Pathology Innovation Collaborative Community

Payor Work

Agenda

1. Welcome
2. Goal of meeting: Better understanding of the innovation options
3. Introduction in PIcc, Digital Pathology (DP) and problem statement
4. Would there be options for innovative pilot projects to obtain funding for establishing reimbursement for DP?
5. What would be the process and timelines?
6. What are requirements for innovative pilot projects to obtain funding?
7. What are chances on success to obtain funding and how to increase them?

Summary of last meetings

Payor Strategies Working Group

I. Work to date
   a. Published whitepaper: Aligning Reimbursement of Digital Pathology with its Value
   b. Met with representatives from AMA to 1) Educate on the field of digital pathology and 2) Get advice on strategies for pursuing a CPT code for AI in pathology
   c. Several unsuccessful attempts to establish contact with radiology trade groups

II. Working group strategy
   a. After meeting with AMA representatives, the working group had determined to reach out to radiology trade groups to learn about strategy employed and experience in gaining CPT codes for AI in radiology prior to reaching out to trade groups more broadly.
   b. The question was posed to the group of whether we need to reassess the current strategy given failure to make connections to radiology groups.
      i. The group also discussed how this plan to get CPT codes fits into the broader strategy to establish reimbursement for digital pathology. In other words, if efforts to gain traction on establishment of new CPTs fail, what are potential alternative avenues to reimbursement?
         1. The group discussed the need to better define the value add or value proposition for digital pathology.
         2. It was mentioned that a potential value proposition could be to identify a use case that could only be achieved by using ML/AI in pathology, not by a human.
      ii. It was also mentioned that some payers are willing to provide funds for innovative pilot projects which could be explored.
      iii. Last, there was short discussion about alternative parties of interest such as medical malpractice insurance (need for better documentation) or electronic health record vendors who value access to pathology slides/data. This could be another avenue to pursue, particularly where high cost of lab set up for digital pathology, is a barrier to widespread implementation.

III. Next Steps
   a. Eric will facilitate setting up a call with a payer representative to explore payer concerns and potential avenues to reimbursement.
   b. Reach out to American College of Radiology via Joe's contact and set up a call to discuss strategy and potential partnering on CPT coding for digital pathology.
   c. Schedule a call with CAP to discuss need for reimbursement of digital pathology and explore potential concerns with establishment of new CPT codes.

Next steps

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I. Next Steps
   a. Eric will facilitate setting up a call with a payer representative to explore payer concerns and potential avenues to reimbursement.
      a. Done for innovative pilot project
      b. Still working to confirm the availability of a medical policy director from a Blue Cross Blue Shield insurance plan for next week's meeting.

   b. Reach out to American College of Radiology via Joe’s contact and set up a call to discuss strategy and potential partnering on CPT coding for digital pathology.
      a. Done by Laura
      b. Response?
   c. Schedule a call with CAP to discuss need for reimbursement of digital pathology and explore potential concerns with establishment of new CPT codes.
      a. Owner?

What is the PIcc

The Pathology Innovation Collaborative Community (PIcc) is a regulatory science initiative that aims to facilitate innovations in pathology as well as advance safety and effectiveness evaluation, and to harmonize approaches to speed delivery to patients using collaborative, pre-competitive approaches. The collaborative community (PIcc) is open to all stakeholders, public or private, including, but not limited to, academia, industry, health care providers, patients and advocacy groups.

Background and intro of Payor's workgroup

ROI of investment is not clear

Connection between industry, researchers, payors, health care provider, government and patients

