MedTech Assessment : a Comprehensive proces

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eral Manager, Greece & Cyprus
Healthcare

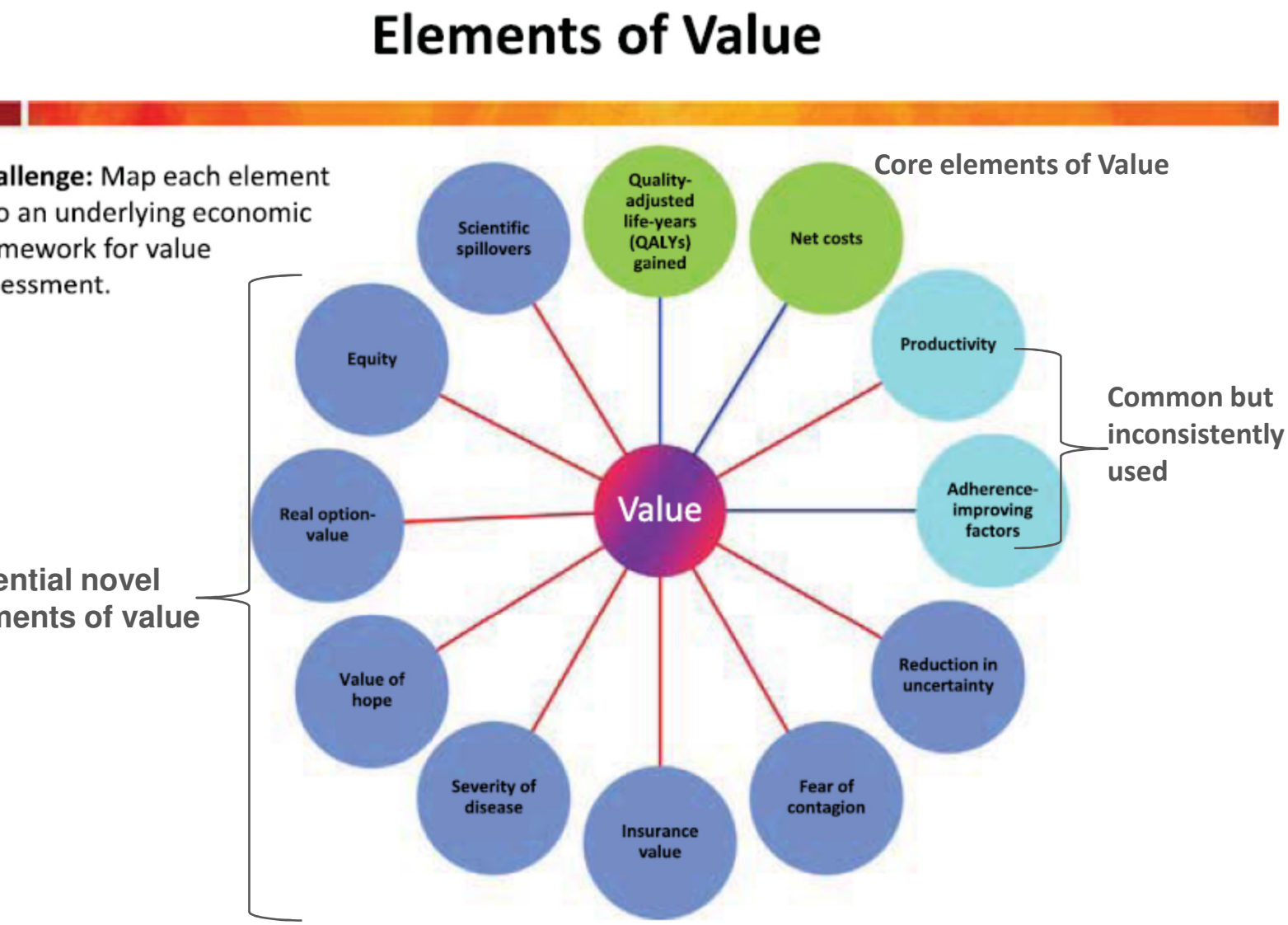
- Improve Operational Efficiency
- Reduce Operation Costs
- Optimized Patient Care
- Increase Patient Satisfaction

nagination at work.

Value Frameworks

	Indications	Audience	Criteria	Output
D Value	Oncology	Clinicians, patients	Efficacy; safety; quality, quantity and consistency of supporting evidence; affordability	Net health Bene score Average sales c drug/month
Drug Abacus		Policymakers, payers, industry	Efficacy ($ per life year); Toxicity ;Novelty ; R&D cost; Rarity; Population burden of disease	Abacus price for oncology drug
N Evidence	Oncology	Clinicians, patients	Efficacy; safety; quality and consistency of supporting evidence; affordability	Evidence Blocks cancer regimens scales 1-5, base average of pane votes
Value	Any Indications	Payers, policymakers, industry	Care value (QALYs); Budget impact; provisional value to the health system	Value-based pric benchmark for a

Value Elements Inventory



D. N. Lakdawalla et al. 2018, Defining Elements of Value in Health Care—A Health Economics Approach: An ISPOR Special Task Force Report [3], Value in Health 21 (2018) 131-139

Net Costs	
QALY	
Productivity	
Adherence – Improving Factors	Where treatment impro adherence with the trea
Value of reduction of Uncertainty due to a New Diagnostic	When the treatment is accompanied by a com diagnostic test
Fear of Contagion Risk of Contagion	When dealing with trea for infectious diseases
Insurance Value	When baseline health s particularly poor
Severity of Disease	When considering treat for end-of-life care of h severity conditions
Value of Hope	Where therapies have uncertain effects that c predicted beforehand b diagnostic
Real Option Value	Where technology exte life of patient
Equity	
Scientific Spillovers	Where technology iden new mechanism of acti mode of delivery

Source : IS

EUnetHTA Core Model

EUnetHTA HTA Core Model®

SCOPE

Rapid REA

HTA Core Model DOMAINS
1. Health problem and current use of technology (CUR)
2. Description and technical characteristics (TEC)
3. Safety (SAF)
4. Clinical effectiveness (EFF)
5. Costs and economic evaluation (ECO)
6. Ethical analysis (ETH)
7. Organisational aspects (ORG)
8. Patient and social aspects (SOC)
9. Legal aspects (LEG)

