Value Assessment of Medical Devices - Overview

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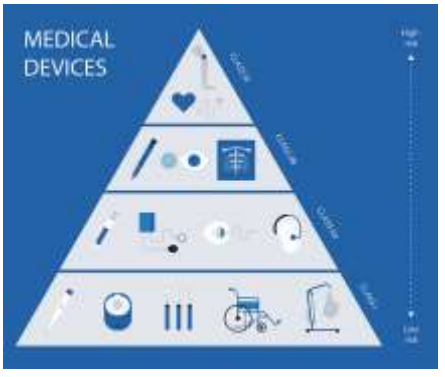
Declaration of Interest

- I currently work as Global Director at ISPOR (International Society for Pharmacoeconomics & Out comes research)

Concepts in this presentation do not represent ISPOR's point of view, except those that are clearly stated

Medical Device: a wide landscape



Any instrument, apparatus or machine, implant, software or other similar material whose utility by itself or in combination is intended to be used throughout the health care process

Medical Device & Diagnostic Challenges

- Diversity in the Medical Device landscape
- Evidence generation presents challenges
- End user can determine efficacy / outcome
- Benefits to organisation efficiency
- Reduction of prices due to rapid innovation
- Rapid innovation renders obsolete

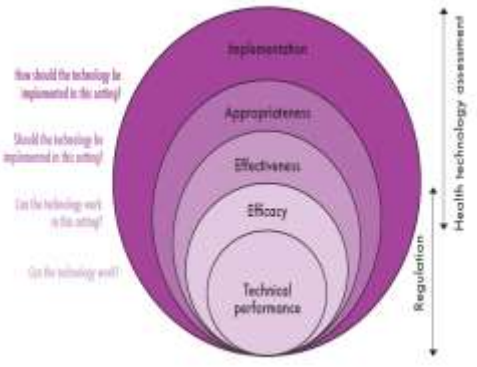
Drummond M, Griffin A, Tarricone R. Value in health 2009;12(4):402

Comparing Drugs vs. Devices

Table 1. Key differences between pharmaceuticals and medical devices influencing value assessment		
	Pharmaceuticals	Devices
Product lifecycle	Typically three periods over 10+ years: (1) an extensive development period, (often Phase I-III clinical trial testing) (2) an exclusive market period, (includes Phase IV post-market approval monitoring) (3) a highly competitive post-patent period.	Lifecycle of specific type or version of a device can be as short as 12-18 months. Product improvement often reflects input from multiple users over short periods of time.
Comparator(s)	Generally, existing standard of care, best available, usual care, or best supportive care	Differences in device features can make comparison difficult, comparators can compose of an entire care pathway or procedure.
Safety measures	Toxicity, incompatibility, resistance and side effects	Technical reliability, user skill, ergonomics
Evidence for regulatory approval	Often double-blinded randomized controlled trial (RCT) evidence to prove clinical effectiveness and safety; typically, multiple confirmatory studies are necessary.	Evidence to prove device achieves its intended purpose; rarely RCT; RCT as well as blinding not always feasible; non-clinical evidence is often used (e.g., performance testing for product safety and reliability, human factors and usability engineering testing, computer simulations); single confirmatory study may be sufficient.
Reimbursement	Most are reimbursed through national and private payers	Few are reimbursed through national or private payers. Many are purchased at the facility level and are reimbursed by prospective payment such as DRG or are capital equipment.
HTA	Prescriptive and typically required for reimbursement	Very few undergo HTA review
Generation of new evidence	New evidence is generated for every formulation and throughout the lengthy product lifecycle	Cost of evidence generation can be prohibitive due to short product lifecycle as well as company size.
Measuring long term outcomes	Product lifecycle supports measurement of short and longer term outcomes over the duration of patent protection	Product lifecycle can discourage measurement of long term outcomes and decisions are often made on budget cycles.
User	Generally, physician prescribed for patient use; can be administered by health care professional or directly by patient	User can vary depending on device, including various types of health care professionals or patients
User skill	Requires pharmacology knowledge, technical skill not a factor	User skill can significantly affect outcomes; learning curve can be difficult and lengthy
Organizational aspects	Usually low organizational impact	Can have significant organizational impact (e.g., training requirements, facility renovation) which may have one-time or ongoing cost implications.

https://www.ispor.org/sigs/MedDevicesDiag/Value_assessment_MD.aspx

Dealing with Efficacy & Effectiveness



World Health Organization (2013).