Patient and outcome demonstrate added value

Its time to refocus efforts

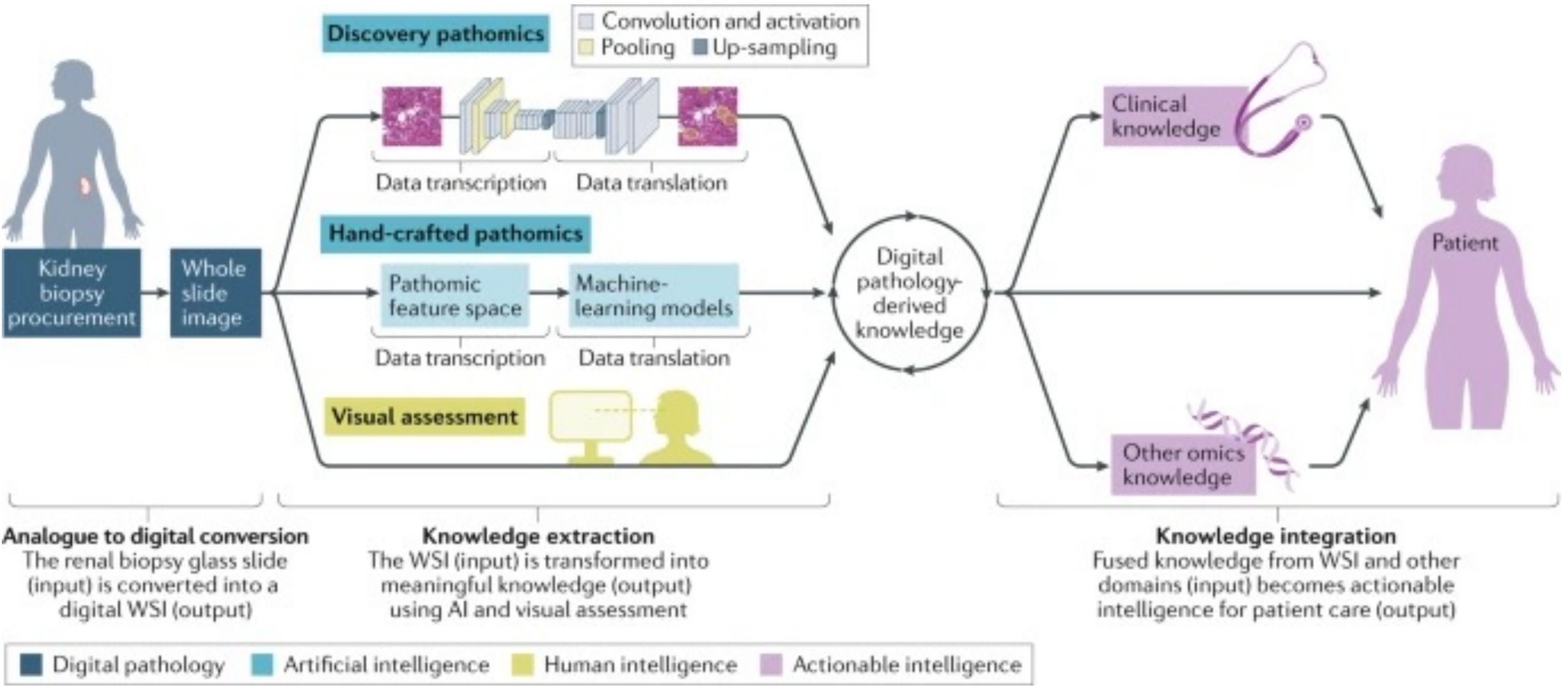
Problem Statement

- RARE EVENTS: There are very subtle, hard to differentiate patterns in tissue which could lead to inaccurate diagnosis or missed and/or misdiagnosis
- LAB FACTORS: Pre analytics and quality in pathology are known to affect diagnosis, i.e., studies shown this could lead to false negatives or false positives in 30% of cases
- HUMAN FACTOR: Human eye has limit capacity, leaving possible pathogenic features as well as potential to better predict patient outcome undiscovered
- COST: In contrast to radiology where an existing technology (film) could be replaced, slide scanning systems and their operation adds cost
- PATIENT ACCESS: pathology and especially subspecialty expertise is not available everywhere (e.g., underserved areas)