European network for Health Technology Assessment | JA3 2016 - 2020 | www.eunethta.eu

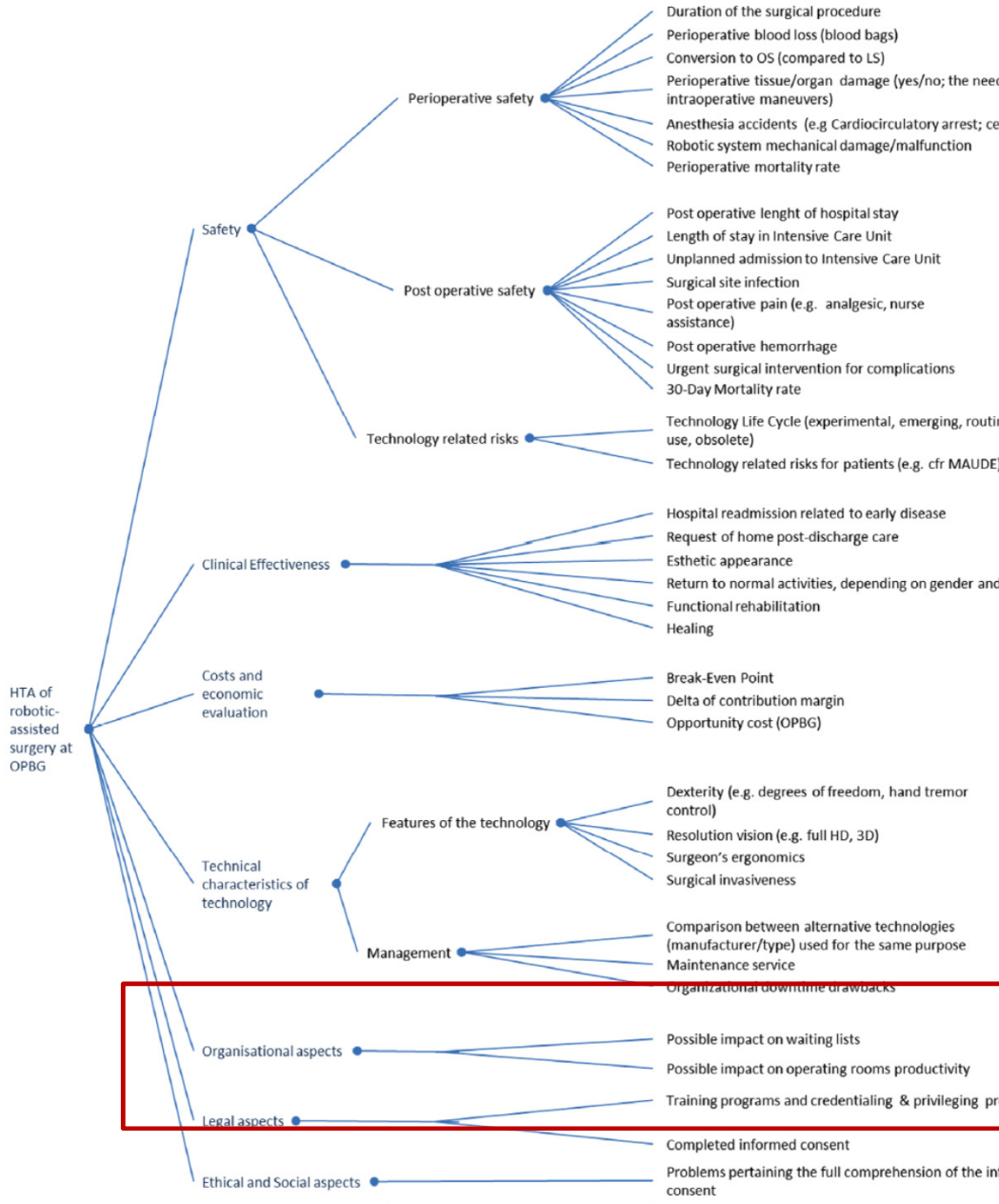


Fig. 1 – Decisional tree. EUnetHTA domains and KPIs arranged into a hierarchical decision tree. EUnetHTA, Europe for Health Technology Assessment; KPI, key performance indicators.

M. Ritrovato et al., Decision-Oriented Health Technology Assessment: One Step Forward in Supp Decision-Making Process in Hospitals, Value in Health (2015), 18, 501-505

Reconciling – The Advance Value Framework

Multiple Criteria Decision Analysis (MCDA) for evaluating new medicines in Health Technology Assessment and beyond: The Advance Value Framework

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alue tree (Advance Value Tree) - five key domains that can be xplicitly measured and assessed:

- burden of disease,
- therapeutic impact
- safety profile
- innovation level and
- socioeconomic impact