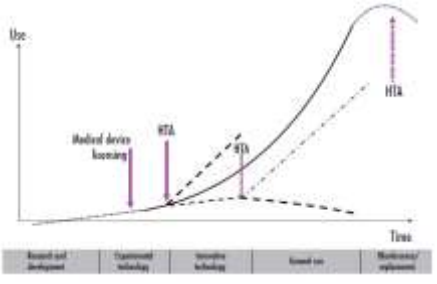
- I.D.E.A.L. Framework (Idea, Development, Exploration, Assessment, Long term results) could be used in High Risk devices assessment.
- Challenging RCT in case of comparative effectiveness research needed
- Observational studies based on safety and eficacy registry are recommended.

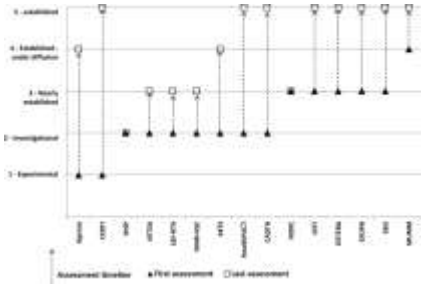
Capporale J, Gilardino R, Najun L, Quinones V, Peirano I (2017)

All Devices should undergo HTA?

Classification criteria of EU Directives according to risk aspects		Classification according to the relevance of product and service/ and reimbursement characteristics + HTA logic					
		Diagnostic			Therapeutic		
		(A1) Assistive technology devices (directly used by patients)	(B1) Artificial body parts (implanted by medical procedure)	(C1) Medical devices for the assistance of medical professional	(A2) Assistive technology devices (directly used by patients)	(B2) Artificial body parts (implanted by medical procedure)	(C2) Medical devices for the assistance of medical professional
93/42/EEC and 90/385/EEC	(I) Low risk	[illegible]		[illegible]	[illegible]		[illegible]
	(IIa) Medium risk, non-active	pulse oximeter		ultrasonic device clinical thermometer	contact lenses hearing aid device	dental crown	tracheal tube infusion cannula
	(IIb) Medium risk, active			x-ray machine PET, CT	insulin pen long term corrective contact lenses	dental implant bone prosthesis	laser radio-therapy unit
	(III) High risk			neuro-endoscope intracardiac catheter	condom with spermicide	hip/ knee joint replacement cardiac stent breast implant	stent delivery catheter system angioplasty balloon catheter
	(IV) High risk, active implantable		ICD, heart monitor unit neurostimulator, monitor unit			ICD, defibrillator unit neurostimulator, active unit cardiac pacemaker	
98/79/EC (IVD, in vitro diagnostic)	V			ABO/Rh(D) blood grouping analyser			
	VI	glucose strip		Trisomy 21 IVD			
	VII	pregnancy test		blood coagulation selftest			
	VIII			Ebola virus antigen IVD			

When HTA should be required?





Adapted from Phrma (2011)

World Health Organization (2013).

Packer C, Int J Technol Assess Health Care. 31:1/2 (2015), 78–85.

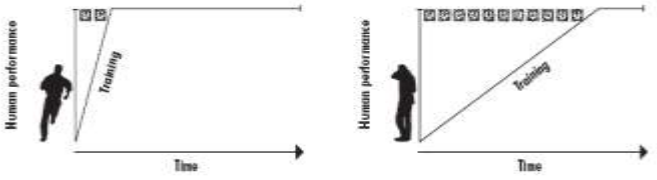
User Life Cycle

- The efficacy of a device depends not only on the device itself, but how it is used..

Figure 1: Learning curve related to design

Quick learning curve: well-designed device (i.e. effective human factors engineering) that requires little training.

Slow learning curve: poorly-designed device (i.e. not easy to use) that results in poor performance even after extensive training.



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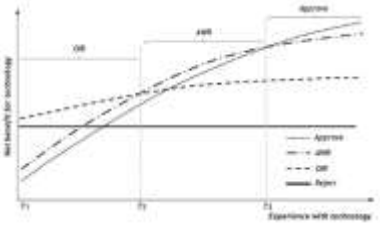
Assessing Medical Devices Value

- Decisions about the adoption of medical interventions are informed by evidence on their costs and effects.
- The evidence requirements and pathway for regulatory approval are less stringent for devices.



Rothery et al; Health Econ. 26(Suppl. 1): 109–123 (2017)

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Some talking points

Value Demostration	• Value Based Innovation • Building proper Value Story.
Early ***Adoption***	•Innovative access models •Health Technology Management •**Evidence Generation (RWE)**
Improve Healthcare delivery	• Training / Profesional Education • Value Based Healthcare / Patient Centered decision making.