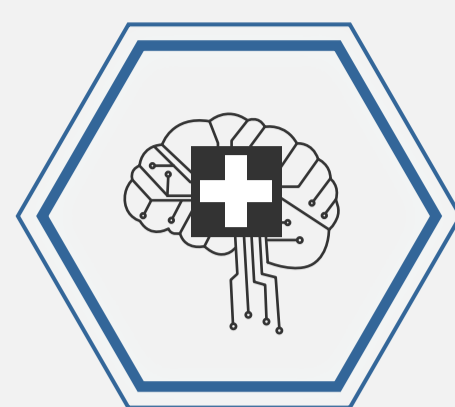MINISTRY OF HEALTH
SINGAPORE

ARTIFICIAL INTELLIGENCE IN HEALTHCARE GUIDELINES (AIHGle)

Is your Healthcare Institution using AI Safely?

While there are **potential benefits** of AI in healthcare, there are **risks and ethical concerns** if the AI is not properly designed and implemented

The AIHGle aims to:

Support patient safety and improve trust in the use of AI by:

- Sharing good practices with **Developers** (e.g. AI Medical Device manufacturers) and **Implementers** (e.g. Healthcare Institutions)

- Complementing HSA's regulations for AI Medical Devices[1]

- Periodically being updated as a **'living' document** with good practices

ACCESS THE AIHGle HERE

https://go.gov.sg/aihgle
GO.gov.sg

Who is the AIHGle for?

Developers
(e.g. AI Medical Device companies/manufacturers)

Implementers
(e.g. healthcare institutions - hospitals, clinics, laboratories, etc.)

KEY RECOMMENDATIONS

Development

1 Design
» Obtain clinical and end-user input
» Ensure testing datasets are representative
» Secure-by-design: Prepare to prevent, detect, respond, and recover from cybersecurity risks

2 Build
» Adopt appropriate development standards (e.g. risk and quality management systems)
» Ensure version control for iterative builds
» Incorporate self-validation mechanisms
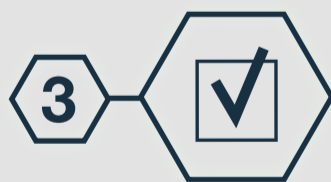
3 Test
» Validate on retrospective and representative data
» Peer-review of validation results
» Document how the AI should be incorporated into clinical workflows

Implementation

4 Use
» Ensure clinical governance and Organisational Leadership[2] approvals (e.g. Chairman, Medical Board (or equivalent))
» Track performance at the point of deployment "ground-truthing"
» Be transparent to the end-user that an AI is in use and be able to explain AI decisions

5 Monitor
» Continue performance monitoring post deployment
» Set escalation thresholds and pathways
» Establish processes to receive, respond, and investigate any adverse events

6 Review
» Implement regular and ad-hoc reviews for safety, efficacy, and utility
» Perform periodic maintenance (e.g. cybersecurity vulnerabilities, data handling)

NEXT STEPS

- **Review your internal development and implementation governance and controls** and align these to the recommendations

- **Consult HSA early** if you are developing AI medical devices (pre-market consultation route)

- **Check in with MOH if you have comments/queries on the AIHGle** https://go.gov.sg/aihgle-feedback

[1] Solutions regulated by HSA for investigation, detection, diagnosis or treatment of any medical condition or disease (e.g. diagnostics tools for sleeping disorders and cancers, retinal image detection of diabetic retinopathy, etc.)

[2] Organisational Leadership refers to those who are responsible for the overall leadership and governance of the healthcare service and varies based on the organisational size and structure. For large healthcare organisations (i.e. hospitals, nursing homes, laboratories) this could be e.g. Board of Directors, Clinical Director, and Chairman, Medical Board. For solo practitioner clinics/organisations, this could be the business owner and/or the clinical lead.