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Hull Associates LLC
MARKET ACCESS

CRAASH Barcelona 2018 Market Access

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Objectives

1. **Explain basic elements of reimbursement and market access**

2. **Review market access tools and strategic steps**

3. **Course work: Let´s look at the type of key questions you should ask yourself as part of developing a market access strategy for your technology!**

Contents

1. **Macro Economic Background on Health Care Expenditure**

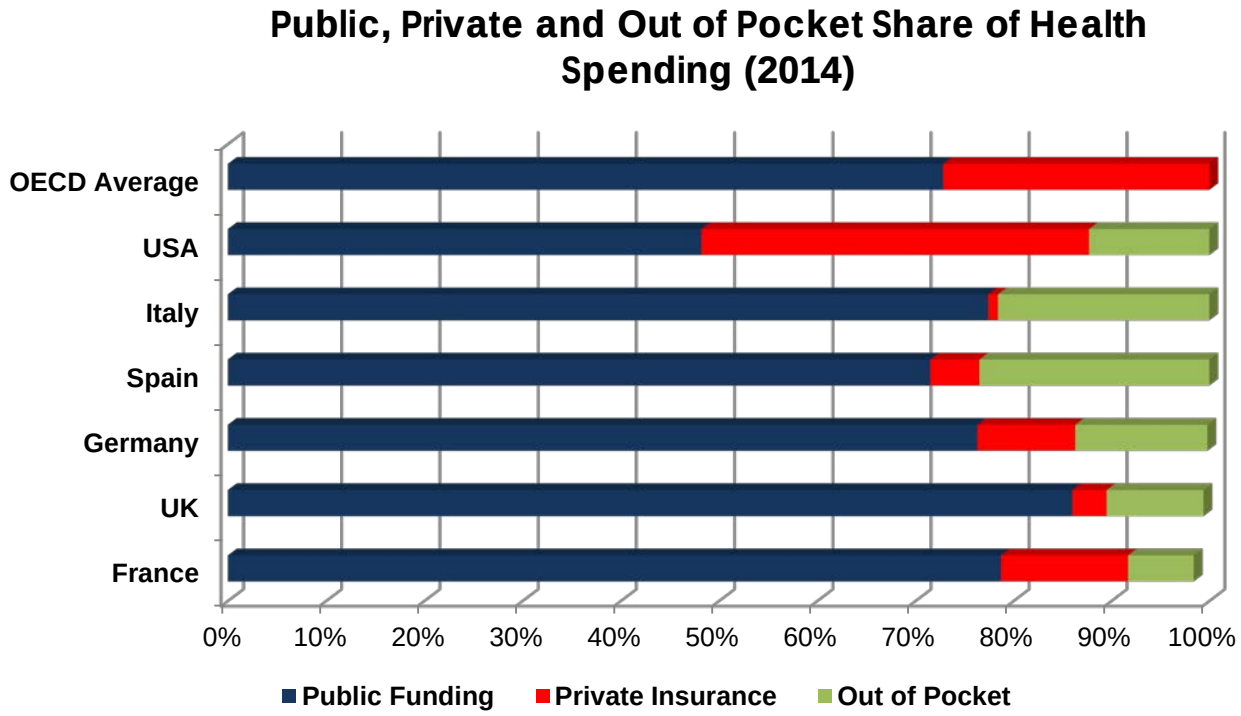
2. **What is: “Reimbursement and Payment Policy”?**

3. **Market Access Tools:** Clinical & Economic Evidence and Health Technology Assessments

4. **Sample Steps for Market Access Strategy Development**

1. Macro Economic Background on Health Care Expenditure

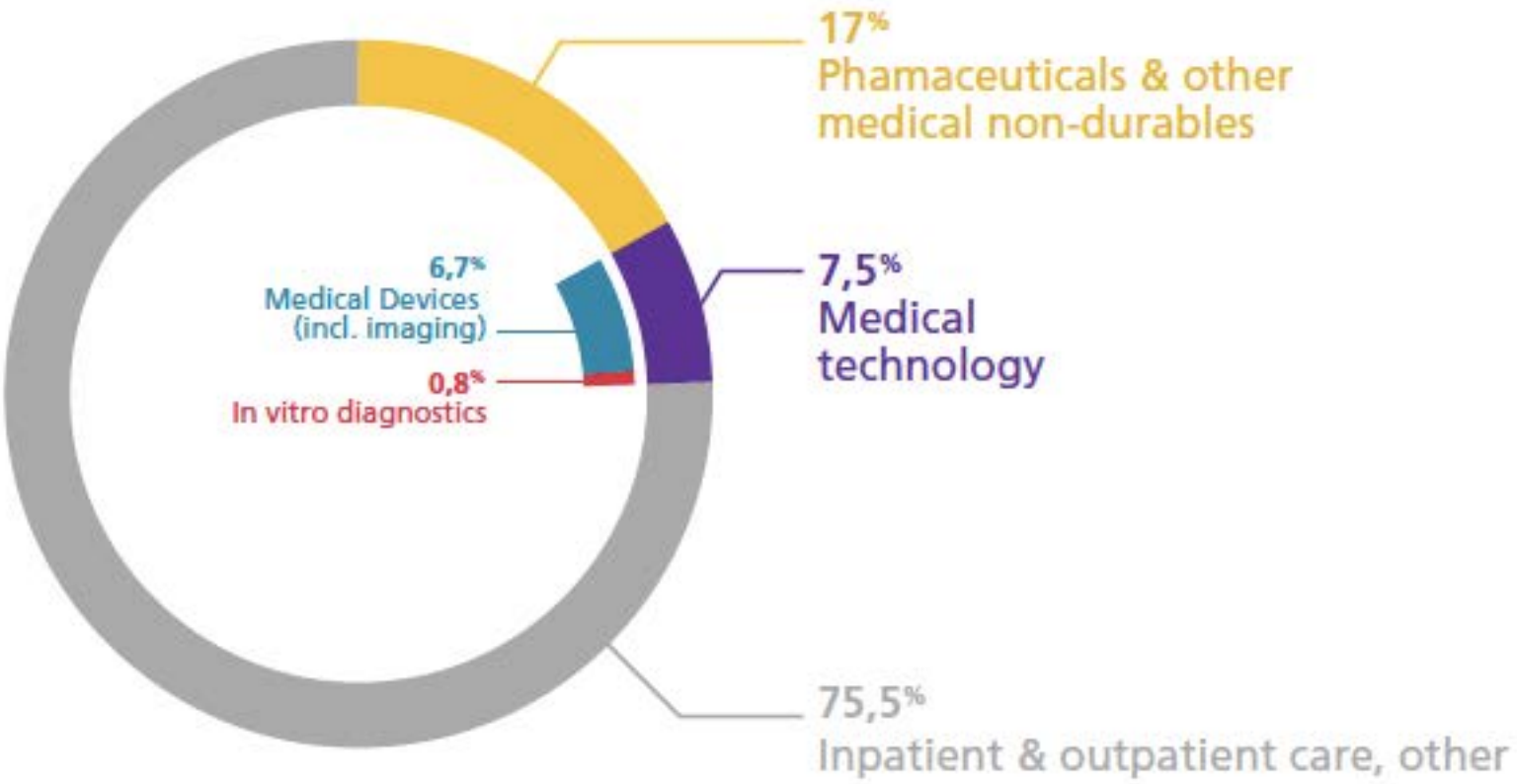
Public sector funding maintains a dominant role in most EU markets.



