Early Health Technology Assessment and Prospective Clinical Research: Setting the Stage

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Evidentiary Expectations

- Depending on the age & type of the health technology being evaluated the amount & quality of evidence may vary.
  - Drugs
    - Will find randomized controlled trials (RCTs)
    - Regulatory requirement
  - Medical Devices
    - May or not find RCTs
    - Observational studies possibly comparative.
    - Studies may examine previous version of device by the same manufacturer

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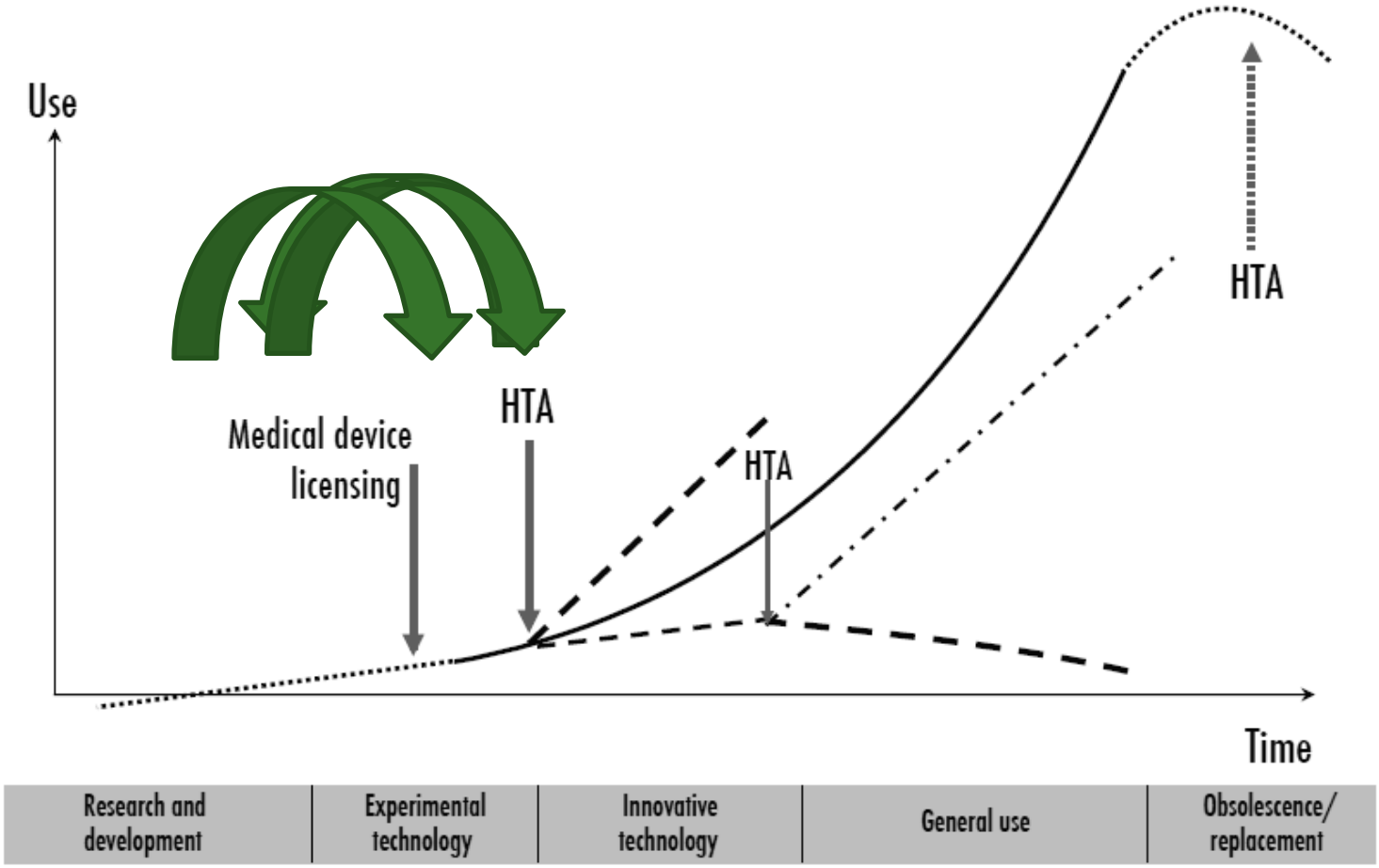
Health technology assessment and diffusion of health technologies



