

Best-practice guidance for the HTA of technologies for COVID-19

Development and key recommendations

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Policy sandbox



A way of framing engagement

Safe space to challenge and innovate

Some use in healthcare regulation, but not HTA

First step towards future HTx sandboxes



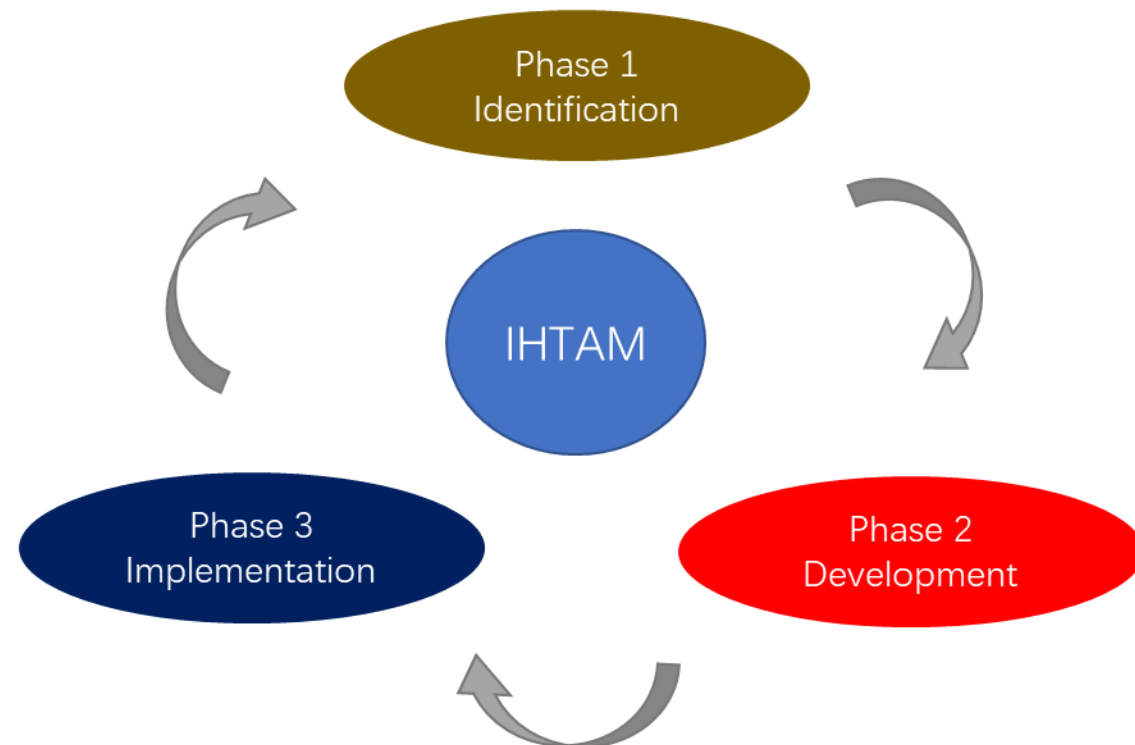
Leckenby et al. (2021), *App Health Econ Health Policy* 19(6)



