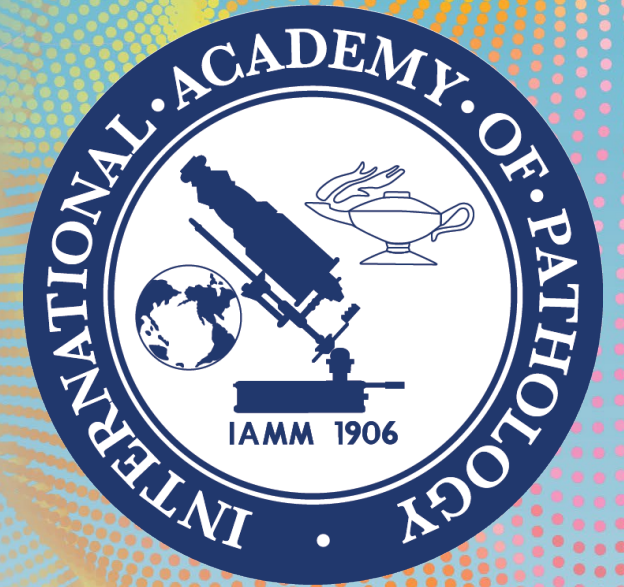


RCPA Draft Guidance Document for Artificial Intelligence in Pathology

Nigel Maher

Melanoma Institute Australia
The University of Sydney



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Australasian Division of the
International Academy of Pathology

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No relevant financial relationships

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-> Guided by RANZCR Standards of Practice for Clinical Radiology V11.2 July 2020– chapter on AI including ethical principles on use of AI in medicine.

The RCPA AI in Pathology Working Group

Document Purpose

Designed to mitigate clinical risks and ensure best clinical care when using AI in pathology

Aim to guide development and deployment and monitoring of AI in pathology settings and guide governance bodies

Purpose of Today

Let you know what's underway

Seek your feedback

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Definitions

- AI
- Machine Learning
- Neural Network
- Deep Learning
- Algorithm
- Expert System
- Types of machine learning – fully/weakly/unsupervised
- Training, Validation and Test Data Sets
- Ground truth
- Machine Learning Medical Device
- Locked device and continuous learning
- Designated Person
- Chief Pathology Information Officer (CPIO)

Ground truth

- The ‘reference standard’ by which model trained and evaluated against
- Established by a suitably trained pathologist(s) or qualified scientist with appropriate domain knowledge.
 - Not necessarily FRCPA qualified
 - FRCPA qualified to oversee validation in NATA accredited laboratory

Chief Pathology Information Officer

- Pathologist with registration, qualifications, competence and relevant scope of practice
- Delegated by the Designed Person for the oversight and supervision of pathology testing being performed by AI methods
- Includes the selection, deployment, and monitoring of AI tools, and associated staff training

8 Ethical Principles for the use of AI in Medicine

1. Safety
2. Privacy and Protection of Data
3. Avoidance of Bias – related to volume/variety of data/algorithmic design
4. Transparency and Explainability
5. Application of Human Values – avoid exacerbating disparities in health outcomes by applicability only for certain groups of people
6. Teamwork
7. Responsibility for Decisions
8. Governance

Responsibility for Decisions

Instances where responsibility varies either between:

- The medical practitioner caring for the patient (pathologists/clinicians)
- The hospital or laboratory management who took the decision to use the systems or tools
- The manufacturer that developed the AI

Given responsibility may be shared – this should be recorded upfront when researching/implementing

Governance

AI should be subject to **internal quality control measures** and **external quality assurance programs**

Difficulty at Present: No external quality assurance program exists for AI pathology software

Standards

1. **Algorithm Development**
2. **Information Management**
3. **Algorithm Deployment**
4. **Professional Standards**
5. **Audit**
6. **Governance**

Standards

1. Algorithm Development

Expert advice, Design for Clinical Use, Transparency and Explainability

Input from computer and data scientists, relevant medical experts required
Consider advice from non-clinical perspective: regulatory/legal/risk management
Understand AI limitations, locked model, regulatory approval

Understanding the model:

- Context in which it was developed (e.g. populations, training/test set sizes, ground-truth, limitations, hardware, software, techniques in training the model)
- Should only be used locked (can continue to learn in the background), and updates incorporated only once performance tested.