- Most EU countries rely on a mix of private and public funding.
- The private share of funding is usually concentrated in certain elective areas.
- Only a few countries rely heavily on private funding for medically essential care
- The market is characterized by stable or reduced expenditure

Approximately 7,5% of total healthcare expenditure in Europe is spent on medical technology

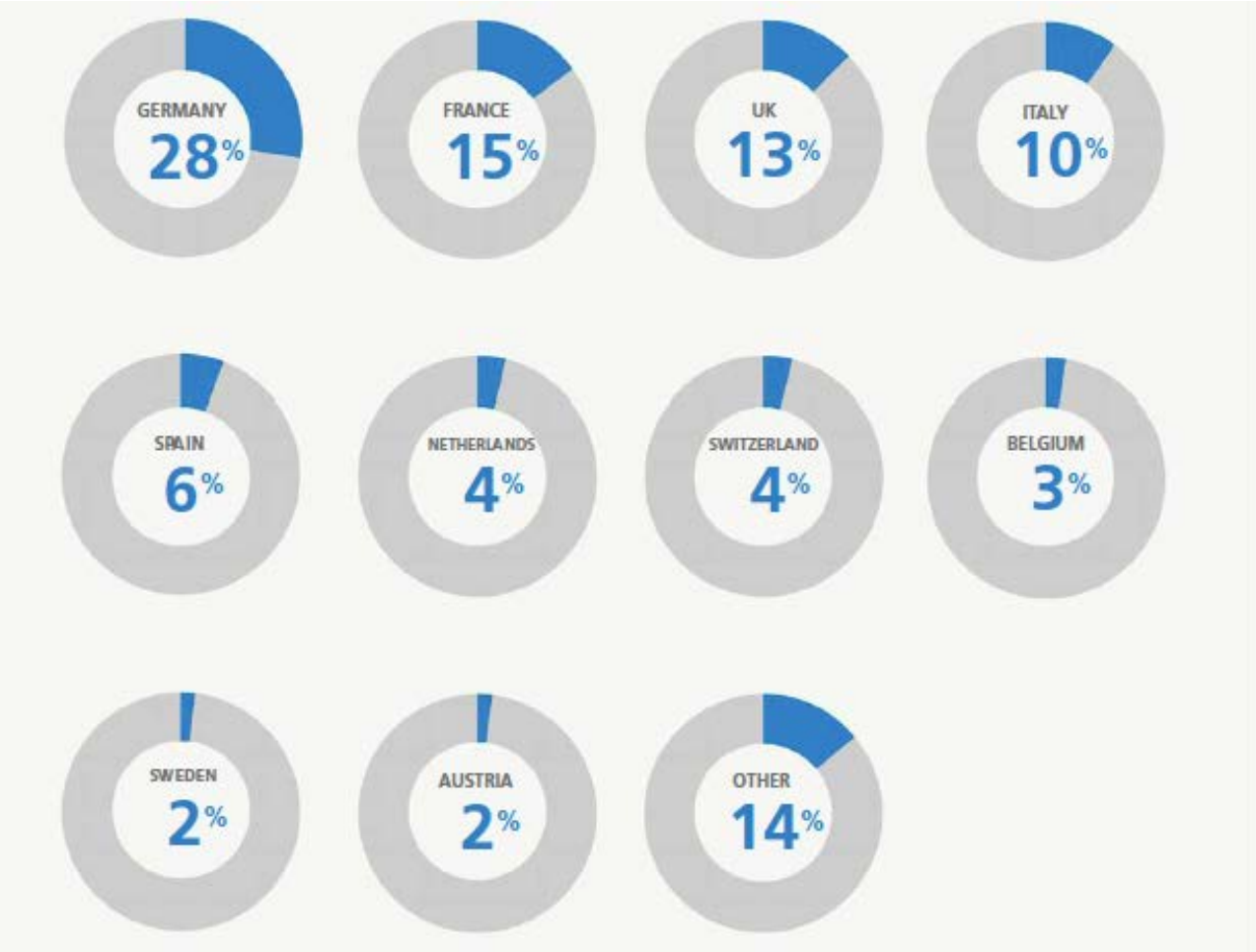
Breakdown of total healthcare expenditure in Europe



MedTech Europe "The European Medical Technology industry in figures"

Germany, France and UK together represent 56% of total expenditure on Medical Devices in Europe

European Medical Device Market by Country, Based Upon Manufacturer Prices, 2016



Homework Questions:
Macro Economic Background on Health Care Expenditure

1) What market are you focussing on, and why?

2) What is the macro economic climate of that market?

