Digital Pathology Beyond Primary Diagnosis

Integrating Pathology into the Care Team – A Workflow Solution to Meet Requirements for Quality Reporting and Patient Outcomes
Speakers

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Agenda

Introduction

Benefits of an integrated digital pathology approach

Use Case

Quality reporting and diagnostic accuracy
Learning Objectives

• Review challenges in diagnostic medicine and describe the benefits of an integrated digital pathology approach

Present how digital pathology facilitates MACRA quality reporting and coordination of care

Describe the benefits of using digital pathology to improve diagnostic accuracy in breast cancer
Beyond Digital Pathology - Challenges in Diagnostic Medicine

- **Diagnostics imbalance in healthcare**
  - Influences 70% - 80% of medical decisions
  - 3% of total spend
- **$35B in healthcare waste is attributed to failures of care coordination**
  - Clinical and patient histories are often in separate systems
  - Communications standards are often still varied
  - A lot of diagnostic information is included in unstructured text
- **Reimbursement is ever more tied to clinical utility**
  - 60% of molecular procedures not being reimbursed due to lack of clinical documentation
- **Shortage of pathologists worldwide - seeing an increase in the number and complexity of specimens**
Integrating Pathology into the Care Team

- Patient-Centric Approach / Patient Engagement
- Multi-Disciplinary Team Collaboration (cross specialty)
- Treatment Planning and Tracking
- QA Protocols for improved quality of care and patient outcomes
- Tumor Boards/Peer Review
- Second Opinions
- Surgical Team Collaboration
- Teaching
API for Healthcare
Digital Pathology System
80% of all medical records contain a diagnostic image
Close to 1 billion diagnostic images created annually within U.S. alone
  – DPS is more than just capturing a digital image of a glass slide
Part of an integrated healthcare data exchange and collaboration platform
  – Connects you more closely into the cancer care pathway
  – Facilitates collaboration between you, your peers and care teams
  – Enables access and communication regardless of proximity
  – Enhances timeline and consistent delivery in labs
LIS is the Hub of Digital Pathology Workflow

• LIS is the core system to manage pathology case workflow and reporting
• Pathology will benefit greatly when there is a high degree of integration between the APLIS and DPS
  – Technology and regulators are evolving
  – Single integrated pathology system
  – Slide transport – case turnaround
  – Geographic dispersal of pathologists
  – TCPC
  – Virtual tumor boards
  – Device agnostic – support for any Digital Pathology/WSI system
LIS - DPS Integrated Viewing
Create Consult From LIS
Flag a Patient (Case) for MDT in LIS
Use Cases

ASCP: Partners for Cancer Diagnosis and Treatment in Africa

Kindstar: Secondary consults for China

TC

PC

Reimbursement Tied to Clinical Records
The Role of Digital Pathology in Quality Reporting Initiatives and Patient Outcomes
Quality Reporting Under MACRA (MIPS and APMs)

• Medicare Access and CHIP Reauthorization Act (MACRA)
  – Legislation passed April 27, 2015; Medicare Part B reimbursement
  – Physician based payment reform
  – Focus is on value-based payment and quality reporting; Eliminates Fee-for Service
  – CMS estimates 90% of eligible clinicians (MD’s, DO’s, NP’s, PA’s, others) will participate in MACRA payment reform

• MACRA’s Goal: “to have a single unified program with flexibility for all physicians that benefits patient care”…

Kate Goodrich, M.D., Director and CMS Chief Medical Officer, CMS Center for Clinical Standards and Quality, HIMSS 2017
What Does this Mean?

Reimbursement on Medicare Part B claims will be based on the quality of care and how that quality was reported.

Physician based with very few exceptions.

Reimbursement established and based on composite score derived from all types of submissions (competitive).
MIPS All Non-Patient Facing Clinicians (Pathologists and Labs)

- Payment adjustment based on evidence-based and practice-specific quality data
- Provides a track to demonstrate high quality, efficient care supported by technology
- Reporting for non-patient facing eligible clinicians (pathologists and laboratories)

<table>
<thead>
<tr>
<th>Quality</th>
<th>Improvement Activities</th>
<th>Advancing Care Information</th>
<th>Cost</th>
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<tr>
<td>Replaces PQRS.</td>
<td>New Category.</td>
<td>Replaces the Medicare EHR Incentive Program also known as Meaningful Use.</td>
<td>Replaces the Value-Based Modifier.</td>
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85% Weighted 15% Weighted