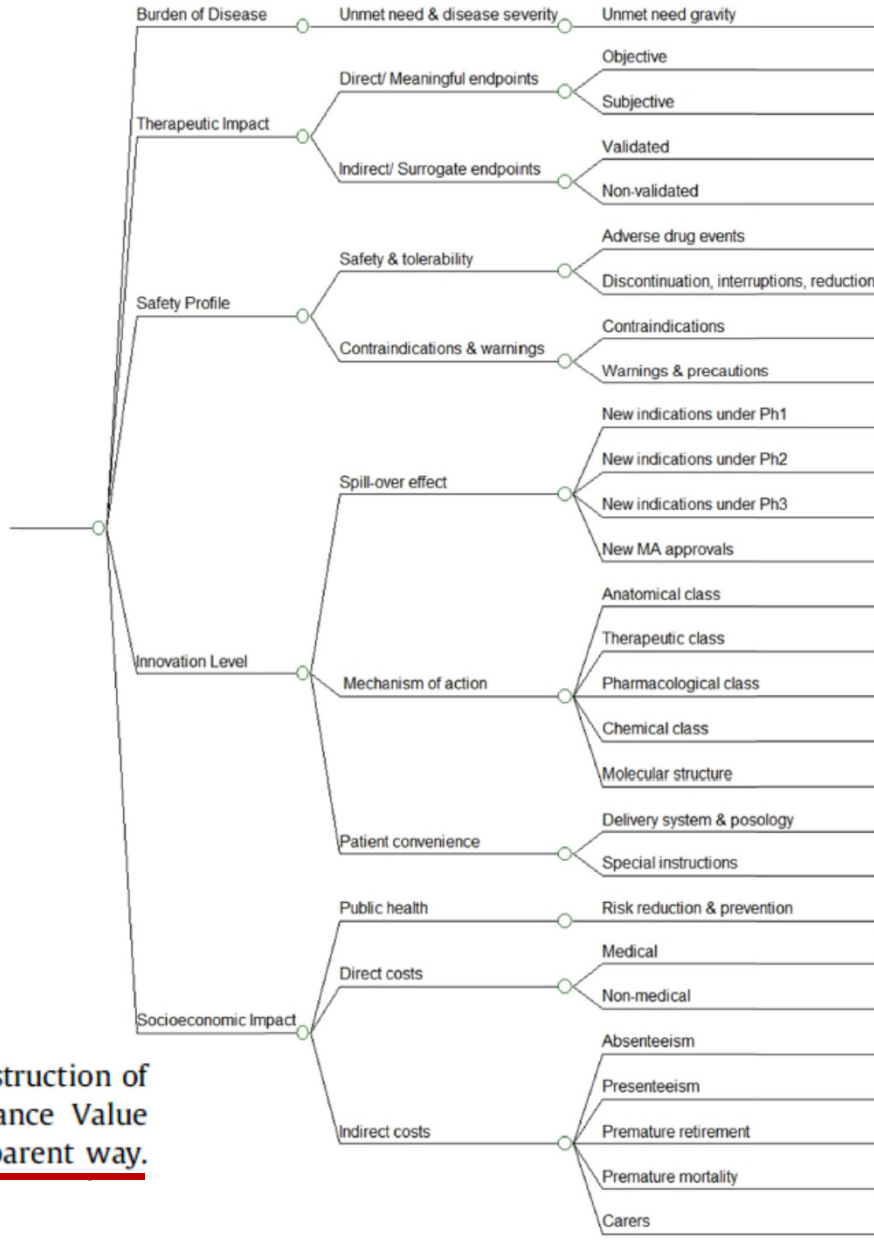


Fig. 3. The Advance Value Tree for new medicines evaluation.
Caption: Hierarchical decomposition of top level criteria clusters, to middle level criteria and bottom level sub-criteria and attributes (from left to right), acro domains (from top to bottom).

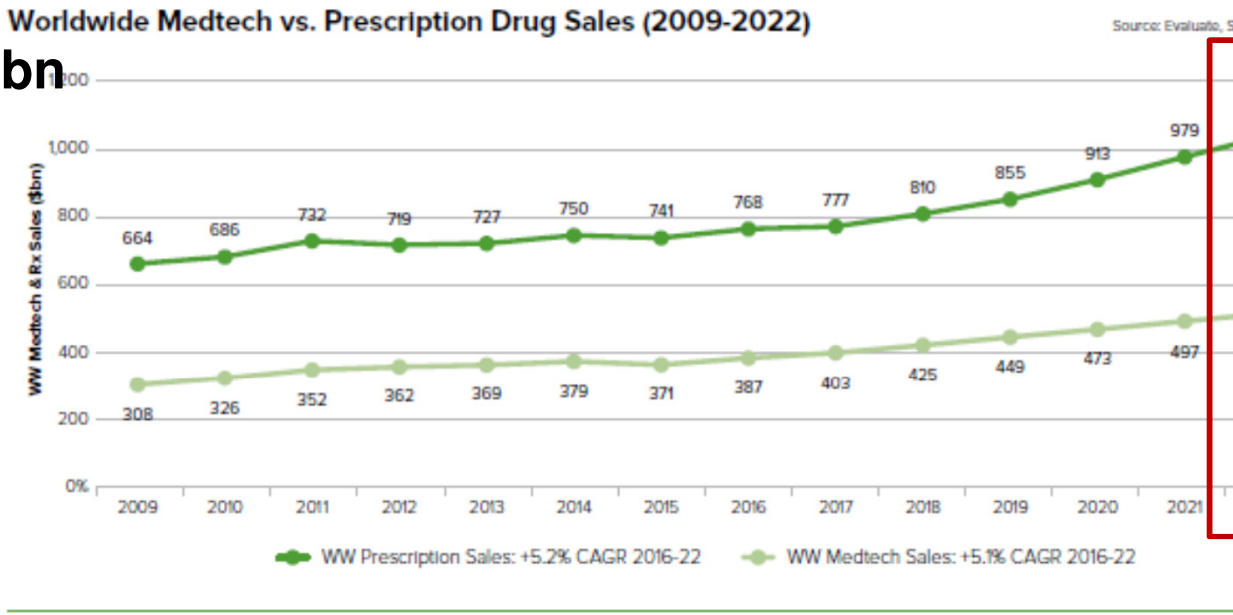
Overall, the combination of these MCDA modelling techniques for the elicitation and construction of value preferences across the generic value tree provides a new value framework (Advance Value Framework) enabling the comprehensive measurement of value in a structured and transparent way.