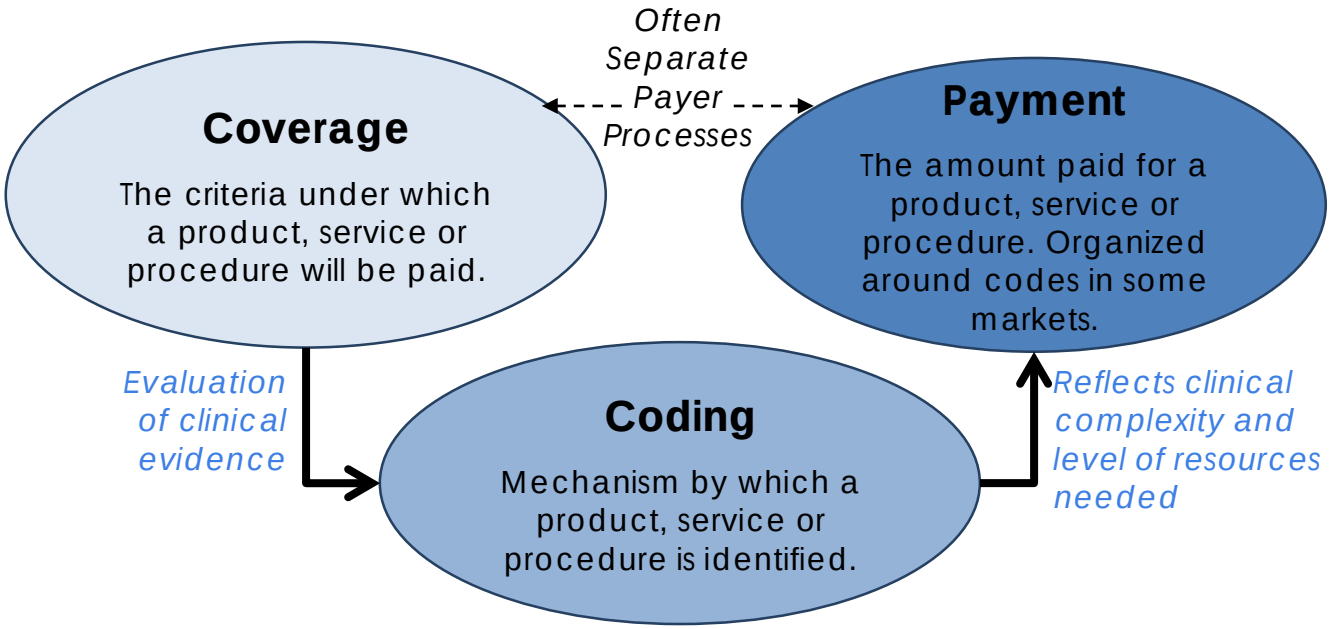
3) How is healthcare financed predominantly in your target market?

4) Is your product targeted to be adopted within the public or private sector?

2. What is: Reimbursement and Payment policy?

Reimbursement and payment policy consist of 3 elements: Coverage, Coding and Payment

- Reimbursement has 3 distinct elements: Coverage, Coding, and Payment



- Routine tendering and procurement is an aspect of "payment policy" but typically managed locally, as part of the sales process.

Coverage: Examples of "coverage" policy

- **Spain: Cartera de Servicios Comunes del Sistema Nacional de Salud**; "Common Services Portfolio"

Elements of the CSP

Basic Healthcare Services *"…encompass all preventive, diagnostic, treatment – including surgical implants - and rehabilitation care activities which take place in healthcare or social care centers [….]* ***covered fully by public funds****."*
Supplementary Services *"…includes all the services dispensed on an outpatient basis and are* ***subject to user co-payment****." These include pharmaceuticals, orthopedic prostheses, and dietary products.*
Ancillary Services *"… includes all activities, services or techniques which are not characterized as care and not considered essential and/or are aids or support the improvement of a chronic pathology, being* ***subject to co-payment and/or reimbursement by the user."***

  - Regions are "free" to cover additional Services

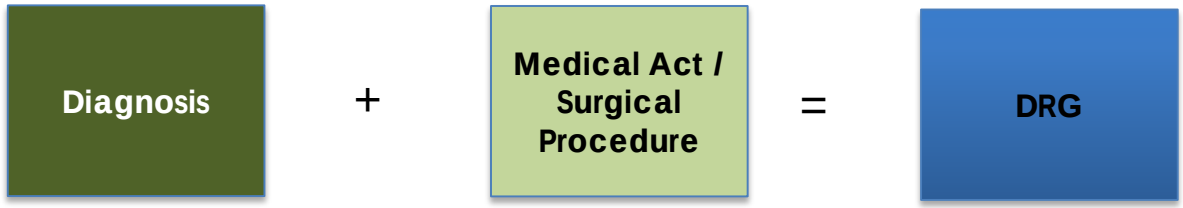
- **Italy: LEA "Essential Levels of Assistance"**
  - Example: "Intra Ocular Lens" – IOL.
    - Cataract surgery is covered by the LEA
    - Correction of refractive errors, through use of glasses or excimer laser is not covered.
    - Hospitals may correct refractive pathologies, charging patients a "fee" for the purchase of prosthetic materials

- **The Netherlands: Mandatory Basic Basket of Healthcare Services** + additional services offered by Insurance Companies

Coding: All diagnosis and medical acts are coded but EU countries use different coding systems, depending on setting of care

