ACE
agency for
care effectiveness

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ANNUAL MEETING
ADELAIDE AUSTRALIA

Are We Ready For It? Developing Criteria To Include Artificial Intelligence Medical Devices For Health Technology Assessment

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Aim

To describe the Agency for Care Effectiveness' (ACE) approach to develop criteria to include artificial intelligence medical devices (AI-MDs) for health technology assessment (HTA).

Background

The increasing pace at which AI-MDs or digital health technologies (DHTs) have been introduced and integrated in healthcare has not been matched with appropriate selection criteria for HTA to inform funding decision-making. To align with international best practice and local regulatory guidance, ACE developed criteria to include AI-MDs as part of its 2022 topic prioritization process for medical technologies.

CHALLENGES of AI-MD

- Rapid Pace of Development
- Reliability in Real-world Clinical Decision-Making
- Limited Rigour in Current Evidence
- Cybersecurity Risks

Methods

To supplement ACE's existing topic selection criteria for medical technology, a search of international HTA agency websites was conducted to identify relevant information on inclusion of AI-MDs in healthcare for reimbursement recommendations. Additionally, local regulatory guidelines for AI-MDs in healthcare were also identified. From these, the inclusion criteria were developed and piloted with AI-MDs identified from ACE's horizon scanning workstream to examine their feasibility for HTA topic selection.

Results

One overseas evaluation framework for DHTs and two local regulatory guidelines were identified. Based on the key findings that AI-MDs were considered useful in guiding clinical management and its associated risks, the following criteria were developed:

i. full registration with the regulatory body;
ii. device characteristics should be interventional, have direct impact on patient safety, or support accurate diagnosis or treatment; and
iii. the AI algorithm should be fixed as opposed to adaptable as per regulatory requirements.

Using these inclusion criteria, eight AI-MDs surfaced from horizon scanning were deemed suitable for HTA topic selection.

INFORMATION GATHERING

ACE Medical Technologies Evaluation Methods and Process Guide

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Overseas HTA agency websites or databases
- NICE Evidence Standards Framework for DHTs

Local regulatory guidelines
- HSA Regulatory Guidelines for Software Medical Devices
- MOH AI in Healthcare Guidelines

SELECTION CRITERIA DEVELOPED

- Full registration by regulatory body
- Interventional devices for accurate diagnoses or treatment
- Fixed AI algorithm

PILOT APPLICATION OF CRITERIA

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IT & Software Technologies from **ACE Horizon Scanning** assessed to be eligible for **HTA Topic Prioritisation**

FUTURE DIRECTIONS

Agile Adaptation | Application in Practice | Active Collaboration

Conclusion

As AI technologies are increasingly used to replace or supplement current clinical practice, continuous adaptation of HTA method is needed to ensure appropriate topic selection.