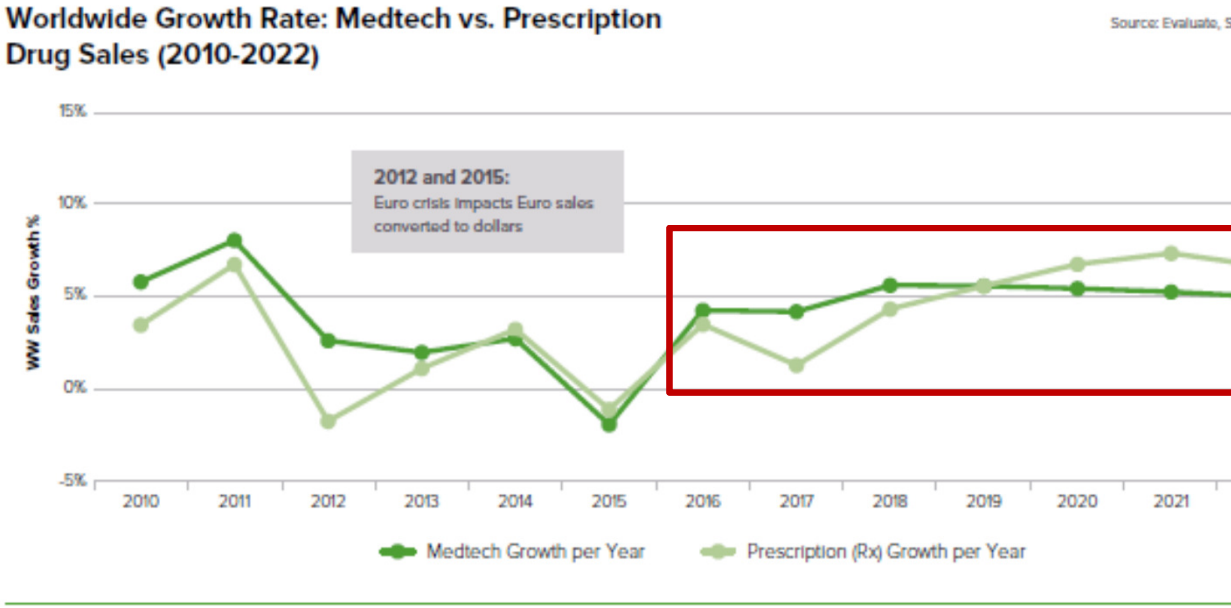
MedTech vs PharmaTech

wide Medtech sales forecast to reach **$522bn**
22

22, the Medtech industry will be
% of the size of the prescription drug
et, not showing much variation from
.

dwide prescription drug market only
ast to grow at a marginally faster rate
the Medtech market, with a CAGR of
between 2016 and 2022, versus
for Medtech





Source : EvaluateMedTech® World Previ

Medical Devices vs Pharmaceuticals

Assessing the Clinical and Cost-Effectiveness of Medical Devices and Drugs: Are They That Different?

Rod S. Taylor, MSc, PhD,[1] Cynthia P. Iglesias, MSc, PhD[2,3]

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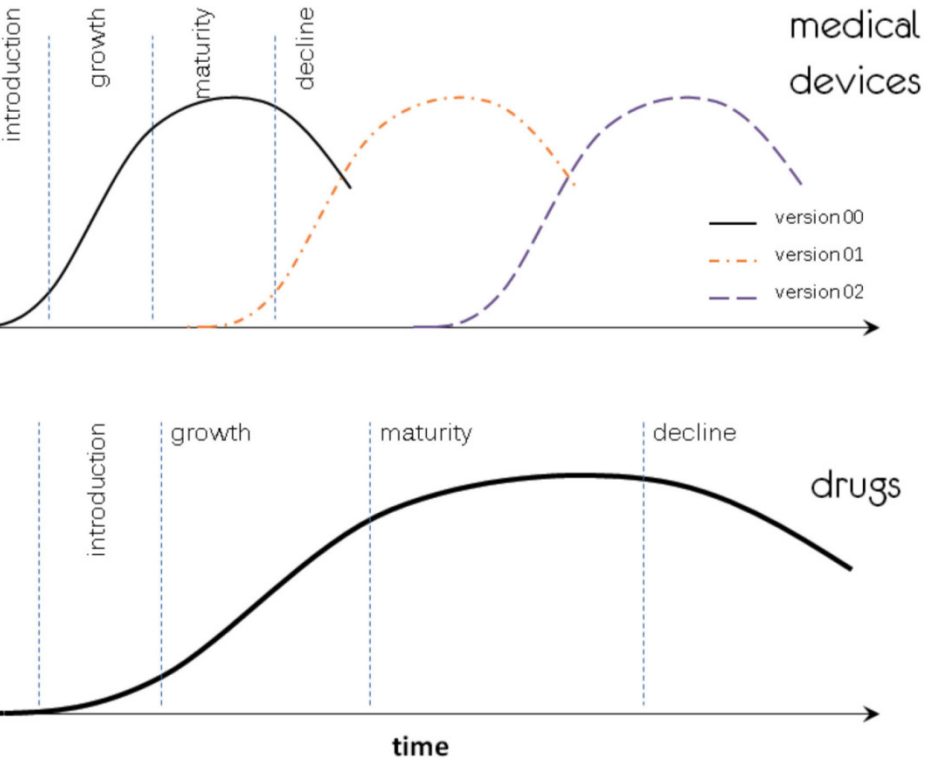
VALUE IN HE

Economic Evaluation for Devices and Drugs—Same or Different?

Michael Drummond, PhD,[1] Adrian Griffin, MSc,[2] Rosanna Tarricone, MSc, PhD[3]

[1]Centre for Health Economics, University of York, York, England, UK; [2]LifeScan EMEA, High Wycombe, England, UK; [3]Eucomed, Belgiu
Department for Institutional Analysis and Public Management, Bocconi University, Milan, Italy

uct life cycle curve for medical devices and drugs.



et al., Medical device specificities: opportunities for a dedicated product development dology, *Expert Rev. Med. Devices* 9(3), 299–311 (2012)

Diverse in various aspects (usage, application, design, implementation). Many devices are diagnostic.

Difficulties in evidence generation (i.e performing experimental studies - undertaking RCTs)

'Learning curve' associated with the use of a device (device-operator interaction)

Wider economic and organizational implications

Different Product Life Cycle – Rapid Innovation Class effect

Pricing strategy (rapid innovation driving prices) and procurement methods

M. Drummond et al.,Economic Evaluation for Devices and Drugs – Same or DifferentValue in Health (2009), 12

ADVAMED Framework

Four (4) broad categories of value drivers
Assess value elements beyond the clinical and safety outcomes of a pr
Collaborative approach – alignment among different stakeholders

y Diagnostic Stakeholder Groups

Figure 4. AdvaMedDx's Approach for Effective Value Assessment: A Schematic

ADVAMED. 2017. *A Framework for Comprehensive Assessment of Medical Technologies : Defining Value in the New Health Car*

MEDTECH Framework – Most Economically Advantageous Tender

ramework where all stakeholders (patients, providers, health system and society) would be aligned arou
nmon vision of maximizing value

The objective is to achieve Value based procurement thr
the Most Economically Advantageous Tender (MEAT)

ommon framework and practical tool to align all stakeholders on MEAT tendering

The framework has 3 layers

Core of value: outcomes & costs

Core value creation in terms of outcom that matter for patients vs. the related product / service and provider costs

Other benefits for key stakeholders

Secondary benefits for patients, health care professionals, providers and the health system a whole

Broader impact on society

Broader impact on society in terms of socio-economics[1] , sustainability and innovation

Each layer contains several categories of criteria, with importance of criteria decreasing from core outwards

BCG

'MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. MedTech represents Diagnostics and Medical Devices manufacturers operating in Europe'

Source BCG : Boston Consulting Group. 2017. *Moving Beyond the " Milkman " Model*

MEDTECH Framework – procurement as the most-industry shaping decision

ement is considered as the *enabler* into promoting the shift towards value-based assessments and from costs into value investments since 'procurer
nost-industry shaping decision' and it is at this phase when most stakeholders are involved.