Role of Digital Pathology in Quality Reporting
• IRB approved study; 60 randomly selected; retrospective analysis
• Previously diagnosed including review of slides by digital pathology (WSI)
• Designed to measure diagnostic agreement of WSI (inter rater) to record accurate diagnosis and coding
• The study included breast histologic grade and stage to meet the CMS requirement for quality reporting to:
  – PQRS 99 with histologic grade
  – PQRS 251 Quantitative IHC Evaluation of HER2 clinical guidelines for reporting effective clinical care
Background: Qualified Clinical Data Registries (QCDR) capture quality measures as part of PQRS. A QCDR is a CMS-approved entity that collects medical and/or clinical data for patient and disease tracking to foster improvement in the quality of care provided to patients. Accurate reporting to a QCDR is dependent on review of digital pathology as a critical component to pathology diagnosis and the ability to report accurate CPT and ICD codes that can drive reporting to a QCDR.

Methods: IRB approval was obtained for a retrospective review of 60 randomly selected breast pathology reports that were diagnosed at Ohio State University. All cases, including review of slides by digital pathology was included with the pathology report for an accurate and appropriately coded diagnosis. Breast histologic type pT, pN was included to meet the CMS requirement for quality reporting.

Results: The OSU study consisted of 60 Breast randomly selected pathology reports and mix of race and positive and negative results. Lack of CPT codes for ER/PR negative results along with proper stage reporting presents challenges in the QCDR. 36 cases were ER/PR positive while the remaining cases were mixed.

Conclusions: Pathologists remuneration will be calculated on the quality of information submitted to CMS. Operations may be hindered to accurately submit data to a QCDR. As the quality scores will be higher, the clinical data submitted to a QCDR will improve.
Digital Pathology Concordance in Quality Reporting

Data quality established for WSI use in diagnosis

Diagnosis of Breast Cancer Quantitative non-HER2 IHC Evaluation

Cancer Staging by ASCO/CAP Guidelines

Quality Reporting

Statistical Analysis of Pathology-Pathology to Know Outcomes

Compare to Known Outcomes

Pathology-Pathology Tumor Board Determined Agreement

QCDR
2017 Registry Individual Measure Flow

#251 NQF #1855: Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients

- Denominator - Patient demographics; ICD; CPT
- Numerator - Diagnosis; Stage; Histologic type
- Report completeness of data
- Report performance rate
Clinical Improvement Activities – Coordination of Care – 15% weighted

- Example of a CCD report
  - Case-mix summary report
- Clinical measure report for Coordination of Care
- Adheres to MIPS reporting requirements
  - Format is compliant with CMS QPP portal requirements

- ACTIVITY ID - IA_CC_12
- SUBCATEGORY NAME Care Coordination
- ACTIVITY WEIGHTING - Medium
Why is this Important?

• Digital pathology / WSI play a key role from a diagnostics and quality perspective

• Digital pathology / WSI provide the basis for downstream quality reporting
  – Radiology and oncology in cancer care
  – Key to full spectrum of patient encounter reporting

• Adoption of digital pathology solutions allows laboratories to become the supporting network for physician partners
  – Support their clients reporting needs – clinical documentation
  – Support for referrals – patient navigation
Diagnostic Outcomes and Patient Care
Use Case: Invasive Ductal Carcinoma (IDC) Breast Cancer

• 68 y/o female; ER+/PR+/HER2-
• Stage IV metastasis (bone)
• WSI supports diagnosis and aligned with path report
• Communication with med oncologist via CCD
• Determine correct therapy (Xgeva + Ibrance)
• Turn around time to treatment is tracked for quality
• Managed by accession ID from LIS
• Linked to BRCA testing in LIS
• Pathology images 6MB-1GB each
Retrospective Analysis and Trending

- Interactive distribution data map of all patients; age/stage linked to diagnosis/grade
Prospective Analysis and Trending

**Total count and Diagnosis and Race**

Number of Patients with IDC by age, race, and HR+/HER2-

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<th>Number of Records</th>
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**Patients flagged as eligible for additional gBRCA testing for hereditary markers and track recurrence**

Number of Patients with IDC by age, race, and HR+/HER2-
Stage IV (Metastasis)

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**Patients flagged as eligible for additional gBRCA testing (PARP inhibitor) and treatment options as of January 2018**
Summary: Why the Laboratory Informatics Approach is Important

- Integrated digital pathology with the LIS will expand the laboratory and pathologist role with the care team
- Digital pathology systems will establish a standard of quality and value to the partner health system and physician partners
- Facilitates quality reporting to external entities (FDA, CMS)
- Serves a central role for visualization and analysis of data aggregates
Speaker Contact Information

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