Standards

2. Information Management

Information security, Consent and Privacy, Information Sharing

Appropriate measures to safely store and transmit data, and comply with existing laws.
Implement a user registry to track access to patient information

Abide by current regulations/best practices/security measures/obtain ethics approval (waivers)/data sharing agreements (including secure disposal of data at project completion)

Care to deidentify to prevent someone's identity being reconstructed ('as confidential as reasonably achievable')

Aim to use standard annotations/terminologies as inputs/outputs (e.g LOINC)

Standards

3. Algorithm Deployment

Clinical Oversight – Coordinated by a CPIO

CPIO – oversee selection, deployment, monitoring of AI in lab, including staff training

CPIO – assess benefits and risk, manage upgrades, contingency planning

CPIO – needs appropriate domain expertise, and understand mode of operation of algorithm in AI.

Suitability and appropriateness

CPIO and team – determine degree of AI autonomy and evidence of impact on clinical service provision

Record an assessment of AI's appropriateness for its different patient groups

Compliance and Records

Register of risks specific to the lab and AI, and should be derived and regularly updated, with outline on how these are to be mitigated or managed.

Traceability of AI – for each patient instance, record of software/version of tool at that time

Standards

3. Algorithm Deployment

Integration

Consider impact on existing workflows – including timeliness, safety, OHS, performance

Assess interoperability with existing systems, e.g. LIS

Abide and consider existing requirements and regulations of digital pathology (RCPA separate reference document)

Control access to data (internal/external data)

Risk management

Systems to ensure lab continues to function if AI temporarily unavailable or withdrawn

Subject to internal/external QA

Initial audit

Performance audit with set periods of time, no longer than 6 months for low-risk AI, regular audit schedule as per CPIO determination (based on volume and clinical impact of incorrect diagnosis);

Validation to ensure calibration, analytical validation and clinical validation

Standards

4. Professional Standards

Patient safety

Supervising pathologist retains primary responsibility in the use of AI for a particular patient

Primary responsibility for ensure AI used ethically and in line with RCPA Standards of Practice with designated person and governance body that chose to deploy AI.

Lab will include details in lab reports about the use of AI in clinical care

Training in AI

All staff be adequately trained, including when to escalate, and understanding outputs.

Decision-making

Pathologist involved in care of that patient to consider AI output together with other clinical information

Cannot exclusively rely on AI to make value judgements for further patient management decisions

Responsibilities of the Designated Person (or delegated supervisor, i.e. CPIO)

Broad understanding of various frameworks related to digital health (IT, business and risk management) including cultural values that may affect use of AI in lab

Standards

5. Audit

Audit

Ensure objectivity and impartiality of auditors and audit process

Use a set of 'benchmark' or 'test' cases to measure ongoing validity

Consider feedback from downstream users and impact on patient outcomes

Annual review of corrective/preventative actions and their effectiveness –
(qualitative and quantitative)

Retains records of audit and external QA

Monitoring and maintenance

Ensure systems kept up-to-date

Record and act of any discrepancies of performances

Standards

6. Governance

Governance

Governance committee to be set up at the lab prior to deployment to oversee

Committee must include either designated person or CPIO

Formal records kept from committee decisions

Account for conflicts of interest

Due diligence of suppliers of AI who may have potential access to private health data

Internal/external QA

Responsibility

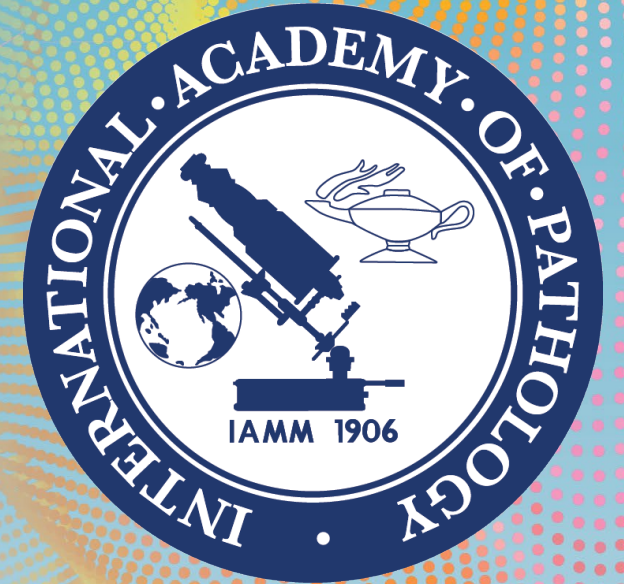
Individual responsibility of all entities should be assessed and assigned prior to implementing AI tool

Designated person or their delegate carries ultimate responsibility for safety/selection/deployment/monitoring of any AI tool used

Teamwork

Governance body to ensure all team members working collaboratively

Acknowledgements



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