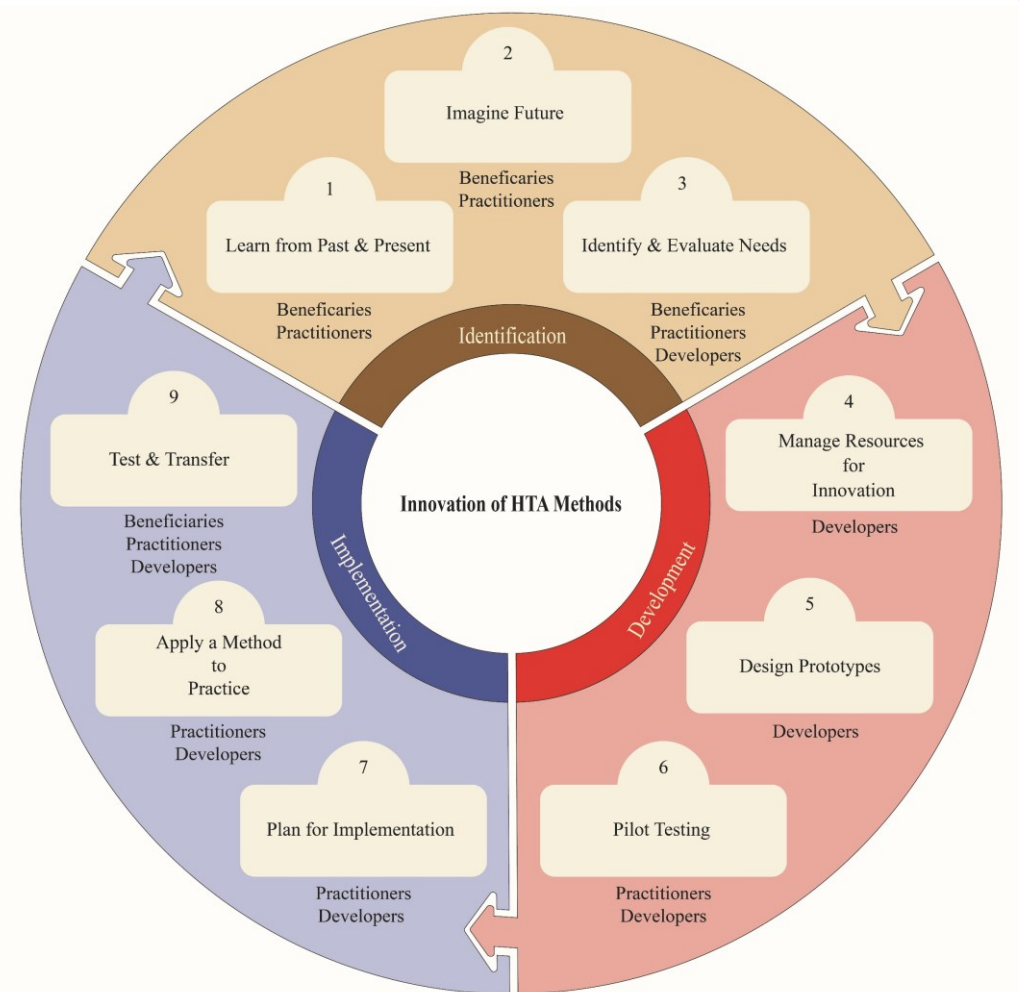
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Innovation of HTA methods