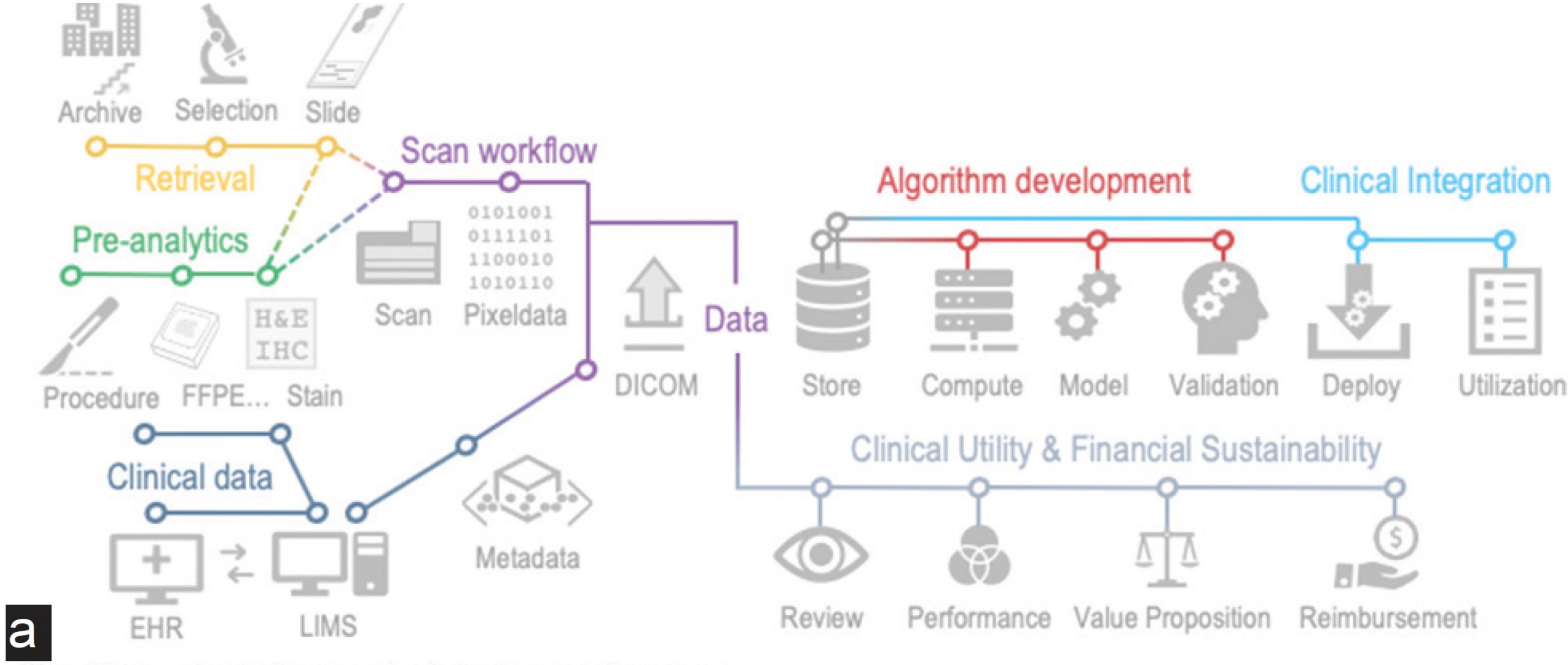
As a result, incorrect patient management, increasing health care costs.

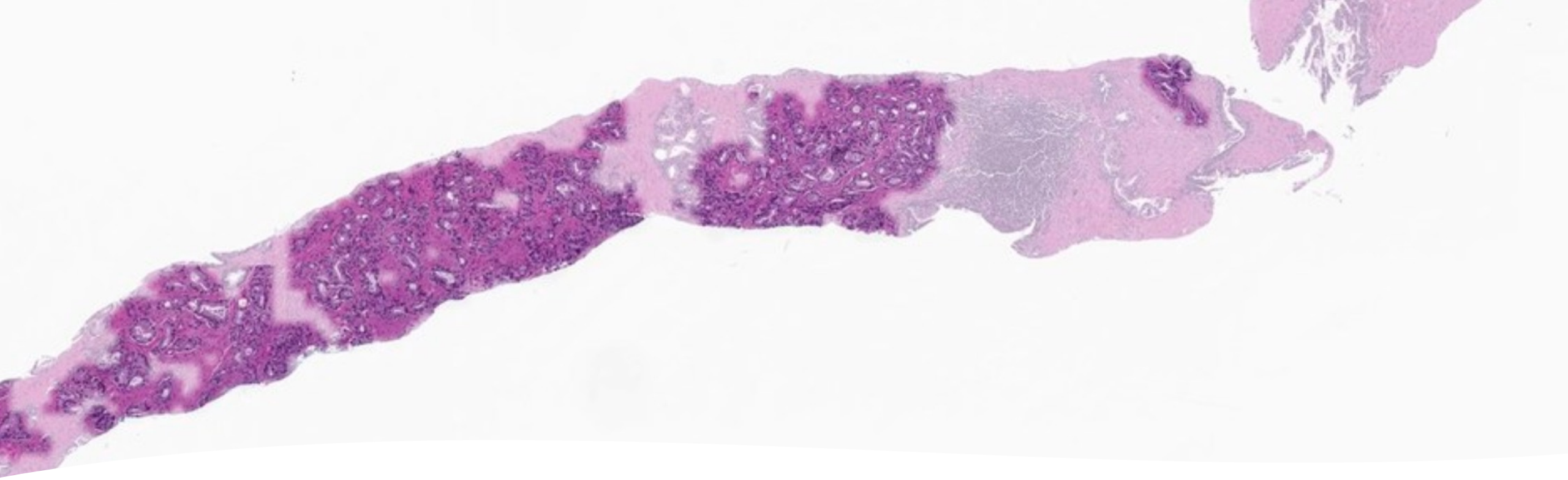
Traditional image analysis as well as AI technologies can help improve accuracy and consistency in the field, but digital adoption in the US has lagged due to lack of funding, making these benefits inaccessible to many labs and hospitals