Layer	Category	Criteria
Outcomes	Outcomes & evidence	1 Evidence of relevant outcomes improvement
		2 Existence of high quality outcomes data
	Outcomes focus	3 Support in measuring and reporting on outcomes
		4 Willingness to offer outcomes-dep. risk-sharing
Costs – Product	Purchasing	5 Price of purchasing / renting product
		6 Compatibility: required upgrades to infrastructure
		7 Conversion: staff training for new product
		8 Compatibility: upgrades to systems / infrastructure
	Maintenance	9 Spare parts
		10 Technical staff time
		11 Service contract
	Disposal	12 Disposal / decommissioning
Costs – Care delivery	Operating / healthcare delivery	13 Medical staff time using device
		14 Ongoing staff training
		15 Cost of consumables
		16 Unplanned usage: failure rate
		17 Infrastructure usage
		18 Power/gas usage
		19 Reprocessing costs

Layer	Category	Criteria
Other benefits for key stakeholders	Patients' secondary benefits	20 Patient and/or relative comfort and convenience
		21 Patient flexibility & mobility
		22 Impact on treatment adherence
	HCP benefits	23 Secure usage for care providers
		24 Ease-of-use / handling & functionality
		25 Training and access to education
	Provider benefits	26 Maintainability, warranty & tech. service support
		27 Support improving efficiency along patient pathway
		28 Alignment and support with reimburse. structure
		29 Support on admin., storage or logistics
		30 Strategic fit for provider and support of strategy
	Health system benefits	31 Reduced long term costs of treatment[1]
		32 Reduction of rehospitalization / # of treatments
Broader impact on society	Innovation	33 Develop. of new and substantially improved tech.
		34 Contribution to development of health care
	Sustainability	35 Environmental impact
		36 Socially responsible product value chain
	Socio-economic impact	37 Impact of people not in the workforce
		38 Burden carried by non professional care providers
		39 Impact on competition in MedTech sector

MedTech Assessment : a Comprehensive process

Source BCG : Boston Consulting Group. 2017. *Moving Beyond the " Milkman " Model*

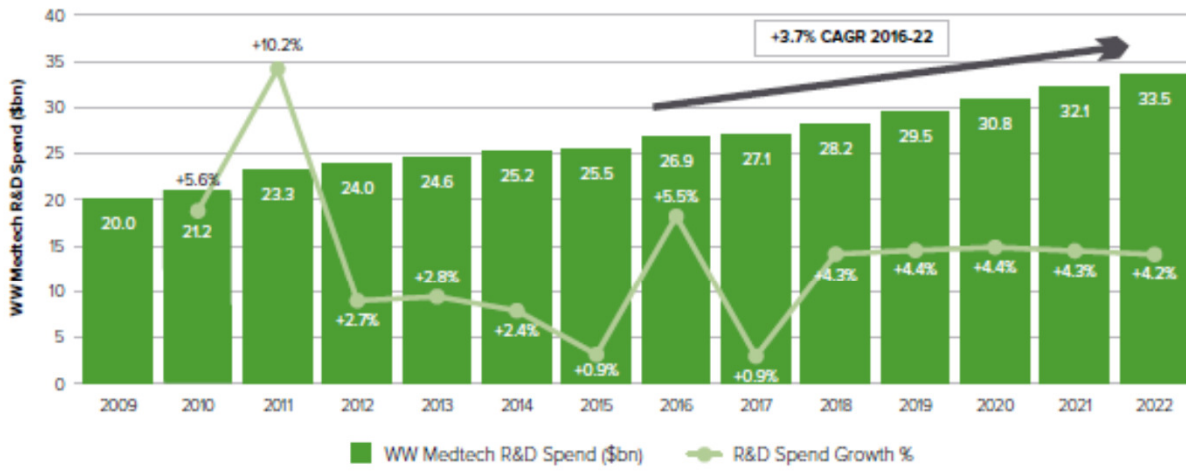
MedTech Innovation Investment

l medtech R&D spend set to grow by 3.7%
R) to $33.5bn by 2022.

&D investment rate, as a percentage of sales,
ected to decline from 6.9% in 2016 to 6.4% in

Worldwide Medtech R&D Spend (2009-2022)

Source: Evaluate,



Worldwide Medtech R&D Spend (2009-2022)