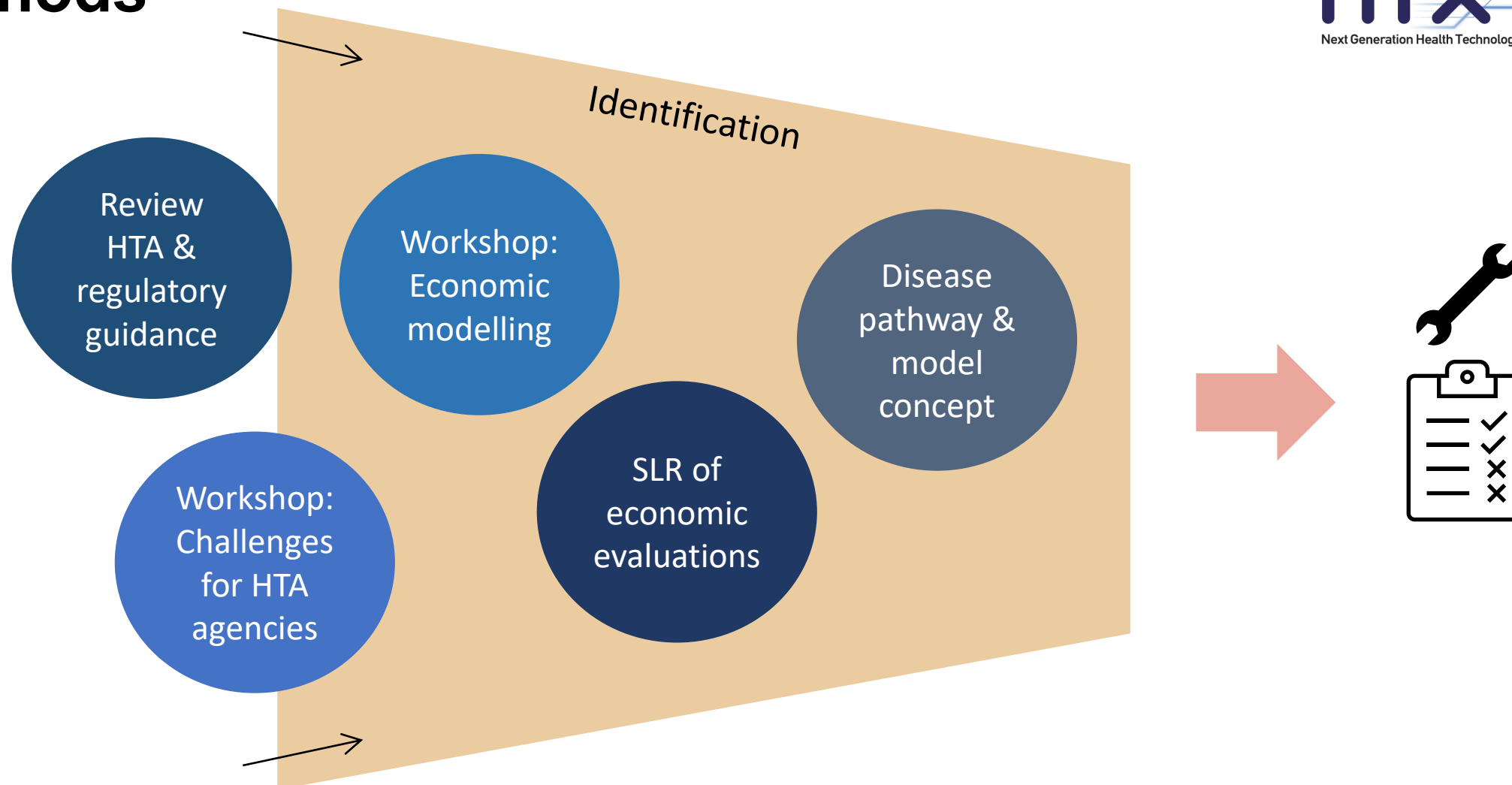
 Jiu et al. (2021), *Int J Technol Assess Health Care* 38(1)