Country	Setting	Diagnosis Coding	Procedure Coding
USA	Inpatient	ICD-9 (ICD-10 PCS as of 2014)	ICD-9 for hospitals; CPT for Physicians
	Outpatient	ICD-9 (ICD-10 PCS as of 2014)	CPT for both hospitals and physicians
Germany	Inpatient	ICD-10-GM Diagnosis Codes, German Modification	OPS (Operation and Procedure Coding System, *Operationen- und ProzedurenSchlüssel*
	Outpatient	ICD-10-GM Diagnosis Codes, German Modification	EBM: Uniform Value Scale *Einheitlicher Bemessungsmassstab*
France	Inpatient	ICD-10 Diagnosis Codes	CCAM: Common Classification onf Medical Acts *Classification Commune des Actes Médicaux*
	Outpatient	ICD-10 Diagnosis Codes	CCAM coding
UK	All Settings (Public Hospitals)	ICD-10 Diagnosis Codes	OPCS: Office for Population Censuses and Surveys Classification
Italy	Inpatient	ICD-9 Diagnosis Codes	ICD-9 Procedure Codes
	Outpatient	ICD-9 Diagnosis Codes	Local NTPA: *Nomenclatore Tariffario delle Prestazioni Ambulatoriali*

Diagnosis + Procedure = DRG



Example Procedure Coding and DRG Mapping for Ablation Treatment for Liver Cancer

ICD9 Disease Classification 155.XX "Malignant neoplasm of liver and intrahepatic bile ducts"

Procedure	Code and Description	DRG	Description
Microwave ablation Cryotherapy	**99.85** Hyperthermia for treatment of cancer induced by microwave, ultrasound, low energy radio frequency, probes **+ 38.19** Arterial catheterization	**203**	**Malignancy of Hepatobiliary System or Pancreas**
Radiofrequency ablation	**50.29** Other destruction of lesion of liver (cauterization, enucleation or evacuation of hepatic lesion) **50.25** Laparoscopic ablation of liver lesion or tissue	**191**	**Pancreas, Liver and Shunt Procedures with CC**
Other	**50.24** Percutaneous ablation of liver lesion or tissue		
Surgery	**50.22** Partial hepatectomy / **50.23** Open ablation of liver lesion or tissue / **50.30** Lobectomy of liver / **50.40** Total hepatectomy	**192**	**Pancreas, Liver and Shunt Procedures w/o CC**

Payment: Procedure coding often result in tariffs used differently depending on setting of care

Types of Payment Systems and Their Impact on Technology

Type of System	Examples	Unit of Payment	Impact on Technology
Fee Schedules	Physician Fees Tariffs for prostheses, home use equipment	Per Procedure + Device Payment / Device Maximum Price	Need code + tariff for devices
Bundled Procedure Based Coding and Fee Schedule	Outpatient Nomenclature	Per Procedure incl. most costs	Can allow pass-through payments for technologies
"DRG" Diagnosis Related Groups	German DRG / UK HRG / Spain GRD	Per hospital stay (diagnosis + procedure)	Hospitals absorb costs within a fixed payment + supplements
Case Rates	Private Payer: "pregnancy"	Per patient (set period)	Depends on negotiated amount
Fixed Annual Hospital Budgets	Common in Spain, Italy	Yearly irregardless of volume	Mayor disincentive for costly devices

The heterogeneity of coding and payment systems across and within countries affects market access due to the unique and often conflicting characteristics of each payment system type

Complexity of Global Reimbursement Landscape

Sample Country Public Reimbursement System Analysis

Country	DRG	FFS	Global Budget
Australia (AU)	●		
Belgium (BE)		●	●
Brazil (BR)		●	●
Canada (CA)			●
China (CN)	◐	●	◐
France (FR)	●		
Germany (DE)	●	◐	
India (IN)		◐	●
Italy (IT)	●		
Japan (JP)	●	●	
Mexico (MX)			●
Netherlands (NE)	●		
Poland (PL)	●		
Russia (RU)	●	●	●
South Africa (SA)			●
South Korea (SK)	◐	●	
Spain (SP)	◐		●
Taiwan (TA)	◐	●	
Turkey (TK)		●	●
United Kingdom (UK)	●		

Example of a Fee Schedule

Murcia Public Fee Schedule

GRD.824	Quemaduras de espesor total con inj, piel o lesiones inhalación sin cc o trauma sig,	11.528,13 €
GRD.825	Quemaduras de espesor total sin inj, piel o lesiones inhalación con cc o trauma sig,	8.495,01 €
GRD.826	Quemaduras de espesor total sin inj, piel o lesiones inhalación sin cc o trauma sig,	8.239,55 €
GRD.827	Quemaduras no extensas con lesión por inhalación, cc o trauma significativo	8.403,31 €
GRD.828	Quemaduras no extensas sin lesión por inhalación, cc o trauma significativo	5.918,17 €

	Consultas	
Código	**Concepto**	
A.4.1	Cirugía Menor	277,37 €
A.4.2	Consulta sucesiva	99,86 €
A.4.3	Curas ambulatorias	44,38 €
A.4.4	Primera consulta	166,42 €
A.4.5	Urgencia	199,72 €

	Pruebas funcionales y exploraciones	
Especialidad	**Código**	
Alergología	A.5.1.A.1 Provocaciones	32,57 €
	A.5.1.A.2 Pruebas alergicas a medicamentos	122,11 €
	A.5.1.A.3 Pruebas de función respiratoria	32,57 €
	A.5.1.A.4 Pruebas epicutaneas	56,98 €
Anatomía Patológica	A.5.1.B.1 Diagnostico microscópico electrónico	325,65 €
	A.5.1.B.2 Estudio de muestras citologicas	48,84 €

http://www.borm.es/borm/documento?obj=anu&id=559495

Example: Where coding and tariffs become an issue…

Ablation of Neoplasm of the Liver or Pancreas Procedure Coding and Italy Tariff

Procedure Code and Description	DRG	Description	Tariff
99.85 Hyperthermia for treatment of cancer induced by microwave, ultrasound, low energy radio frequency, probes **+ 38.19** Arterial catheterization	**203**	**Malignancy of Hepatobiliary System or Pancreas**	**€ 3.115**
50.29 Other destruction of lesion of liver (cauterization, enucleation or evacuation of hepatic lesion) **50.25** Laparoscopic ablation of liver lesion or tissue **50.24** Percutaneous ablation of liver lesion or tissue	**191**	**Pancreas, Liver and Shunt Procedures with CC**	**€ 14.198**
50.22 Partial hepatectomy / **50.23** Open ablation of liver lesion or tissue / **50.30** Lobectomy of liver / **50.40** Total hepatectomy	**192**	**Pancreas, Liver and Shunt Procedures w/o CC**	**€ 8.437**

