

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 & Outcomes 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

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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

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Comparing Drugs vs. Devices



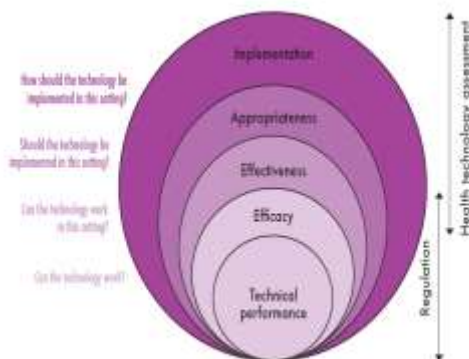
Table 1. Key differences between pharmaceuticals and medical devices influencing value assessment

	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/signs/MedDevicesDiag/Value_assessment_MD.aspx

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Dealing with Efficacy & Effectiveness



- 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 efficacy registry are recommended.

World Health Organization (2013).

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

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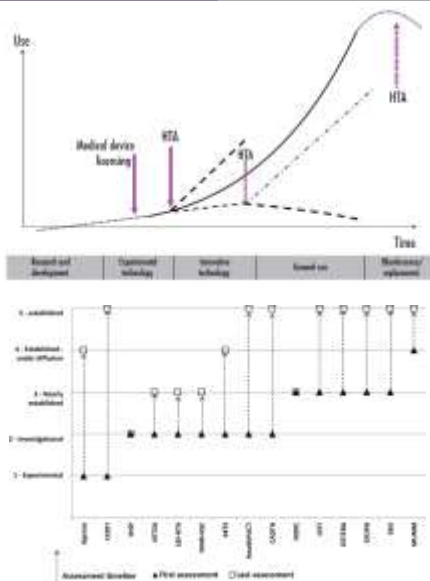
All Devices should undergo HTA?

Classification criteria of EU Directives according to risk aspects	Classification according to the relevance of product and service ¹ 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	
MD/MDCEC and MD/MDCEC	(I) Low risk	intra-aortic balloon pump transcatheter aortic valve replacement	cardiac resynchronisation therapy	walking frame artificial conventional wheelchair		in vitro sperm analysis	
	(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			in-vitro machine PET, CT	insulin pen long term corrective contact lenses	dental implant bone prosthesis	lens radio-therapy unit
	(III) High risk			neuro-endoscope intracranial catheter	coronary with stents/catheter	hip knee joint replacement cardiac stent	stem 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	
MD/MDCEC (alignability)	V			ABO/Rh(D) blood grouping analyser			
	VI	glucose strip		Troponin 21 IVD			
	VII	pregnancy test		blood coagulation self-test			
	VIII			Ebola virus antigen IVD			

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When HTA should be required?



Device	HTA is considered for pharmaceuticals, devices, generics, biologics and combination products	Prevalence of HTA: combination of some pharmaceuticals, devices, biologics, combination products and combination products	HTA is considered for all products as they are developed	Prevalence of HTA: combination of some pharmaceuticals, devices, biologics, combination products and combination products
Cardiac	●	●	●	●
Diabetes	●	●	●	●
Immunology	●	●	●	●
Neurology	●	●	●	●
Respiratory	●	●	●	●
Specialty	●	●	●	●
Transcatheter	●	●	●	●
Urology	●	●	●	●
Women's health	●	●	●	●
Other	●	●	●	●
Total	●	●	●	●

Adapted from Phrma (2011)

World Health Organization (2013).

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

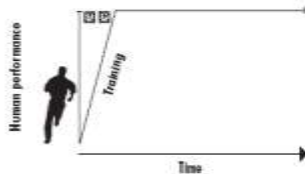
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User Life Cycle

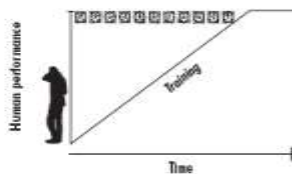
- The efficacy of a device depends not only on the device itself, but how it is used..

Figure 1: Learning curve related to design

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

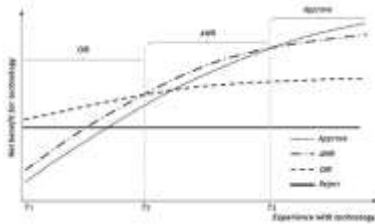


Slow learning curve: poorly-designed device (i.e. not easy to use) that results in poor performance even after extensive training.



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)

Assessments	Decision options
Value of a technology Assessment of health opportunity cost to health system (health system assessment)? Economic cost of the device	<p>Adoption Allow access to pending case. The knowledge that the response is the product of a pending case is not a decision.</p> <p>Rejection Requires access to pending case technology.</p> <p>Only in research (OIR) Not in research. No research funding until further research results are clear.</p> <p>Approval with research (AWR) Allow access to pending case but only result in laboratory approval when further research completed.</p>
Investment & process costs Significance of investment? In accessible (e.g. capital requirements, facilities, training and knowledge) learning curve costs of investment? Cost	
Technical assessment Assessment of accuracy - Acceptable in existing medical case - Acceptable in learning curve effects	
Decision uncertainty Implications for decision uncertainty - Is the device pending a pending case? - Effect on health consequences	
Value of further research Assessment of the value of further research - Is research required? - How and design of research - Clinical trial design - Cost of conducting research - How likely for research to occur?	
Uncertainty in research Value of research to different entities - Who pays for the research? - Value of health to health system - Value of research to manufacturer - Value of early access to manufacturer?	
Future changes Anticipated future changes - Change in price of technology as a component - Technological case (technological evolution) - Effect changes expected over time	
Value of early access Value of early access to the technology - Are the benefits of early access greater than opportunity costs of research? (e.g. cost of research) - Value of research to opportunity cost of access	
Overall decision Make a combined assessment of the four decision options: Approved, Rejected, OIR or AWR	

Some talking points

Value Demonstration

- Value Based Innovation
- Building proper Value Story.

Early Adoption

- Innovative access models
- Health Technology Management
- **Evidence Generation (RWE)**

Improve Healthcare delivery

- Training / Professional Education
- Value Based Healthcare / Patient Centered decision making.