

Enhancing the Uptake of Core Outcome Sets: an essential role for HTA

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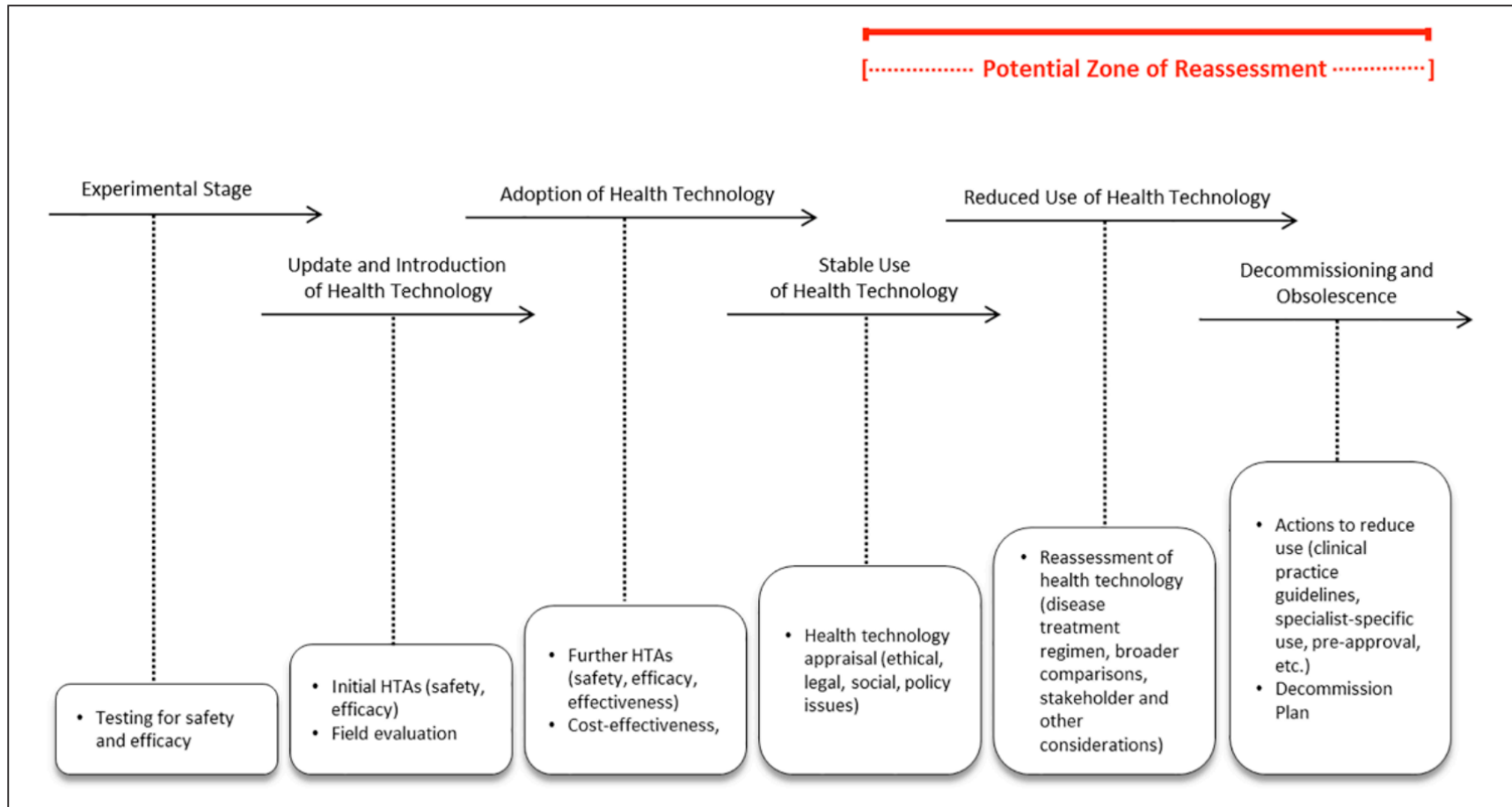
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What is Health Technology Assessment?

“Systematic evaluation of properties and effects of a health technology (drug, device, procedure, test, program), addressing the direct and intended effects of the technology as well as its indirect and unintended consequences.”

Comparative clinical & cost effectiveness,
ELSI

A life-cycle approach to HTA



https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5406119/pdf/10.1177_2050312117704861.pdf

How might this work?

1. Scientific advice/Early dialogues

- Provision of methodological advice to technology developers at early stage of product development
 - Joint with regulator and/or with other HTA
 - Clinical (PICOS) & economic elements
 - Much discussion about outcome measures (primary/second, surrogate)
- Existing COS?
 - Validate & suggest its use
 - With patient input & with other (recent) HTAs for similar conditions
- No existing COS?
 - in development? similar condition?
 - Informed by: Patient input & other HTAs
- Feedback mechanism from HTA/evidence synthesis to **COS** developers?

How might this work?

2. Initial HTA

- Protocol development → **PICOS**
 - Select a **COS**
 - If early scientific advice provided during product development process, pull through COS discussions
 - Validate with patient/caregiver input
 - No existing COS?
 - in development?
 - similar condition?
 - Informed by: Patient input & other HTAs
- Conduct HTA:
 - Report outcomes according to **COS & non-COS**
 - Explicitly note where reported outcomes discordant to **COS**
- Feedback mechanism from HTA/evidence synthesis to **COS** developers

How might this work?

3. Reassessments/Updates

- Was a COS used in initial HTA?
 - Is that COS still current and valid?
 - If there was no COS at time of initial assessment, is a COS now available?
 - If no COS exists: is there one in development? Can another COS from a similar condition inform/guide?
- Patient/caregiver input to validate
- As per initial HTA
- Feedback mechanism from HTA/evidence synthesis to **COS** developers?

Benefits

For patients, payers, clinicians, industry, researchers, research funders, journals

- Measuring what matters
- Facilitates comparisons across interventions for a particular condition and across conditions
- ↓ uncertainty ↑ confidence in clinical effectiveness estimates....and cost-effectiveness analyses too
- Increased efficiency throughout evidence ecosystem
 - ↓ research waste
- Support for conditional (~coverage with evidence development) recommendations
 - Earlier access
- Enables reassessments/living systematic reviews

Opportunities

- COS registration number?
 - Inclusion in PRISMA/PRISMA extension updates
 - A priori inclusion in PROSPERO registrations
- Research funders
 - Funded studies should refer to & make use of existing COS
- Evaluate & report on uptake, use and benefits of COS

Evidence ecosystem/Learning health systems



<https://journals.plos.org/plosmedicine/article/figure?id=10.1371/journal.pmed.1001603.g002>

Thank you!

Questions?