Digital Pathology Current Status and Future Directions

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Disclosures

• I, Dr. Ehab A. ElGabry am the Senior Medical Director Of Personlised Health Care Solutions (PHCS) and Head of Companion Diagnostics Pathology for Roche Tissue Diagnostics
Objectives:

• Define the scope of digital pathology and provide the rationale for why Digital applications will continue to expand and transform the pathology practice.

• Describe whole slide image technology and the concepts of digitizing pathology workflow.

• List current and future digital pathology applications and highlight their benefits for pathology practice.
Presentation overview

- Digital Pathology Historical Milestones
- Challenges of current practice model and the need for digital pathology solutions
- Definition of DP
- Digital pathology LAB infrastructure essentials
- Current and future digital pathology applications
Historic Milestones

• 1968 : Black and white photos of Blood smears sent via video from Logan airport

• 1980 : Remote Tele Pathology

• 1986 : Robotic Telepathology system

• 2000 : WSI comes to market

• 2009 : FDA panel meeting addresses the use of digital pathology for primary diagnosis

• 2017: FDA approval of the first WSI platform for primary diagnosis.
Adoption Barriers

- Digital solutions technology infrastructure challenges
- Regulatory Issues
- Payers evidence for reimbursement
- Learning curve
- Regional specific challenges: regulatory, reimbursement, and technology infrastructure
- Silos
- Skepticism by the medical community (Academics, hospitals, community labs)
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Global state of cancer today

Cancer continues to be one of the leading causes of death worldwide

14 million people worldwide develop cancer\(^1\)

And will rise to more than 21 million by year 2030\(^1\)

Tumors Are Developing Ecosystems

Critical Interactions Between Cancer Cells and the Tumor Microenvironment

- Macrophages
  - M2 phenotype
  - Cytokines
  - Tumor-associated Ag presentation inhibited
  - Inhibition of M1 phenotype
  - Inhibition of cytolytic granule release
- Cancer Associated Fibroblasts (CAFs)
  - TGF-β, MCP1, PDGF, FGF, proteases
- MDSCs
  - ECM
  - Angiogenesis
- Immune suppression
- VEGF
- T regs
- Checkpoint pathways
  - Inhibition of B and T cell responses
Increasing number of approvals for PD-1/PD-L1 inhibitors*
Challenging for pathologists to assess PD-L1 across multiple tumor types/indications

Squamous Cell Head & Neck Cancer
1L/2L nivolumab after platinum chemotherapy
1L/2L pembrolizumab after platinum chemotherapy

Malignant Melanoma
Adjuvant/1L ipilimumab
1L nivolumab ± ipilimumab
Adjuvant nivolumab
1L pembrolizumab

Merkel Cell Carcinoma
2L avelumab

Hepatocellular Carcinoma
2L nivolumab after sorafenib

Adv. Renal Cell Carcinoma
1L nivolumab plus ipilimumab
2L nivolumab after anti-angiogenic therapy

MSI-H or dMMR Cancers
2L nivolumab in CRC
2L nivolumab plus ipilimumab in CRC
2L pembrolizumab in any MSI-H/dMMR cancer

Cervical Cancer
2L pembrolizumab CPS≥1

Non-Small Cell Lung Cancer
1L pembrolizumab TPS≥50%
1L pembrolizumab + pemetrexed/carboplatin in non-squamous NSCLC
2L pembrolizumab TPS≥1%
2L nivolumab
2L atezolizumab NSCLC
Maintenance durvalumab after chemoradiation

Small Cell Lung Cancer
3L nivolumab

Gastric & GEJ Carcinoma
3L pembrolizumab after fluoropyrimidine- and platinum-chemotherapy +/- HER2 therapy & CPS≥1

Classical Hodkin Lymphoma
4L pembrolizumab
3L nivolumab after auto-HSCT and BV
4L nivolumab and after auto-HSCT

PMBCL
3L pembrolizumab

Locally Adv. or Met. Urothelial Cancer
1L/2L nivolumab after platinum chemotherapy
1L/2L pembrolizumab
1L atezolizumab in cisplatin ineligible IC≥5%
2L atezolizumab after platinum chemotherapy
1L/2L avelumab after platinum chemotherapy
1L/2L durvalumab after platinum chemotherapy

*U.S. FDA Approved Immune Checkpoint Inhibitors as of 20-Jul-2018

Adapted from https://medi-paper.com/us-fda-approved-immune-checkpoint-inhibitors-approved-immunotherapies/
Scoring Methods

TPS

CPS

H-score

Tils

ICP
Embracing Complexity To Develop Better Diagnostic Strategies

Challenges increase with combination therapies

334 new immunotherapy combo trials have started in 9 months

- Need for new biomarker strategies to make rational therapeutic decisions
- Multiplexed assays will be required

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1105 combo trials as of September 2017

1449 combo trials as of June 2018
Too few pathologists to meet demand
Growing problems fuel new solutions

Canada
26K

United States
19K

China
74K

Malaysia
103K

Australia
15K

New Zealand
20K

1www.clpmag.com/2017/10/digital-pathology-gives-rise-computational-pathology/
Paradigm Shift
Welcome To The Era Of Digital Pathology
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DP Definition:

- Digital pathology is a dynamic, image-based environment that enables the acquisition, management and interpretation of pathology information generated from a digitized glass slide.
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Digital Pathology Workflow Essential Components

Pathologist Interface

Scanning

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