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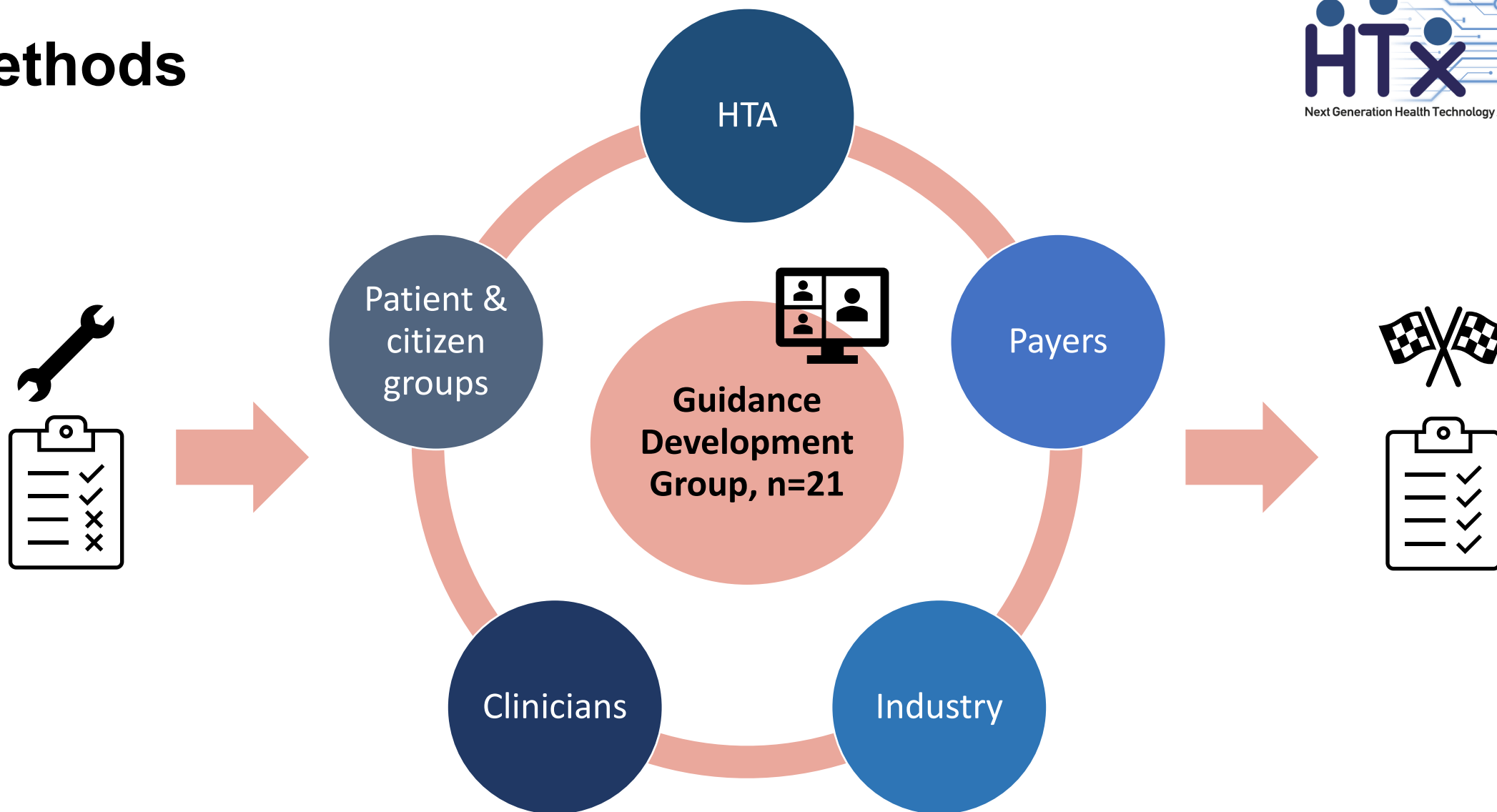
Methods



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Methods



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Best-practice guidance for the health technology assessment of diagnostics and treatments for COVID-19

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On behalf of the COVID-19 HTA best-practice guidance development group*

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[Best-practice guidance for the health technology assessment of diagnostics and treatments for COVID-19](#)



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Assessing effectiveness

- ♦ Adaptive RCTs preferred for efficacy
- ♦ Promote high-quality RWE to fill evidence gaps
- ♦ Use “living” evidence reviews
- ♦ Carefully consider generalisability to the relevant setting
- ♦ Prespecify subgroup analyses
- ♦ Refer to the list of suggested core outcomes and core outcomes sets

Economic modelling

- ♦ Ideally, use simulation models to account for patient heterogeneity
- ♦ Include long-term outcomes, disease transmission and system capacity
- ♦ Calibrate uncertain inputs to ensure plausible outputs, e.g. using RWE
- ♦ Develop a whole-disease model for COVID-19, as an epidemiological (SEIR) model with nested diagnosis and treatment components
- ♦ Allow simpler analyses where they may be acceptable for decision-making
- ♦ Regularly update the model to support “living” HTA