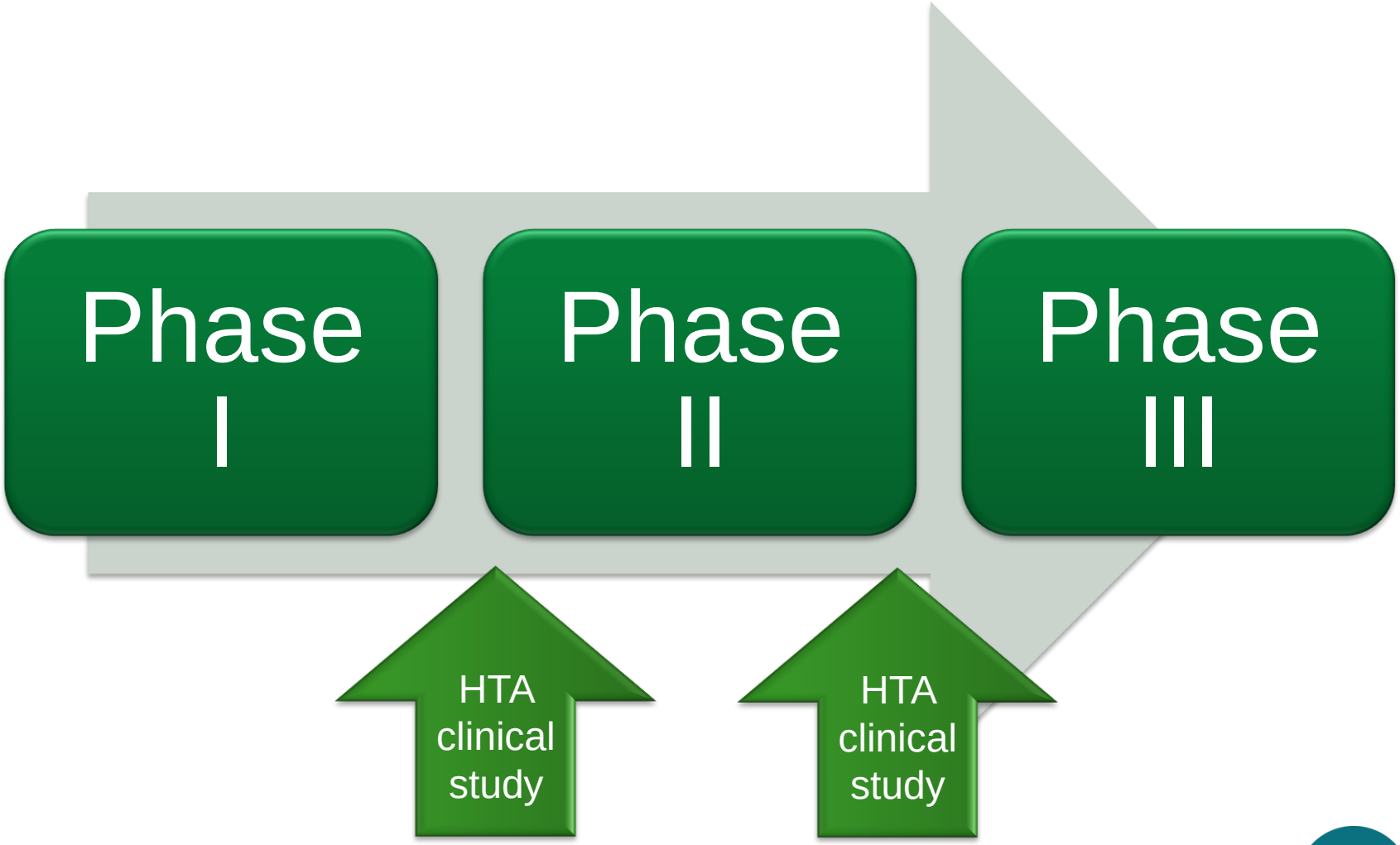
Source: World Health Organization: Health technology assessment of medical devices. June 2011. p. 19

What information is being requested about the medical device?

