Validation

https://www.cap.org/advocacy/payments-for-pathology-services/digital-pathology-codes
## Diagnosis, Special Stains and IHC

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Coming soon on Jan. 1- cytology, expanded surgical and hematology codes

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Digital Pathology: Real-world applications

- Not one size fits all
- Many different applications
  - Specific operational / logistical function
  - Specific mission (education, research, etc)
  - Improved staffing / access
  - Grow business (referrals, consultations)
- Means to an end! (AI deployment)
I have an interesting case and would appreciate your expert opinion.

Thank you. Here is the link: https://digitalslide/case

I see. Is there something specific that concerns you?

Actually, yes. I can set the concerning area as the start view. Here: https://digitalslide/case/zoomLevel

Great, I will take a look…
Inhouse consultation

I have an interesting case and would appreciate your expert opinion.

Of course!

Thank you. Here is the link: https://digitalslide/case

I see. Is there something specific that concerns you?

Actually, yes. I can set the concerning area as the start view. Here: https://digitalslide/case/zoomLevel

Great, I will take a look...

- Easily communicate in real time!
- No shuffling slides between locations!
- Better turnaround time!
External digital consultation / point of care

- Using digital pathology for external consultation
  - Cumbersome physical workflow
    - Extra paperwork
    - Slides packaged / sent
  - Shipping costs and labor add up over time
  - Suboptimal turnaround time
  - Original slides lost, broken, or never returned
Conferences and Tumor Board

- No more pulling slides!
- No more photographing the slides!
- No more PowerPoint presentations!
Consensus Conference
Consensus Conference

- Better attendance!
- No more crowding!
- Sign in from anywhere!
“Tagging” cases

- Advanced cataloging / organizing
- Automated workflow processes
- Easy data sharing and collaboration
- A tag can be any label! Customizable
“Tagging” cases

Tagging through the digital slide viewer
“Tagging” cases

Tagging through the pathology report to send to a common database
“Tagging” cases

FINAL INTEGRATED DIAGNOSIS:
Solitary fibrous tumor, CNS WHO grade 2

HISTOLOGIC DIAGNOSIS:
Spindle cell tumor

RELEVANT ANCILLARY INFORMATION:
STAT6 (IHC): Positive
Consensus Methylation Profiling Class: Solitary fibrous tumor, CNS WHO grade 2 (see Comment)

CNS WHO GRADE:
WHO grade 2

Tagging through other sources
DP Implementation is not without challenges

- Cost/Business case (initial investment and ongoing maintenance)
- Regulatory issues
- Buy in (C-suite, pathologists, clinicians, staff, etc)
- Requires significant workflow adjustments
- Requires IT support, clinical information management, etc
- Vulnerable to interruptions
- Scanning/viewing limitations
  - Cytology, bone marrows, H. pylori, mitoses, polarization, etc
- Requires a QA program
  - Failure rate, re-scanning
Artificial Intelligence

- Basic requirements
- Common AI-based systems for histopathology
- Ensuring trustworthiness in AI pathology
- Maximizing productivity
- AI + DP interoperability
Computational pathology (AI-based approaches)

Digital pathology

High-quality histology
Pathologists: The pillars of precision medicine

• Masters of doing more with less
• Efficiency masters
  o Unparalleled skill in maximizing precision with fixed resources
• Precision medicine champions
  o Crucial to the seamless integration of advanced diagnostics into patient care
• Escalating duties
  o Steering through intricate molecular diagnostics landscape
  o Absorbing rapid growth in medical knowledge
  o Adapting to a tight web of regulatory requirements
• Sustainability check
  o Evaluating the potential for overload
  o Necessity of innovative tools to support pathologists’ expanding roles
The role of AI in pathology

• **AI as a tool**
  - Requires careful exploration and mastery
  - Still in early stages—potential unknown risks
  - Our duty to understand and mitigate risks
  - Robust DP Infrastructure is critical

• **Implementation challenges**
  - Substantial effort for AI system deployment
  - Not universally established infrastructure