Stakeholder engagement

- ♦ Ensure a broad range of stakeholders can contribute to HTA process
- ♦ Including citizens, patients, carers and proxies, and organisations that represent specific groups who are at higher risk or underrepresented
- ♦ Prioritise based on a tiered approach
- ♦ Consider novel approaches to engagement, such as digital and online tools

Other important factors

- ♦ Affordability should be assessed using budget impact analysis
- ♦ Affordability concerns should trigger commercial discussions
- ♦ A “living” HTA approach would facilitate managed access agreements
- ♦ Consider other potentially relevant elements of value, including equity, reduced fear of contagion, and scientific advancement
- ♦ Try to capture them quantitatively (e.g. in utility values), otherwise narratively

Assessing value for money

- ♦ Use cost—utility analysis, if usually preferred, with supportive cost-effectiveness and cost-consequence analyses where useful
- ♦ Consider both a healthcare and a broad societal perspective
- ♦ Use robust data from related conditions where necessary
- ♦ Use usual threshold values, but engage in research about preferences during a pandemic

Handling uncertainty

- ♦ Transparently report evidence gaps, assumptions made and the pandemic context
- ♦ Extensive subgroup, extreme value and threshold analyses
- ♦ Use probabilistic analysis
- ♦ Consider using value of information analysis to inform research priorities
- ♦ Mitigate uncertainty by implementing a “living” HTA approach
- ♦ Responsively update decisions (including reinvestment and disinvestment) based on new information

HTA of diagnostics and treatments for COVID-19



Assessing clinical effectiveness



RCTs remain gold standard to measure relative effectiveness

Fill evidence gaps with high-quality RWE, including federated RWD networks

Lean on available “living” reviews, where appropriate

Use COVID-19 core outcomes and core outcome sets



Assessing value for money

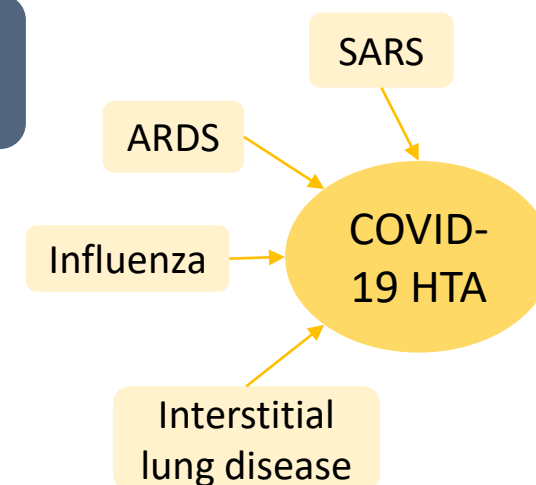
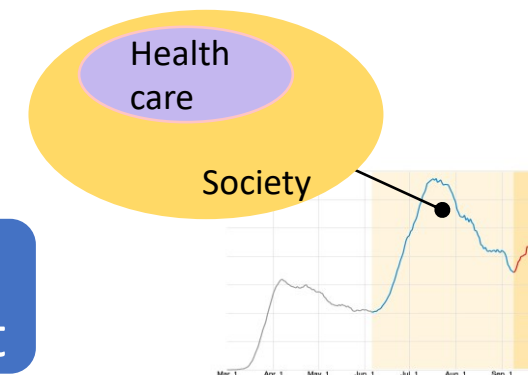


Use CUA where preferred, with other types of evaluation to support this

Use healthcare & societal perspectives; importance depends on pandemic context

Accept data from related or similar conditions where necessary, e.g. utilities

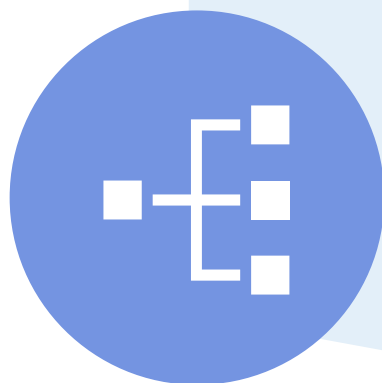
Adopt normal threshold values, but engage in pandemic threshold research