** Emilia Romagna: 50.24 Percutaneous Hepatic Termoablation case tariff €5,040*

- **But the selling price of the Irreversable Electroporation Probes is around €10,000**
- **Add-On tariffs / Innovation "pass-through" payments ??**

DRG versus Global Budget

- Detailed coding-system
- Less detailed coding-system
- 'Global budget'

Conclusion:
Impact of coding varies across countries

Take Aways: Reimbursement and Payment policy

- ✓ Reimbursement is made up of: **Coverage, Coding and Payment**
  - **Coverage:** WHAT services are provided
  - **Coding:** Countries use different procedure, diagnosis and DRG coding systems
  - **Payment:** Fee schedules, Bundled Procedure Based Fee Schedule, DRG, Case Rates and Fixed Annual Budgets
    - Systems vary by setting of care and by country, making market access strategies more complex
- ✓ **DRG systems are used to allocate health care budgets**
- ✓ **The introduction of an inpatient technology is affected by**
  - Abilty to "fit" into an existing procedure or DRG system code and tariff
  - Availability of process to modify a DRG or create a new one
  - Availability of innovation "pass-through" or "add-on" payments

Homework Questions:
Reimbursement and Payment policy

5) COVERAGE: Is your procedure or device "covered" in the target market and setting of care (public and/or private)? *(example: In Spain check the "Cartera Común de Servicios" / In Italy the "LEA" or any local private insurer coverage policy)*
    1) Are physicians required to follow clinical guidelines for your procedure?

6) How are hospitals financed in your target market:
    a. Annual budgets?
    b. DRG?
    c. Fee schedules?
    d. Mix / Other?

(please focus on setting of care for your technology)

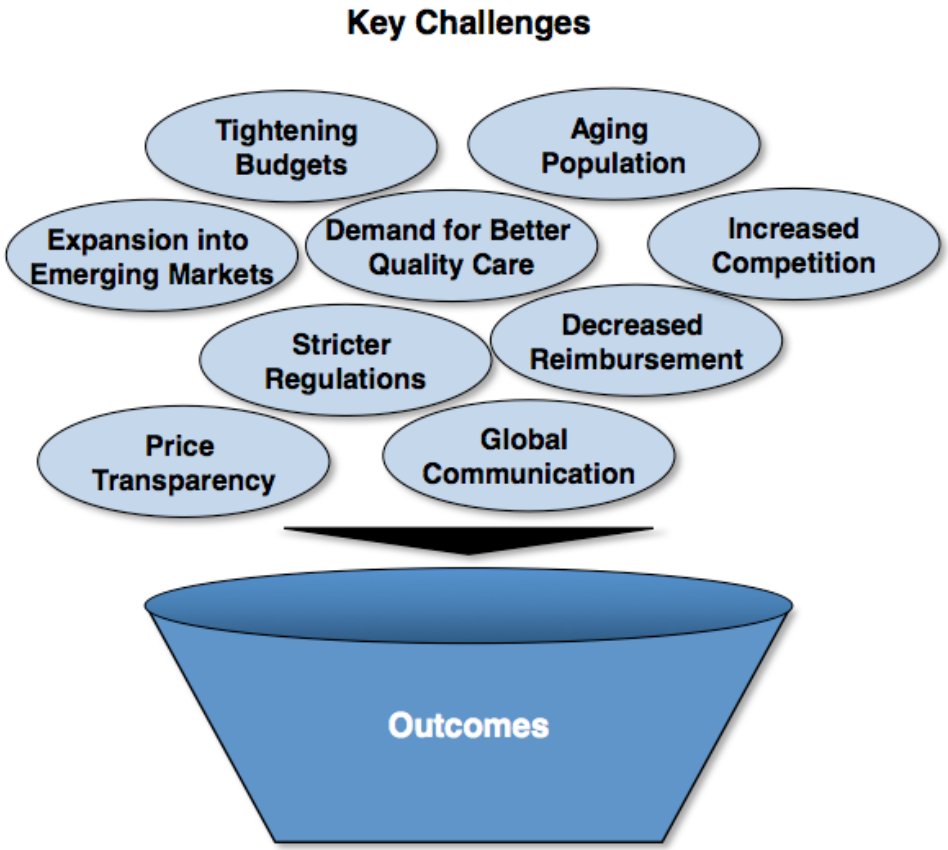
7) INPATIENT / OUTPATIENT CODING:
    a. Does an existing inpatient or outpatient procedure code "fit" your technology?
    b. What DRG # does this code map to?

8) FEE SCHEDULE: Does an existing code on a fee schedule or listing of home use and rehabiliation devices describe your technology?

9) TARIFF: Can you find out the applicable DRG or fee schedule tariff for your technology?