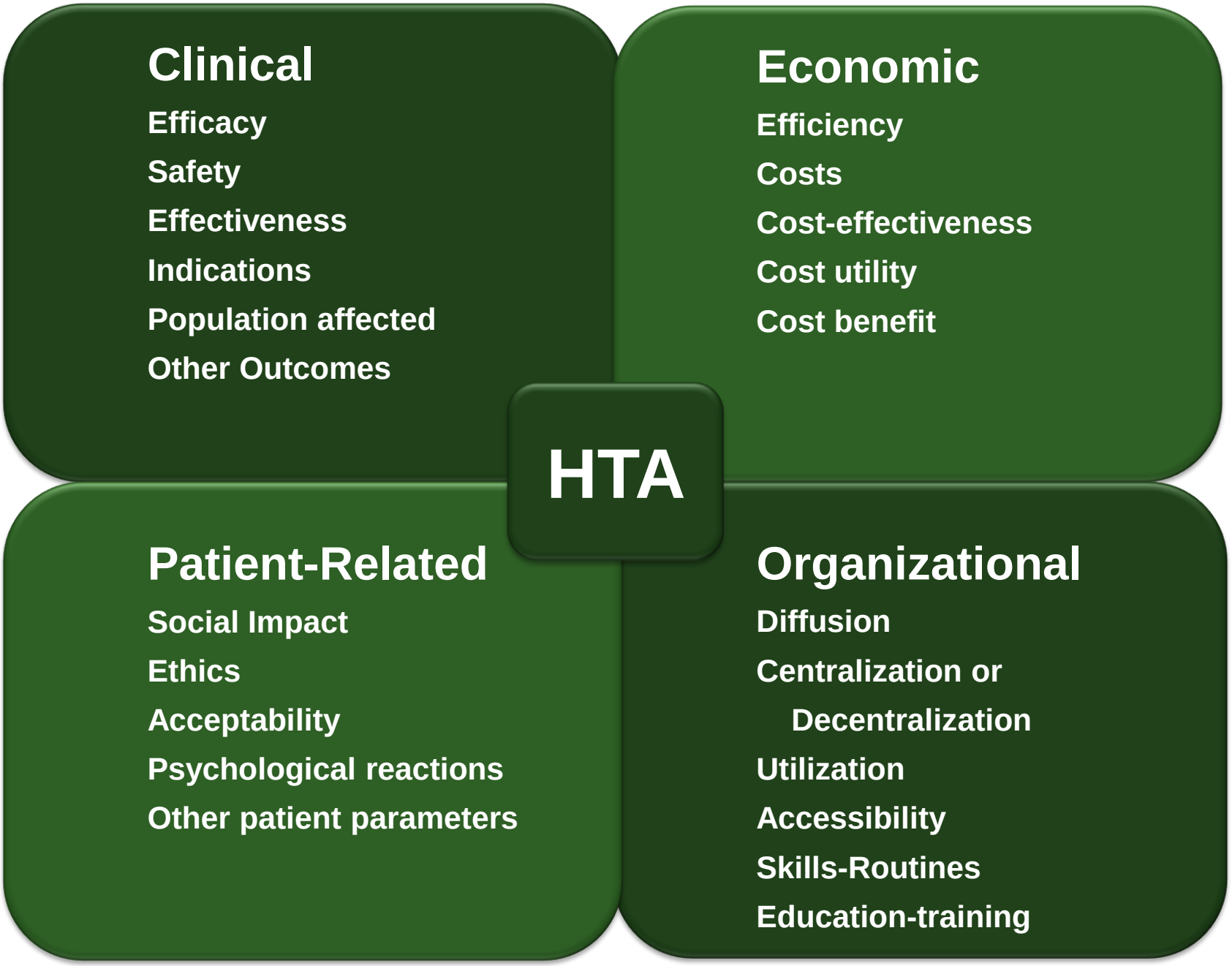
- Health Technology Regulation
  - Safety & Efficacy
- Health Technology Assessment
  - Efficacy, effectiveness, cost-effectiveness, appropriateness
- Health Technology Management
  - Needs analysis, alternatives, specifications

