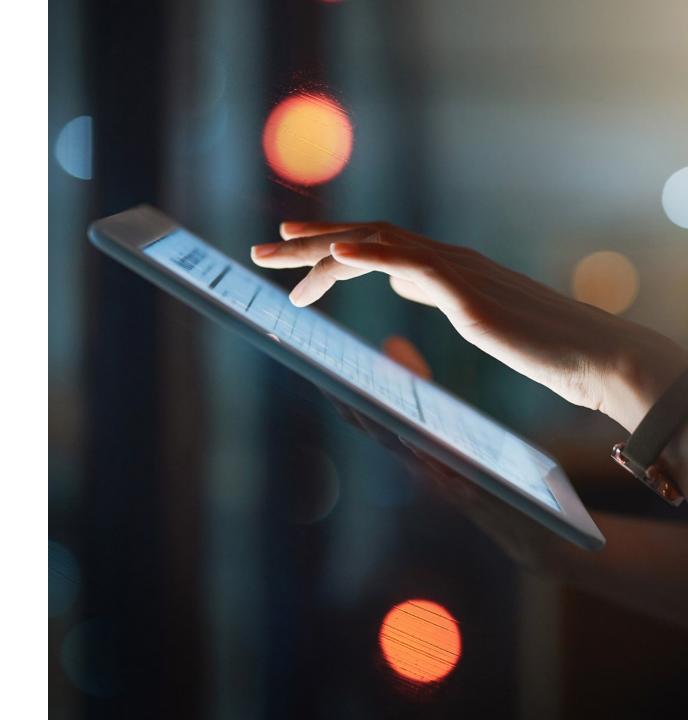
HTA perspective to reimbursement of health apps

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- Co-chair Medical Devices Interest group HTAi
- Views are my own and do not represent views of NICE or HTAi.



Published NICE guidance

- Guided self-help digital cognitive behavioural therapy for children and young people with mild to moderate symptoms of anxiety or low mood
- Digitally enabled therapies for adults with depression
- Digitally enabled therapies for adults with anxiety disorders
- <u>Digital technologies for delivering specialist weight-management services</u>
 <u>to manage weight-management medicine</u>
- Sleepio to treat insomnia and insomnia symptoms



Digital Healthtech - what is so special about it?

- Diverse field with high prevalence of start-ups and small companies
- Low availability of evidence of clinical and economic comparative effectiveness
- Wide range of outcomes
- Rapid evolution
- Engagement and usability very important to materialise value proposition
- Increase in regulatory burden (CE mark is not enough)



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Evidence availability

- Low availability of evidence of clinical and economic comparative effectiveness
 - Evidence developed mostly against no treatment or treatment that will not be considered standard of care
 - When evidence of comparative effectiveness exist, there is no clear signal of superiority in comparison with standard of care
 - Value for money case for equivalence more difficult to establish. Policy
 question of where the money is best spent (expand standard of care
 access or reimbursement for DHTs?).



Outcomes

- Wide range of outcomes (an example)
 - Intervention-related adverse events
 - Rates of and reasons for attrition
 - Treatment satisfaction and engagement
 - Measures of symptom severity (self-, parental- or practitioner reported)
 - Social, behavioural, and functional outcomes (self, parental or practitioner reported)
 - Suicidal thoughts and behaviour
 - Global functioning
 - Rates of remission
 - Health-related quality of life, including well-being



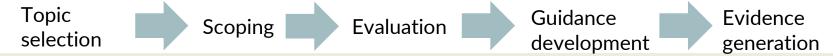
Engagement and usability

- Engagement and usability very important for value for money
 - Direct or indirect impact of low engagement to reimbursement
 - Efficacy linked to engagement
 - Some reimbursement models are at the population level resulting in less cost per use if more people are using them

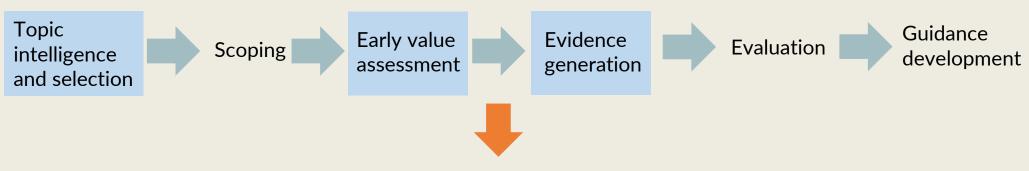


Standard approach vs Early value assessment

Standard approach



Early value assessment



- Recommendations use while collecting real world evidence.
- Evidence generation plan.