3. Market Access Tools: Clinical & Economic Evidence and Health Technology Assessments

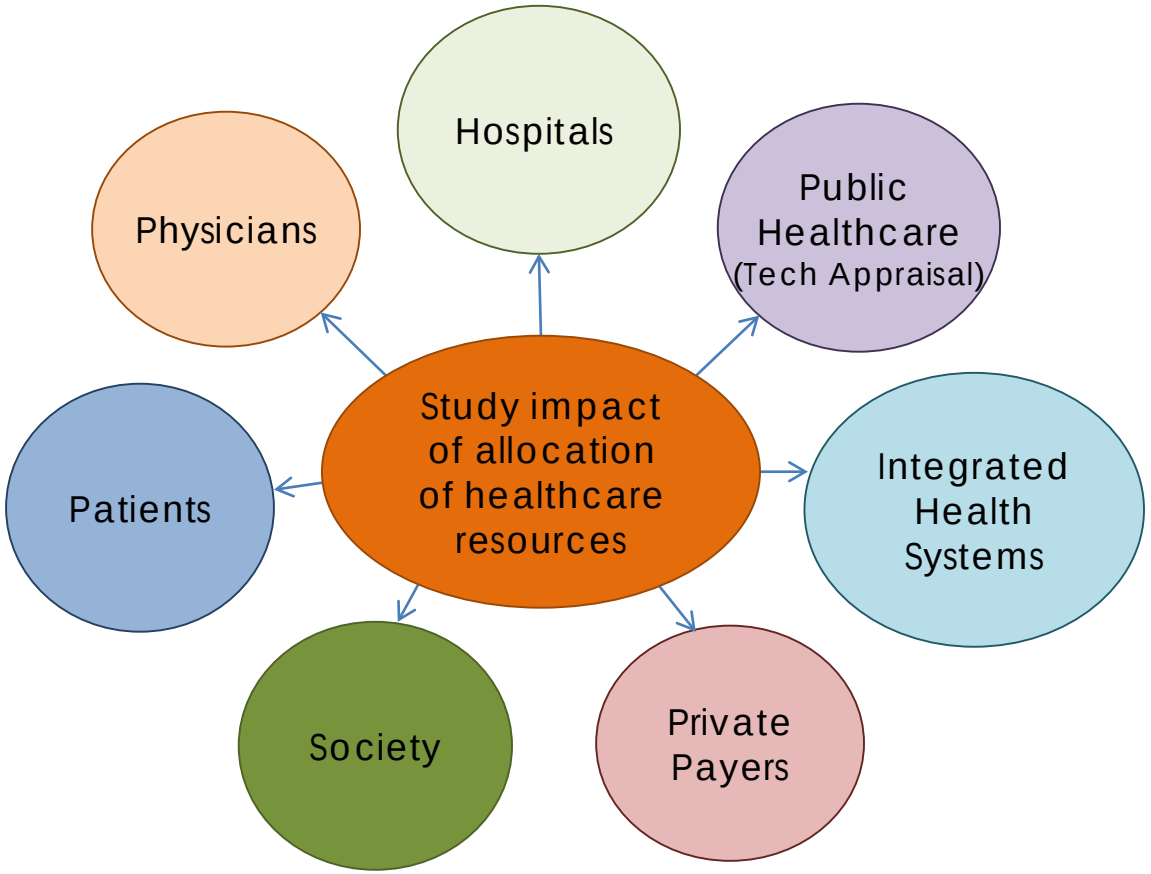
Products will need to demonstrate their value within the context of providing more care with less resources



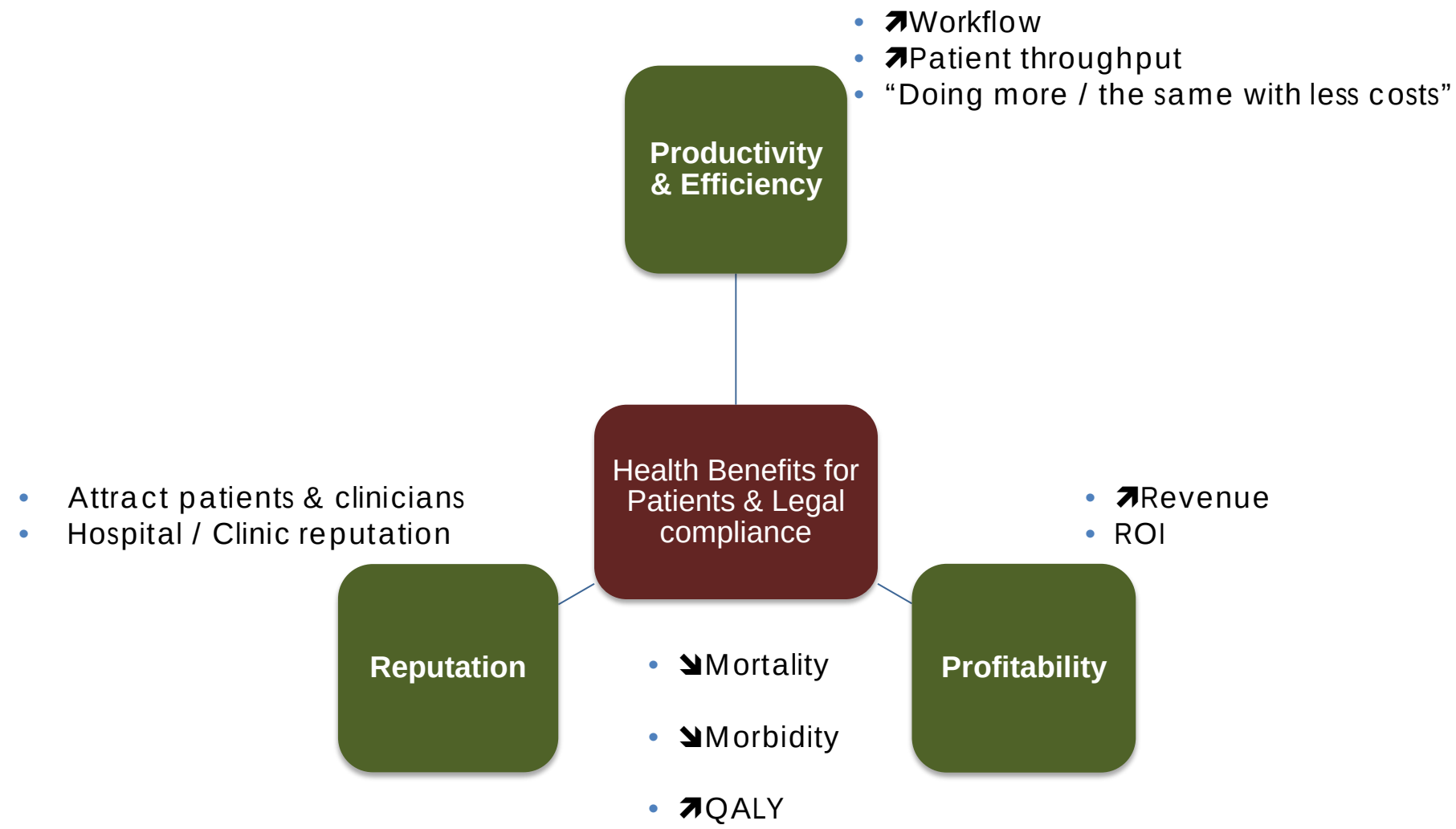
Strong value demonstration needs to address payers' concerns in each market to achieve the critical clinical and economic benchmarks necessary to gain optimal market access