Source: Evaluate,

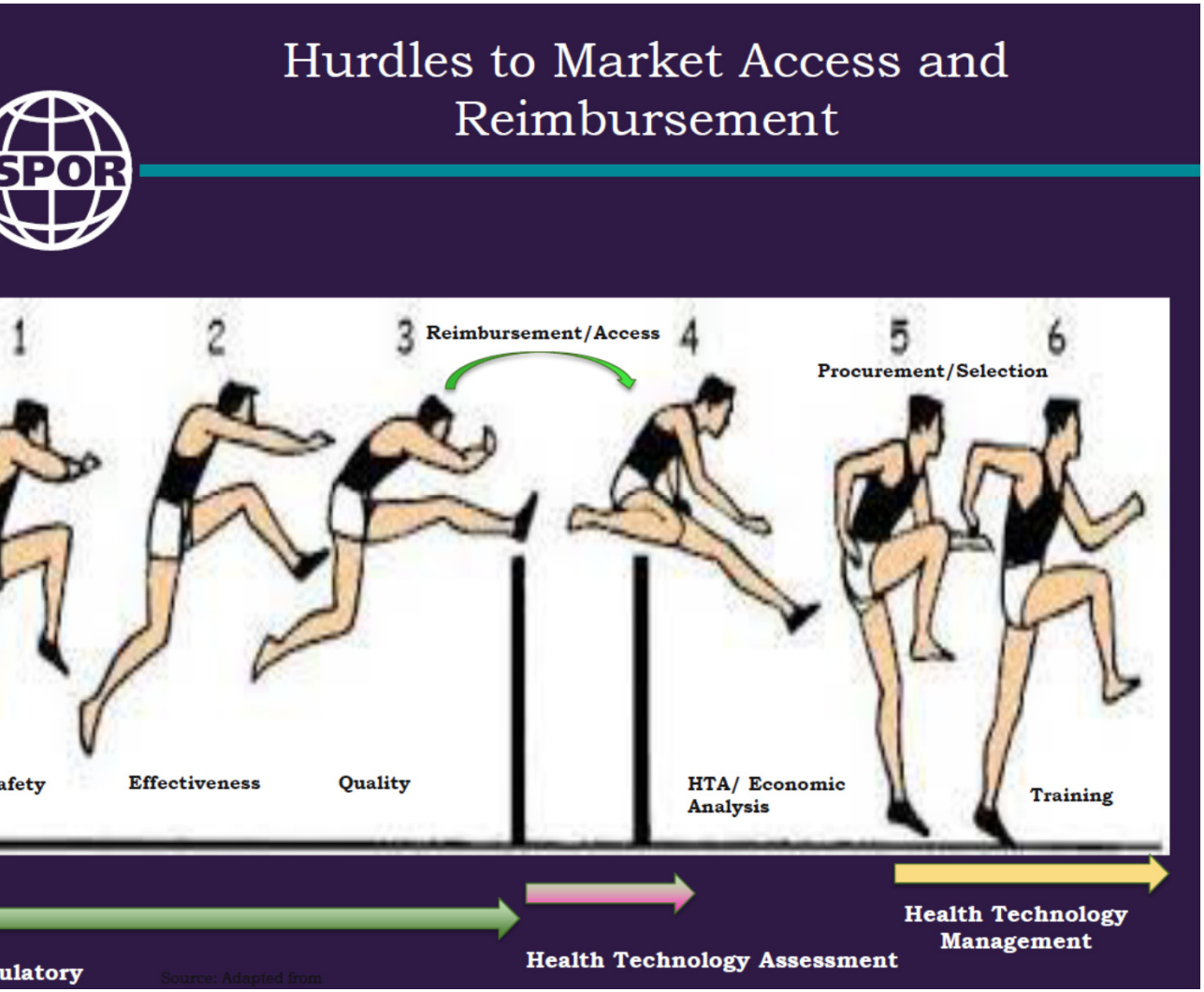
	WW Medtech R&D & Medtech Sales ($bn)												
Year	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	202
Medtech R&D Spend	20.0	21.2	23.3	24.0	24.6	25.2	25.5	26.9	27.1	28.2	29.5	30.8	32
R&D Spend Growth per Year %		+5.6%	+10.2%	+2.7%	+2.8%	+2.4%	+0.9%	+5.5%	+0.9%	+4.3%	+4.4%	+4.4%	+4.3
WW Medtech Sales	308.5	326.3	352.4	361.5	368.6	378.6	371.1	386.8	402.8	425.1	448.5	472.7	497
R&D as % of Medtech Sales	+6.5%	+6.5%	+6.6%	+6.6%	+6.7%	+6.7%	+6.9%	+6.9%	+6.7%	+6.6%	+6.6%	+6.5%	+6.5
R&D as % of Medtech Sales (Top 20 in 2022)								5.7%					

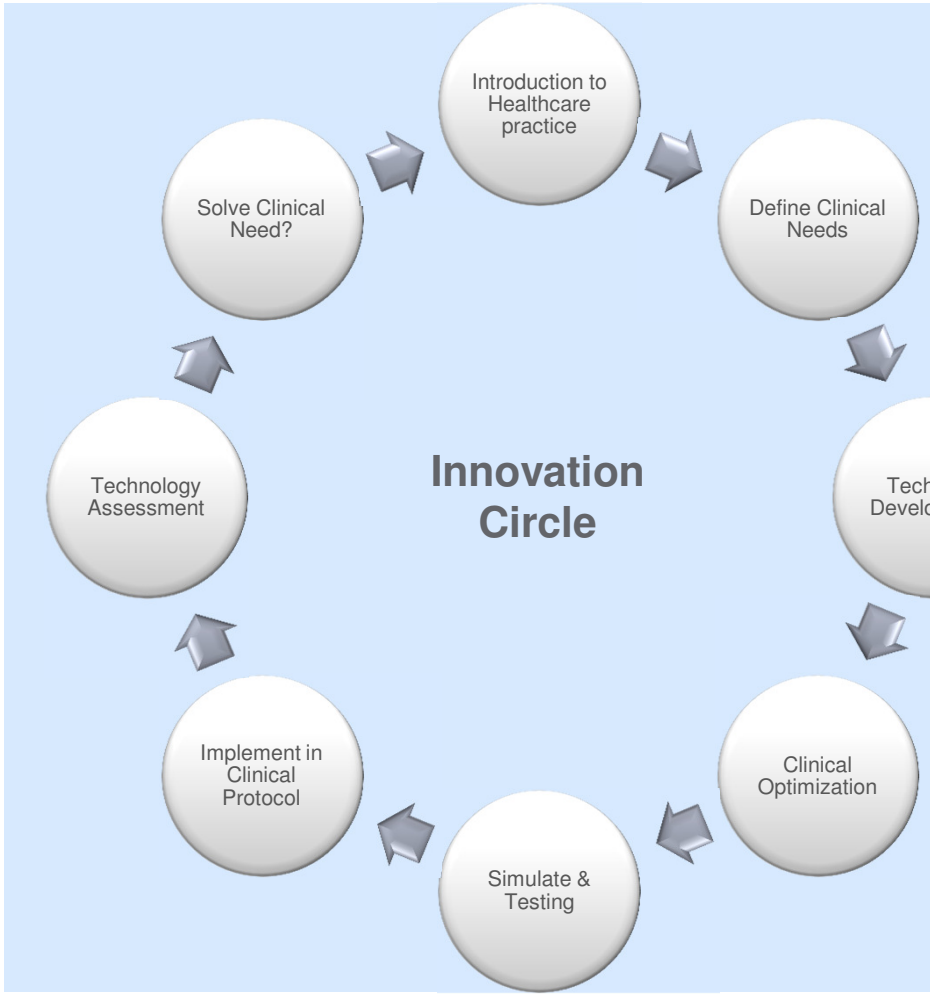
CAGR 2016-22 on Medtech R&D Spend +3.7%
Cumulative 5 year R&D Spend (2012-16) $126.2bn
CAGR 2009-16 on Medtech R&D Spend +4.3%

Note: Analysis is based on the Top 300 medtech companies. R&D spend in 2016 based on company reported data.
Forecast medtech R&D spend based on a consensus of leading equity analysts' estimates for company level R&D spend, extrapolated to medtech R&D when a company has non-medtech
Medtech R&D is not disclosed by a number of companies and this analysis is limited to those companies with sufficient disclosure.

