College Guidelines on Implementation of Digital Pathology and Adoption of Artificial Intelligence

Introduction

Digital Pathology (DP) has gained popularity with the advances in Whole Slide Imaging (WSI) and Artificial intelligence (AI). WSI has the potential to revolutionise conventional pathology practice by digitising the glass slides for easy circulation, archival, diagnosis and image analysis. The adoption of DP is at an early phase in most parts of the world and is usually limited to a subset of specimens. Safe adoption will require concerted effort from pathologists, laboratory technologists, Information Technology team, hospital administrators and regulatory bodies.

These guidelines are highlights of aspects in the implementation of DP which need special attention, and are not meant to include details. The focus is on the application of DP in histopathology practice of Anatomical Pathology (i.e. biopsy specimens and surgical specimens). Pathology practice involving frozen section services, fine needle aspiration specimens and cytology specimens, and practices in other pathology disciplines will be considered for inclusion at a later stage.

A. Planning and selection of equipment

Information Technology

The deployment of DP requires substantial information technology support. Advice from the Information Technology department/service provider should be sought in project planning, medical system integrations, storage system design and continuous helpdesk support.

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Regulations on Medical Devices and Maintenance

Currently, there is no specific legislation that regulates the manufacture, import, export and sale of medical devices in Hong Kong[1]. Some whole slide scanners and software packages (e.g. slide management system and image analysis system) opted to receive clearances for clinical use from other jurisdictions. Using a system not yet cleared for in-vitro diagnostics (IVD) use, such as equipment and/or platforms labelled "research use only (RUO)", shall require more proper validation to demonstrate the safety and effectiveness prior to clinical deployment. The equipment should receive regular maintenance and, if necessary, calibration according to a predetermined maintenance plan.

Workstation and Ergonomic

1. Display Monitor and Workstation

The setting of the workstation is one of the important components in successful implementation of DP. The display monitor, the lighting and the other computer accessories should be properly proven to be suitable for implementation of DP, and in special cases, for subspecialty need. Similarly, it is essential to consider the interrelationship between various components of the DP system, such as slide scanner, to ensure optimal performance.

2. Occupational Safety and Health

Pathologists employing a DP workflow will likely require prolonged use of display screen equipment. Provision of an ergonomic workplace should be in compliance with the relevant provisions of the Occupational Safety and Health Regulations[2], and the wellness of the users should be well considered. Useful information has been published by the Labour Department of Hong Kong SAR[3]. Occupational risk assessment should be considered.

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[1] *Department of Health of the Government of the Hong Kong SAR. Department of Health | Medical Device Division - Frequently Asked Questions [Internet]. [cited 2024 Sep 5]. Available from: https://www.mdd.gov.hk/en/useful-information/frequently-asked-questions/index.html*

[2] *Occupational Safety and Health (Display Screen Equipment) Regulation, (2022) Cap. 509, § 42 (H.K.)*

[3] *Labour Department of the Government of the Hong Kong SAR. Occupational Safety and Health (Display Screen Equipment) regulation [Internet]. 2003 [cited 2024 Sep 5]. Available from: https://www.labour.gov.hk/eng/news/dser.htm*

B. Operation-related issues

Validation of WSI Devices

Meta-analysis[4] has shown DP with WSI to have good overall concordance* (98.3%) and complete concordance (92%) when compared with light microscopy in diagnostic histopathology. Discordance reported in literature commonly involved assessment of nuclear atypia, grading of dysplasia and malignancy, challenging diagnoses and identification of small objects.[4,5] The overall performance of using WSI in routine diagnosis is affected by case spectrum, specimen preparation, hardware employed and user training.

In-house validation/verification involving reasonable case load and spectrum and with clear documentation prior to routine diagnostic work is highly recommended. The process should be relevant to the proposed areas of DP use in a real-world environment. Validation protocol should comply with local regulations and accreditation requirements for comparison of new technologies against the existing standards. Useful information, including the design of a diagnostic accuracy study, has been published by various organizations such as the College of American Pathologists (CAP)[6] and The Royal College of Pathologist (RCPath)[7]. Re-validation is necessary in case of significant change in slide production, image acquisition or image reproduction.