Adapted from: WHO Health technology assessment of medical devices, 2011. Available: http://whqlibdoc.who.int/publications/2011/9789241501361_eng.pdf

Pre-market clinical research



HTA question development



Adapted: Draborg E et al. Int J Technol Assess Health Care 2005;21:89-95.

How can the needs of each stakeholder be addressed?

- Perspective change
  - More than safety and efficacy (25% of what is needed)
- Apply a HTA framework when designing the clinical research trials
  - Across all phases of premarket clinical research trials

Classification of Medical Devices in Canada

Medical device classification system			
Device Class	Risk	Examples	Licence Requirements
Class I	Lowest	Surgical instruments, laboratory culture media	A device licence is not required, but the establishment where it is made and/or distributed must be licensed.
Class II	Low	Contact lenses, pregnancy test kits, endoscopes, ultrasound scanners	Manufacturers require a Health Canada licence before selling or advertising Class II, III and IV devices. Annual licence renewals are required.
Class III	Moderate	Orthopedic implants, glucose monitors, dental implants, hemodialysis machines	
Class IV	High	Cardiac pacemakers, angiography catheters, cranial shunts	

Source: Canadian Agency for Drugs andTechnologies in Health.
Medical Device Regulation in Canada: A Primer. Health Technology Update, Issue 5, January 2007.
Available: http://www.cadth.ca/media/pdf/hta_thupdate_issue5_e.pdf

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Prospective patient level data collection

- Clinical outcomes
  - (e.g. wound measurement, surgical success, diagnostic accuracy)
- Disease specific questionnaires
- Quality of life, patient/provider satisfaction
- Detailed resource utilization and costs
  - (e.g. out-of-pocket, productivity losses)
- Organizational impact

P	opulation	Patient or Practitioner
I	ntervention	Indications & Co-interventions
C	omparator	”Gold standard”, Standard of care, Single vs. multiple
O	utcomes	Clinical, Economic, Patient-related, Organizational
T	ime Frame	Short-term or long-term, frequency of follow-up, interim analysis
S	etting	Hospitals, Community, Long-term Care

Evidence required varies with the question

Question	Study design
How common is the problem?	Systematic review of surveys that allow matching to local circumstances
What will happen if we do not add a therapy? (Prognosis)	Inception cohort studies
Is this diagnostic or monitoring test accurate? (Diagnosis)	Individual cross sectional studies with consistently applied reference standard and blinding
Does this intervention help? (Treatment Benefits)	Randomized trial or observational study with dramatic effect
What are the COMMON harms? (Treatment Harms)	Individual randomized trial or (exceptionally) observational study with dramatic effect
Is this (early detection) test worthwhile? (Screening)	Randomized trial

Source: Oxford Centre for Evidence-Based Medicine. "The Oxford 2011 Levels of Evidence". http://www.cebm.net/mod_product/design/files/CEBM-Levels-of-Evidence-2.1.pdf

Summary

- Possible to conduct clinical research from an HTA perspective in the pre-market environment (e.g. EXCITE)
- Requires the prospective collection of a broader range of relevant outcomes, aligned with reimbursement goal.
- Study design and implementation depends on the purpose of the medical device (i.e. treatment, diagnosis) and the patient population and setting.

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Thank you

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