Source : EvaluateMedTech® World P

A | A long-term commitment to Value



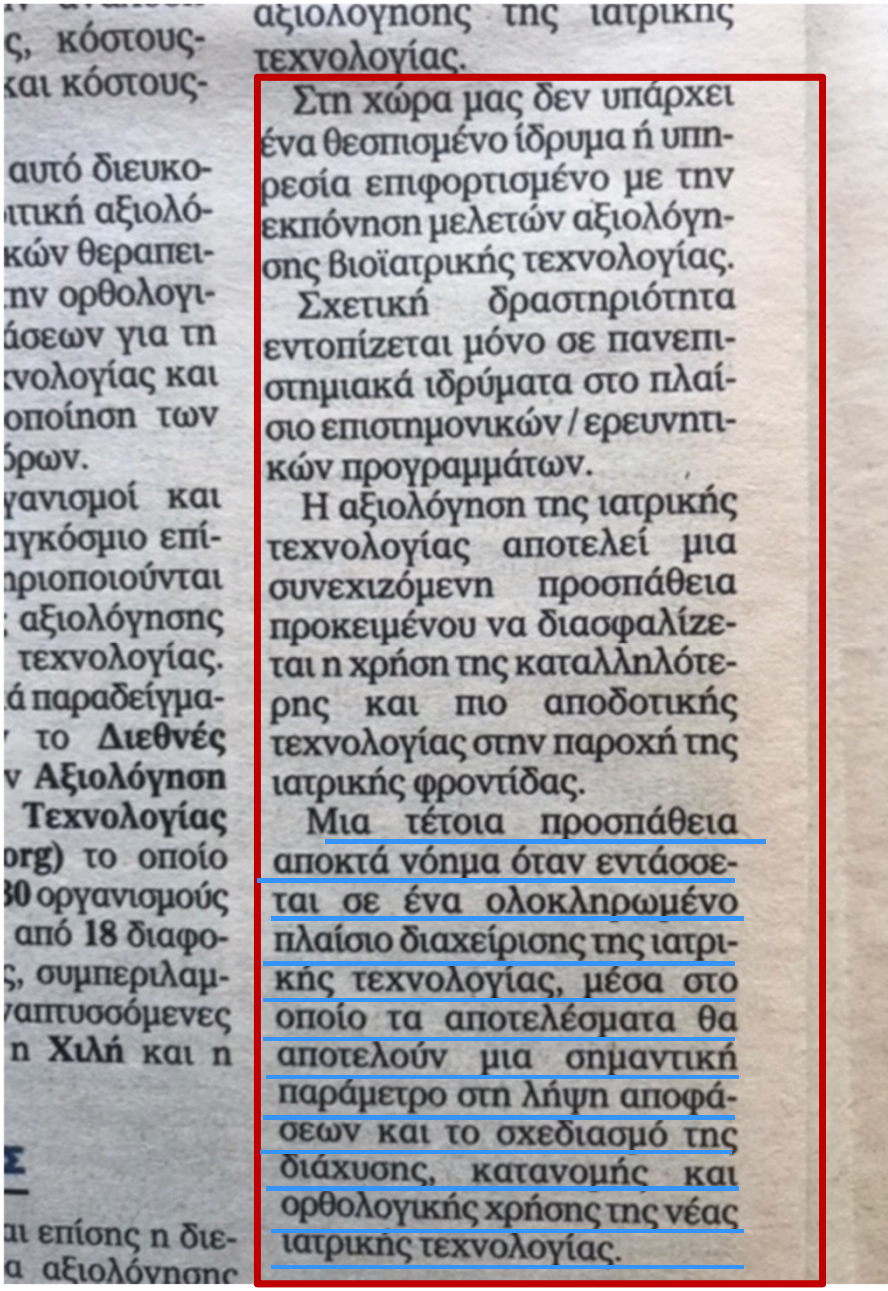


A | A Sisyphus Torment ?

ΥΓΕΙΑ ΟΚΤΩΒΡΙΟΣ 2000 ΗΜΕΡΗΣΙΑ

Στην Ελλάδα η βιοϊατρική τεχνολογία δεν αξιολογείται...

Η τεχνολογία στην υπηρεσία της υγείας



αξιολόγησης της ιατρικής τεχνολογίας.

Στη χώρα μας δεν υπάρχει ένα θεσπισμένο ίδρυμα ή υπηρεσία επιφορτισμένο με την εκπόνηση μελετών αξιολόγησης βιοϊατρικής τεχνολογίας.

Σχετική δραστηριότητα εντοπίζεται μόνο σε πανεπιστημιακά ιδρύματα στο πλαίσιο επιστημονικών / ερευνητικών προγραμμάτων.

Η αξιολόγηση της ιατρικής τεχνολογίας αποτελεί μια συνεχιζόμενη προσπάθεια προκειμένου να διασφαλίζεται η χρήση της καταλληλότερης και πιο αποδοτικής τεχνολογίας στην παροχή της ιατρικής φροντίδας.

Μια τέτοια προσπάθεια αποκτά νόημα όταν εντάσσεται σε ένα ολοκληρωμένο πλαίσιο διαχείρισης της ιατρικής τεχνολογίας, μέσα στο οποίο τα αποτελέσματα θα αποτελούν μια σημαντική παράμετρο στη λήψη αποφάσεων και το σχεδιασμό της διάχυσης, κατανομής και ορθολογικής χρήσης της νέας ιατρικής τεχνολογίας.