Modelling & uncertainty



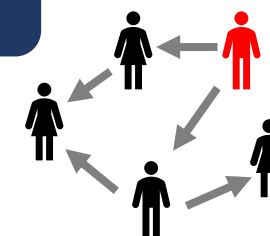
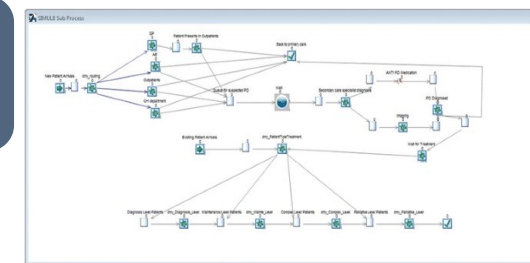
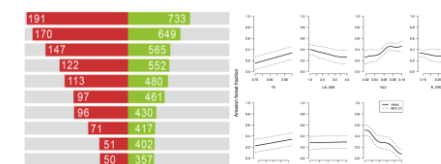
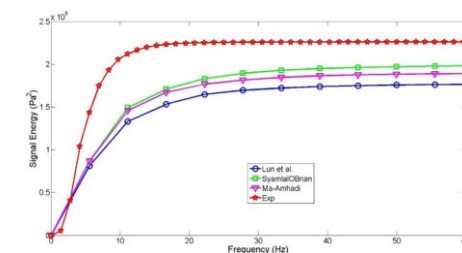
Transparently report evidence gaps, assumptions; extensive sensitivity analysis



Capture long-term effects and outcomes, with extensive sensitivity analysis

Ideally, simulation modelling including transmission and capacity effects

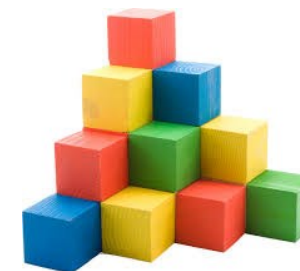
Mitigate risk by implementing a reactive assessment approach...



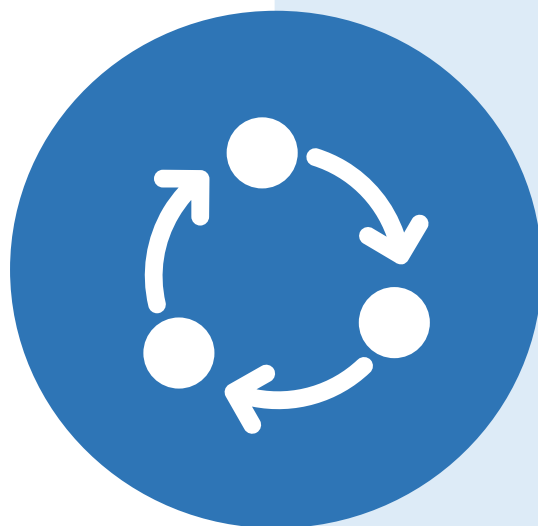
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“Living” HTA



**Coronavirus (COVID-19) Update: FDA Revokes
Emergency Use Authorization for Chloroquine
and Hydroxychloroquine**



Responsively assess and reassess in light
of new information & pandemic context

Supported by a maintained disease model
including diagnosis and treatment

Modular model allowing simple, quicker
analyses where suitable and pragmatic

Commitment to disinvestment if
warranted by new evidence



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Other elements of value



Consider affordability to health systems using routine budget impact analysis

Affordability concerns can trigger commercial engagement

Explicitly consider equity, scientific innovation and fear of contagion

Capture quantitatively where possible



The same pandemic, unequal impacts

How people are experiencing the pandemic differently

5 November 2020



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Summary



Best-practice guidance as HTA agencies begin to assess technologies for COVID-19

Stepping stone towards routine processes, but “living” HTA may be beneficial

Guidance and collaboration can improve pandemic preparedness of HTA

First step towards more thorough use of policy sandbox approach in HTx



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