* *as defined by complete agreement along with clinically insignificant variations between DP and light microscopy reports*

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[4] *Azam AS, Miligy IM, Kimani PK u, Maqbool H, Hewitt K, Rajpoot NM, et al. Diagnostic concordance and discordance in digital pathology: a systematic review and meta-analysis. Journal of Clinical Pathology [Internet]. 2020 Sep 15;74(7):448–55. Available from: https://doi.org/10.1136/jclinpath-2020-206764*

[5] *Williams BJ, DaCosta P, Goacher E, Treanor D. A systematic analysis of discordant diagnoses in digital pathology compared with light microscopy. Archives of Pathology & Laboratory Medicine [Internet]. 2017 Dec 1;141(12):1712–8. Available from: https://doi.org/10.5858/arpa.2016-0494-oa*

[6] *College of American Pathologists. Validating whole slide imaging for diagnostic purposes in pathology [Internet]. College of American Pathologists. 2024. Available from: https://www.cap.org/protocols-and-guidelines/cap-guidelines/current-cap-guidelines/validating-whole-slide-imaging-for-diagnostic-purposes-in-pathology*

[7] *The Royal College of Pathologists. Best practice recommendations for implementing digital pathology [Internet]. https://www.rcpath.org/profession/digital-pathology.html. 2018 Jan [cited 2024 Sep 5]. Report No.: G162. Available from: https://www.rcpath.org/static/f465d1b3-797b-4297-b7fedc00b4d77e51/Best-practice-recommendations-for-implementing-digital-pathology.pdf*

Training

DP deployment requires installation of specific equipment (such as slide scanners and servers) and competent operators. Pathologists as the laboratory leader, should take the primary role in the overall planning and implementation of digital pathology. Proper training for the pathologists, trainees and other laboratory personnel should be provided.

Storage

There is no current consensus on the legal status of WSI as a replacement of glass slides in archival. Compliance with regulatory guidelines and accreditation requirement by respective bodies is recommended.

Patient privacy

WSI images generated for diagnosis should be regarded as the patients' medical record and should be handled in accordance with professional standards[8], accreditation requirements and privacy legislation[9]. Cloud-based storage, image analysis, telepathology and remote work may pose additional challenges to data protection. The benefit and risks of such practices should be carefully balanced, with security measures added if practicable.

Contingency Plan

Laboratories and Information Technology departments should anticipate the possibility of a major Information Technology outage and a contingency plan should be in place and preferably tested from time to time.

[8] *Medical Council of Hong Kong. Code of Professional Conduct for the guidance of Registered Medical Practitioners [Internet]. DH2425 ed. 2022. Available from: https://www.mchk.org.hk/english/code/files/Code_of_Professional_Conduct_(English_Version)_(Revised_in_October_2022).pdf*

[9] *Personal Data (Privacy) Ordinance (2013), Cap. 468 (H.K.)*

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C. Adoption of Artificial Intelligence

DP is a rapidly developing field with evolving technologies and standards. Currently, there are many medical AI solutions focusing on histopathology being proposed for cancer detection and various immunohistochemistry quantification. They are of significant potential value to the practice of histopathology. The adoption of AI should be carefully considered and evaluated before implementation.

Summary

- In-house validation/verification prior to routine diagnostic work is highly recommended.
- Pathologists and other laboratory personnel should be properly trained in the implementation of Digital Pathology.
- Thorough deliberation should be given to the choice of display monitor and workstation ergonomic setting. Occupational risk assessment should be conducted before implementation of Digital Pathology.
- Storage of the digital slides should comply with local regulatory requirements and accreditation requirements.
- Equipment should be properly maintained
- A contingency plan should be in place to respond to the possible event of Information Technology outage
- Digital slide and data storage should be implemented in line with prevailing policy.
- Adoption of AI solution in Digital Pathology should be carefully considered and evaluated before implementation.

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