

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.

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.



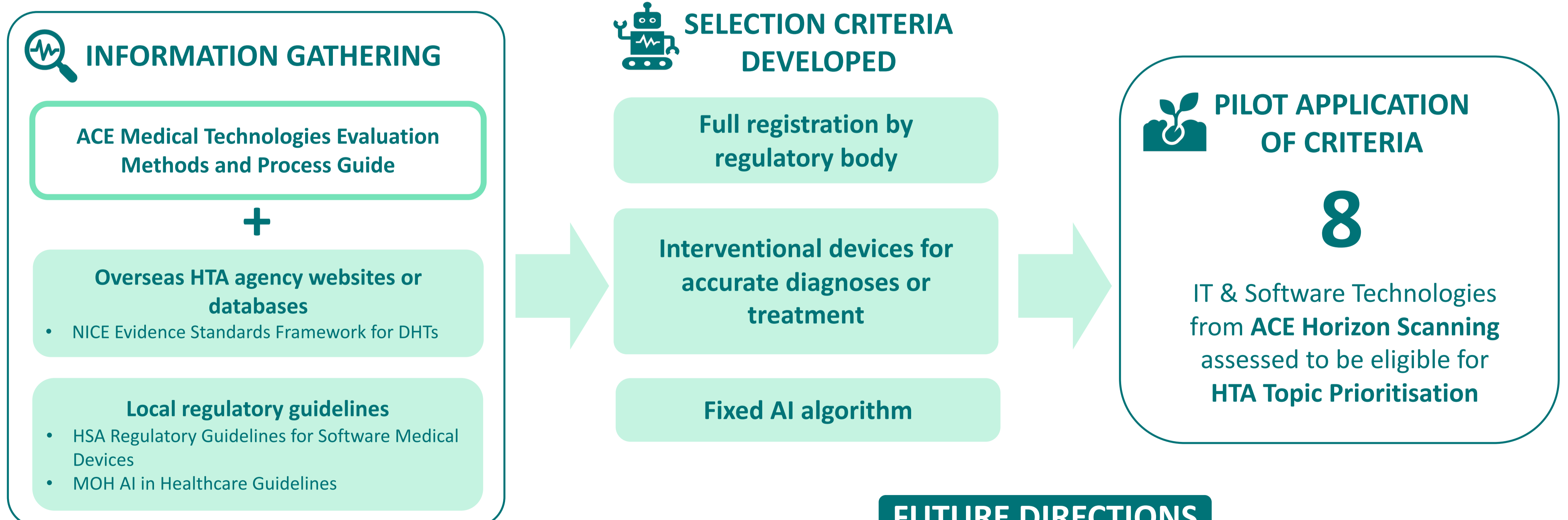
CHALLENGES of AI-MD

Rapid Pace of Development

Reliability in Real-world
Clinical Decision-Making

Limited Rigour in Current
Evidence

Cybersecurity Risks



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.