Integration into Clinical Workflow



Digital Pathology Tool Creation





Digital Pathology in Use Today

- Digital pathology is already in use in some institutions
- The COVID-19 pandemic created an incentive for remote diagnostics
- As a digitization technology, it is an enabler for image analysis
- The example shows computer-based isolation of cancer in a prostate sample
- Opportunities to collect data to support value of this technology

- KEY PROBLEM: cannot easily track additional effort of the medical procedure.

Applications of Digital Pathology

- Creates access to expertise/second opinions in pathology specialties worldwide, without needing to ship tissue, which can be costly and delay diagnosis.

- Aids in identification of rare diseases and the classification of new ones as it enables knowledge sharing.

- Facilitates uniformity/consistency in diagnoses (prostate/breast cancer) where variability exists across and within institutions.

- Improves speed and COULD reduce (overall) cost of diagnosis.

- Enables the development and adoption of advanced image analysis and AI technologies

- Reduces need for reflex testing

- Has potential to discover new diagnostics which the human eye is incapable of

Benefits to Clinicians

- Improve care team communications and collaboration
  - The pathologist is the “doctor’s doctor.”
  - Where digital pathology is employed to increase workflow efficiencies, the availability of pathology consultations for clinicians could increase and, in conjunction with harmonized and standardized pathology reports, clinician understanding of pathology reports and subsequent decision-making could be improved.
- Opportunity to share annotated, whole slide imaging at multidisciplinary tumor board meetings
  - For example, will lend to increased understanding and better implementation of interventions (such as surgery).
- Ability of the pathologist to access and diagnose digitized images of a specimen at any time, especially remotely.
  - Provide the clinician with the information needed to initiate an appropriate course of therapy sooner and thus provide a better outcome for the patient.
- Reducing need for expensive reflex testing
- Increasing a better diagnostic decision making, improve patient management and right treatment for right patient at right time. Thereby reducing downstream costs.

Digital Pathology – In real life – Case Study

Tuesday: 8-year-old girl with edema and abnormal electrolyte pattern

Thursday: Renal biopsy performed at smaller hospital without a renal pathologist

Thursday night: Patient status changes to critical with seizures

Friday morning: Pediatric nephrologist asks about pathology results

Friday afternoon: Slides sent to tertiary academic hospital
Monday morning: Review by renal pathologist => notification of pediatric nephrologist

ALTERNATIVE

Friday morning: Biopsy is scanned by 8 am for renal pathologist to review digitally (at home)

Zoom call to physician to explain results

Without digital pathology, the same consultation would have required shipping of tissue and could have been delayed at least 3 days

Limitations of Current CPT Coding

CPT's for the entire "case":

88305 – Level IV, surgical pathology gross and microscopic examination (if appropriate)
88313 – Special stains, each (if appropriate)
88347 x4 – Immunofluorescent study, each antibody; indirect method (if appropriate)
88348 – Electron microscopy (if appropriate)

Issues:

1) No recognition of the use of slide scanner/image digitization
2) No mechanism for interpretation/analysis of digital image
3) No distinct value for the software/algorithmic component of analysis

Why Proposing a Novel Procedural Codes Are Important

- Similar to other innovative diagnostic technologies, digital pathology faces the dilemma of how best to demonstrate its essential value to stakeholders.
- Current codes do not enable tracking of this medical procedure
- The procedure includes both technical (TC) and professional components (PC).
- Novel, alternative CPT codes for digital techniques that enable the use of these incrementally innovative tools and distinguish their approaches are **needed to facilitate tracking**

Possible Coding Approaches

Could modify each procedural code applicable to whole slide imaging (88305 or 88313), but this would only account for the technical component.