The allocation of health care resources responds to different priorities for each stakeholder

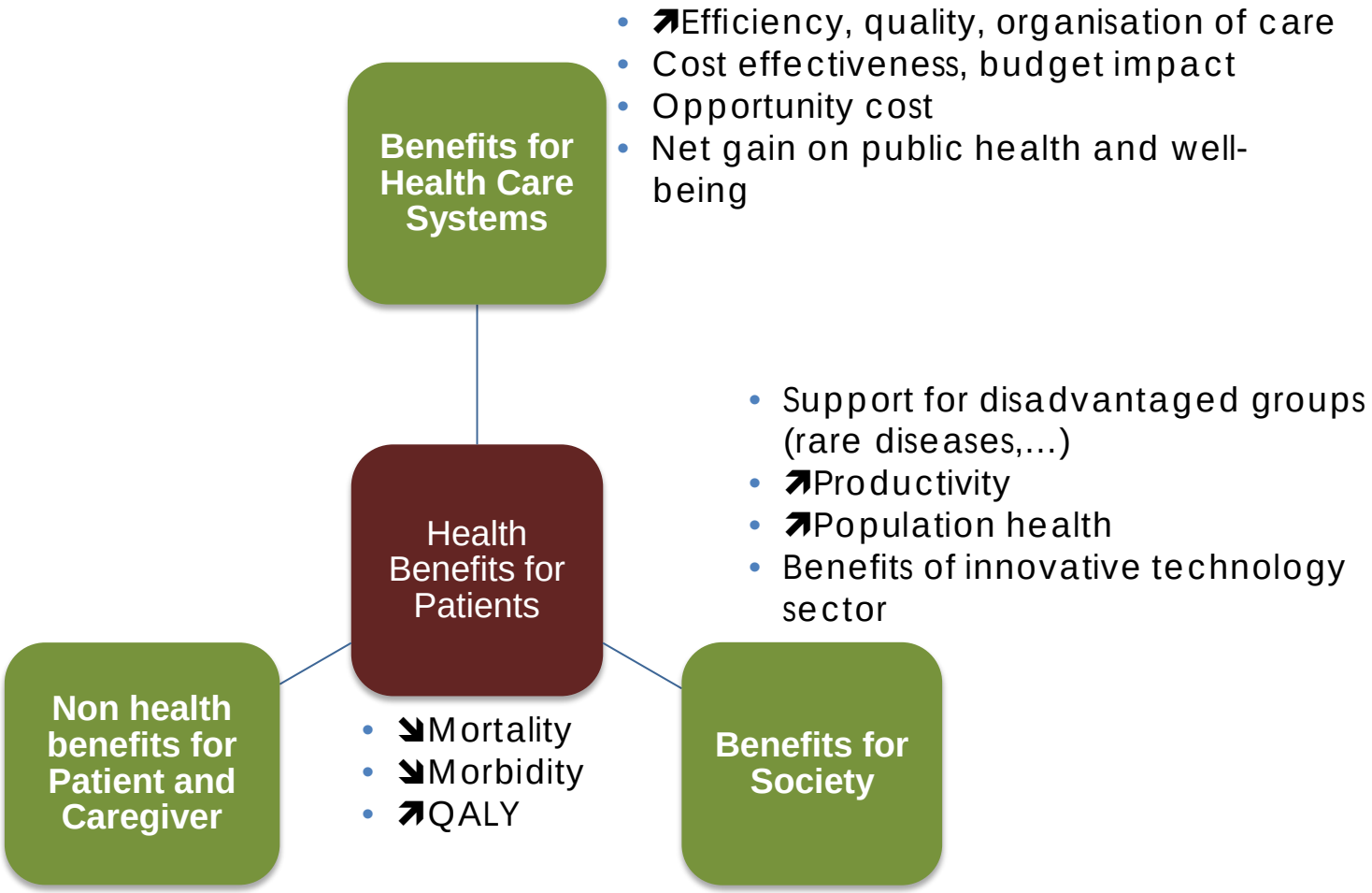
- Priorities, and approach to allocation of healthcare resources and coverage of healthcare services depends on stakeholder needs and perspectives.