Comprehensiveness enabling disruptive innovation and growth

Improve pharma productivity … ↑ yield, scale R&D to mfg

AI that helps choose the right patients for clinical trials

Rapidly emerging … GE well positioned

Biologic drug R&D

Biologic drug manufacturing

Cell Therapy R&D

Cell Therapy prepared in hospital

Pro-active mobile & remote monitoring


Whatman


ÄKTA pure


FlexFactory™


Cytell

InCell Analyzer


Sefia Cell Analyzer


Sepax Cell Processing

DIAGNOSE: PET/MR with nuclear pharmacy

TREAT: Biologic drug treatment

RELAPSE: Imaged guided biopsy

REFRACTORY: Cell Therapy treatment

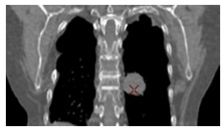
MONITOR: Serial CT scans with Visipaque

AMPLE: patient ymphoma


SIGNA™ PET/MR


FASTLab


LOGIQ E10




Optima IGS

Smart devices that personalize scan to each patient

AI that helps choose the right drug

Augmented reality used to guide procedures


B40 Monitor


Airstrip ONE®


Advanced Visualization

Inpatient monitoring for complications

Opportunities f disruptive inno

ADVAMED Framework

Value Subcategories	Value Driver	Sample Questions to Consider	Sample Value Metrics
Analytical Validity	The ability of a test to measure accurately and reliably the analyte/biomarker of interest in a sample or specimen	• What is the smallest quantity of substance in a sample that can be measured (analytical sensitivity)? • What is the ability of the diagnostic to measure one particular organism or analyte, rather than others (analytical specificity)? • How well does the test measure the condition in a population of patients (accuracy)? • How reliably does the test measure the analyte (precision)? • How consistently will the test results be under different environments and operators (reproducibility)?	• Analytical sensitivity (e.g., Limit of Detection—LoD, Limit of Quantitation—LoQ, Limit of Blank—LoB) • Analytical specificity (i.e., false negative/ false positives amongst cross reactants/ interfering substances) • Accuracy expressed as % of total true positives and true negatives vs. the entire population • Precision expressed as % true positives as compared to all positives • Reproducibility as % of agreement of test results • Image quality
Clinical Validity	The ability to check how consistently and accurately a test detects or predicts the outcomes of interest in a patient population	• Is the target analyte/biomarker relevant to the health state or condition of interest? • Does the test result accurately inform decision-making based on the relationship of the target analyte/biomarker to the health state or condition of interest? • How well does the diagnostic distinguish between patients who have disease and those who do not in the targeted population?	• Clinical specificity (% true negatives, false positives) • Clinical sensitivity (% true positives, false negatives) • Positive Predictive Value (PPV)/Negative Predictive Value (NPV) • Adherence to clinical guidelines and appropriate use
Clinical Utility	The ability of a test to inform an appropriate clinical treatment decision to improve patient outcomes	• What clinical decision is the diagnostic supporting? • How does the diagnostic impact the physician's treatment decision? (i.e. how useful is the diagnostic to making the clinical decision?) • How does it direct downstream clinical decision-making?	• % changed clinician decisions post implementation of diagnostic vs. prior • The resulting difference in endpoints or outcomes from a changed clinical decision (i.e., reduced number of repeat procedures, response to treatment, or best treatment selected initially)
Patient Safety, Tolerability, or Compliance	Improved patient safety, tolerability, and compliance vs. alternative diagnostic options	• Are there differences in the diagnostic options (e.g., blood draw/urine sample versus invasive tissue specimen collection, or off-site radiology vs. on-site)? • How does the diagnostic compare to alternative diagnostics in terms of patient follow-through?	• Adverse reactions or side effects of anesthesia in invasive specimen collection • Patient follow-up for diagnostic result review and compliance to physician guidance • Radiation dose tracking per visit/per exam
Patient Response to Diagnostic Results	Improved physical and psychological wellbeing	• How does the diagnostic result affect physical and psychological well-being (value of "knowing")? • How does the diagnostic help avoid patient demand or physician request for unnecessary procedures?	• Frequency/amount of retesting • Number of additional/wasteful procedures

Value Category	Value Subcategories	Value Driver	Sample Questions to Consider	Sample Value Metrics
Care Delivery Revenue and Cost Impact	Quality of Care Economics	Economic impact of performance-based reimbursement metrics (e.g., hospital-acquired infections, readmissions, length of stay, cost efficiency)	• How does the diagnostic enable the determination of right choice of treatment for the given patient? • What are the direct and indirect economic benefits of the improved quality of care? • How does the diagnostic impact performance-based reimbursement metrics (e.g., hospital-acquired infections, readmissions, length of stay)? • Was the test appropriate for the clinical indication? • How does use of the diagnostic result in cost-offsets (averted complications or unnecessary procedures)?	Costs related to: • Use of toxic therapy • Number of repeat proce surgeries/imaging proce • Number of adverse ever • Number of readmission Compare scores • Number of hospital-acq • Number of follow-ups • Length of stay • Variance in decision-ma • Patient satisfaction scor expectations met, comf • Compliance with follow- recommendations
	Care Efficiency	Economic impact of improved system throughput, workflow/ efficient time, and resource utilization	• How does the diagnostic impact costs related to system throughput, workflows, and care efficiency (e.g., degree of automation)? • How does the diagnostic affect costs related to the elimination of waste and unnecessary procedures and costs? • How does the diagnostic enable more efficient time, resource, and test utilization, both upstream and downstream?	Costs related to: • Patient flow (i.e., overall system efficiency) • Time to effective treatm • Human resource utilizat • Frequency/amount of re • Number of additional/w • Hours of operation • Time from sample collec • Wait times • Uptime aligned to busin emergency service resp
		Impact of costs associated with clinical outcomes variance	• How does the diagnostic affect costs associated with variance in clinical outcomes across individual physicians/ sites of care?	• Costs associated with cl variance
		Economic impact of improved adoption of new care practices due to easier/more effective training/ education	• How does the diagnostic affect costs related to improved adoption of new care practices due to easier/more effective training/education? • How does the diagnostic affect lab or departmental workflow and lab integration, training, ease of maintenance, etc.?	• Training and education t and costs

ADVAMED. 2017. *A Framework for Comprehensive Assessment of Medical Technologies : Defining Value in the New Health Car*