OR

create novel codes for digital pathology procedures:

- XXXXX slide scanning as a procedural code
- XXXXX slide scanning + analysis (for a general use case)/or a specific use case
- XXXXX slide scanning + analysis (simple) - i.e., image-based analytics without multi-parametric analysis)
- XXXXX Computational analysis from whole slide imaging files (comprehensive) - i.e., using computational approaches including machine learning algorithms, perceptrons, prediction-algorithms, or convolutional neural networks

AND/OR

create novel codes for specific applications of the technology (possibly PLA codes)

- XXXXX digital analysis of pathology sample using image analysis software and algorithmic interpretation breast cancer

Discussion

- BCBS current programs
- Test that didn’t have CPT codes
- Build ROI model
- Running pilots:
  - There are associations within BCBS, these contain many different department
  - identifying focus area, e.g. oncology
  - There are 36 project within BCBS
  - Pilots:
    - Objective of the pilot is to identify strategic fit of product within program
    - Bring in solution to test, they drive and execute. Test and learn system.
    - Outcome: should be able to deliver medical policy with the goal of a decision: coverage or no coverage
  - Three players:
    - https://www.healthcore.com/ Anthom’s Healthcore
    - https://www.healthworx.com/
    - https://vitalinnovation.com/

Pilot projects

- ROI is extremely important
  - Work with innovation partner
  - Begins with evaluation of solution
  - Goals of vital program
    - Out of these three metrics, can the innovation move the needle for two out of three metrics:
      - Clinical metrics
      - Economics metrics
      - Experience metrics:
        - Healthcare system is broken; required documentation; can we bring in tools to support. What changes the experience of the clinicians

Business model

- How do you manage costs of pilot programs
  - Vitalinnovation: Upfront commercial model
  - Healthcore and health works:
    - Solutions were aligned with narrow strategic plans
    - Taking equity in solutions
- Costs ca. 60kUSD
  - 6-12weeks process
  - The programs would take the costs to apply the solution into their system (e.g. it would cost 500-1000$ to implement , that cost would absorbed)
    - Charge the company a nominal fee to engage them

What if there is a significant upside for userbut not payor?

- Recommend to collaborate with innovation company and sell it to your provider, make them the champion to go back to the payor system
  - The payor can then overlook the IDN, upfront reimbursement challenge

Time frame and Process

- Time frame and Process in total ~ 24 months
  - Intake
  - Evaluation Phase ~3mo
  - Population sizing
  - Opportunity Assessment ~3mo
  - Mock reimbursement proposal - CPT codes
  - Clinician and business approval
  - Prospective testing~9-12-15 mo
  - Clinician approval
  - Medical policy submission ~long lead time
- Coverage decision ~3months

Explanation of Process

- Time frame and Process in total ~ 24 months
  - Intake:
    - This initial step is to establish fit of the product within the program
    - Evidence needed for intake phase includes what the landscape looks like at time of intake
    - This includes RCT or peer reviewed publication. At minimum need manuscript to guide what current evidence status is.
  - Evaluation Phase ~3mo
  - Population sizing

    Evaluation and population sizing phases go hand-in-hand:
    - Pilot establishes clinician first impression
    - Seek consultation from internal/partner SMEs (inquireing whether SMEs would be interested in serving as SME on the pilot)
  - Opportunity Assessment ~3mo:
    - Determine how to power a prospective study
    - Endpoints: example for cardiology, strength of evidence in cardiology is around rehospitalization and eEDU rates
    - Sometimes Product manufacturer SMEs will be brought in

Explanation of Process, cont.

- Mock reimbursement proposal
  - Assuming product doesn't have a CPT code already.
  - Build out mock reimbursement codes and mock reimubursement to guage how pilot will be conducted
- Clinician and business approval
  - Manage conflicts in incentives for all parties
  - Determine if a solution would actually decrease profit on provider side and what adjustments insurer can employ to make the clinicians whole; manage ahead of prospective testing
  - Step is crucial because have to have early buy-in from providers
- Prospective testing~9-12-15 mo
- Clinician approval
- Medical policy submission:
  - Begin to anticipate final coverage decision and initiate long lead time
  - If outcome policy is coverage, will need to implement and scale across country and plans
- Coverage decision ~3months
  - Policy decisions are longer at the plan level: 6-12months
  - Will review evidence and clinical study reviews

Explanation of Process, cont.

- Other considerations
  - Payers are hesitant to engage with solutions that are positioned in clinical pathway to assist with diagnosis
  - For example, clinicians resist up front solutions such as products that identify potential malignancies and provide triggers to clinician
  - Clinicians see value from AI/ML solutions as confirmatory of diagnosis, not early flags
  - Insurer sees value in early screening diagnosis but take with grain of salt because IVN is there to support clinician; clinician-led organization
  - Potential opportunities:
    - Don’t need to outsource to another clinician for secondary opinion; diagnostic serves as the secondary opinon.
    - Cost of determining who the right physician is and cost of secondary opinion and time to get secondary opinion: could start to see ROI.
    - Important to consider geographic disparities, ROI becomes larger, expand to geographically dispersed regions