• **Productivity and AI**
  - AI deployment alone ≠ guaranteed productivity gains
  - True potential lies in AI + knowledge + optimal implementation
Common AI-based systems for histopathology

#1 Classification & detection
#2 Digital biomarker and virtual staining
#3 Image-based predictive/prognostic model

(Note: This list is not exhaustive)
#1 Classification & detection systems

- **Tumor detection, quantification, and grading**
  - Advanced algorithms for tumor analysis
  - Example: solutions for prostate and breast biopsies
- **Metastasis detection**
  - Automated detection of lymph node metastases
- **Mitotic activity assessment**
  - Al-driven counting of mitotic figures
- **Result verification**
  - Tools for pathologists to confirm AI findings
  - Visualization techniques
    - Use of masks and heatmaps for AI-histology correlation
#1 Example: AI for cancer identification, quantification, grading, and PNI detection
#1 Example: AI for kidney tumor classification with heatmaps

More examples can be found here: http://aistain.com

#2 Digital biomarker and virtual staining

- **Enhanced turnaround time**
  - Accelerate result availability, bypassing the wait for traditional staining or other ancillary studies.

- **Resource efficiency**
  - Decreases dependence on physical instruments, supplies and specialized personnel

- **Consideration of risks**
  - Validation could be performed based on gold standard
  - Challenge prospective monitoring
  - Limited literature about real world deployment
#2 Example: Virtual trichrome for liver


Systems and methods for digital transformation of medical images and fibrosis detection
Provisional patent, US Patent App. 17/845,880
El-Baz, A.S., Gondim, D., Naglah, A., and Khalifa, F.
#3 Image-based predictive/prognostic models

- **Optimal treatment guidance**
  - Utilizing AI to recommend the most effective treatment options tailored to individual patient profiles

- **Prognosis group stratification**
  - AI algorithms assist in categorizing patients into prognosis groups, enabling personalized care plans

- **Case study: ArteraAI prostate test**
  - An example of AI's application in providing prognostic insights for prostate cancer management

- **Verification challenges**
  - The current limitations in secondary methods for independent result confirmation
Ensuring trustworthiness in AI pathology

• Critical role of validation
  o Validation protocols are paramount to establish the reliability of AI results

• Pathologist oversight (human-in-the-loop)
  o Pathologist in the decision-making loop to adjudicate AI findings
  o Pathologist oversight not possible for biomarkers, virtual staining, and predictive/prognostic assessments

• Adjudication workflow integration
  o Incorporating a structured workflow for pathologists to review and adjust AI outcomes

• Risk mitigation
  o Addressing the potential for false negatives or positives, which could inadvertently increase the pathologist’s workload
DP + AI Interoperability

• Full-spectrum integration (ideal)
  o EHR + LIS + DP + AI
  o Lab-centric control (LIS + DP + AI)

• Efficiency in case management
  o Eliminates the need for manual retrieval across different applications
  o Allows order placement from image management systems (IMS) to laboratory information system (LIS)
  o Easy export of images from digital pathology (DP) to LIS

• Seamless asset tracking
  o Simplifies the monitoring of asset status, improving turnaround times and resource allocation
DP + AI Interoperability

- Integrated (same vendor)
- Custom interface
- Standard-based interface
Standard-based interfaces
Potential to plug and play
(NOT A REALITY IN THE MARKET)
Custom interfaces
(Not scalable – Not sustainable)
Custom interfaces
(Not scalable – Not sustainable)
Custom interfaces
(Not scalable – Not sustainable)
Example: LIS + DP + AI Interoperability

- Tracking system: Vantage Roche
- LIS: Cerner PathNet
- Image management system: Paige
- AI systems
- IMS access outside firewall
- Storage

Custom interface
Conclusion & take-home messages

• DP and AI offer the potential for enhanced accuracy and productivity
• High-quality histology and lab operational efficiency are paramount
• Leveraging AI’s full potential
  o Expertise, exploration, validation, and interoperability
• Adjudication risk
  o Suboptimal accuracy = workflow complexities and higher workloads
• Interoperability risk
  o Inadequate interoperability = workflow complexities and higher workloads
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