“Value” – Healthcare Administrator Perspective

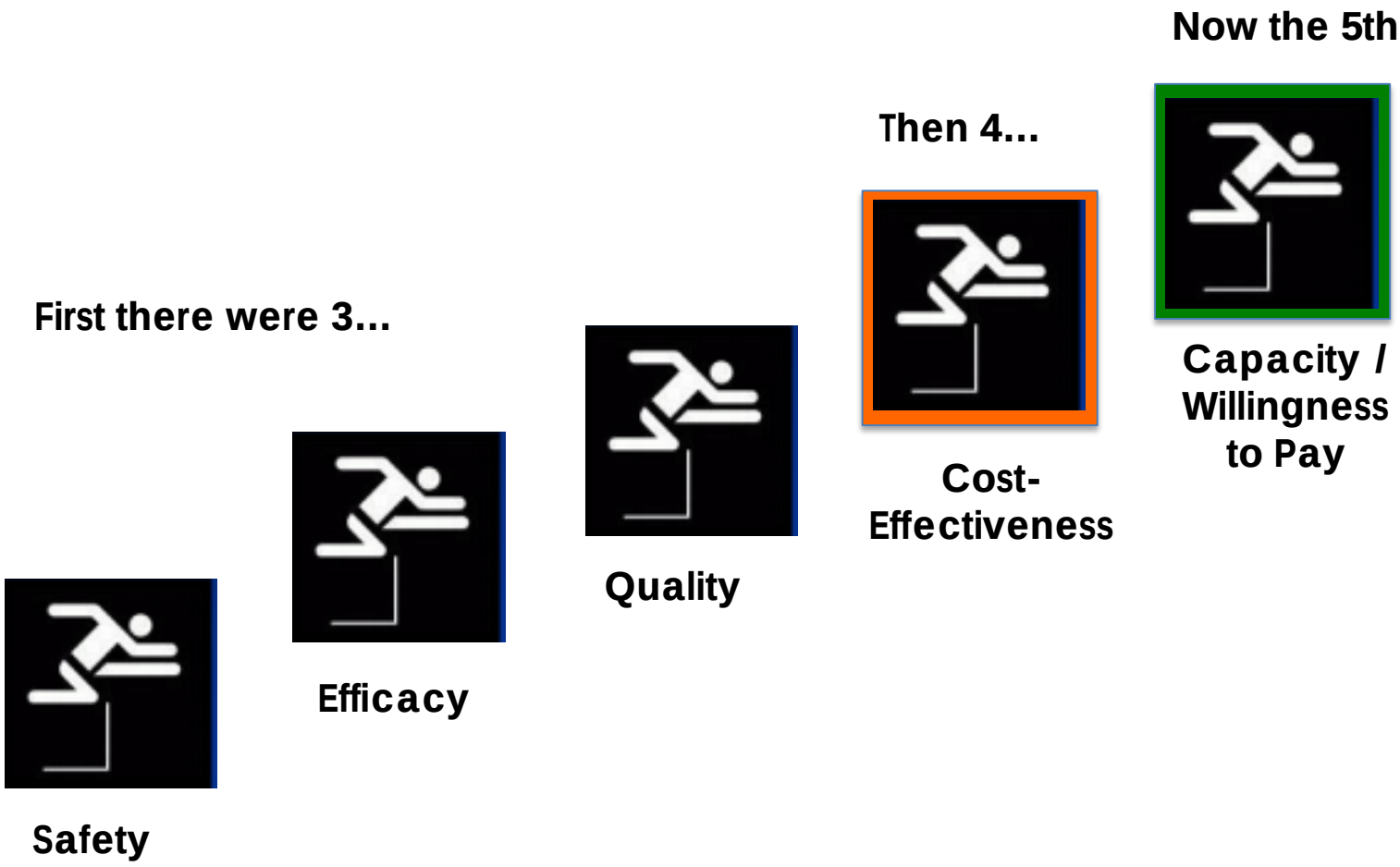


“Value” – Payer Perspective

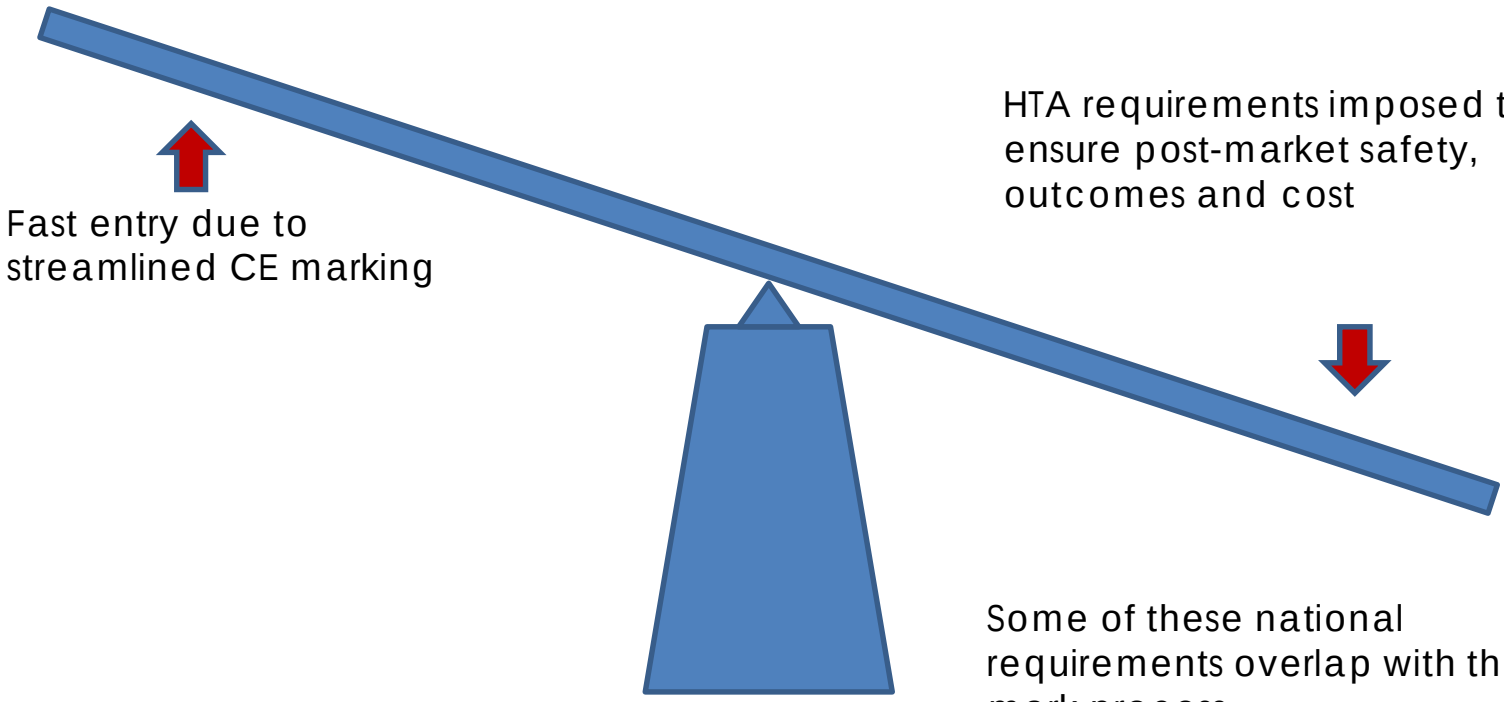


Most reimbursement pathways start with clinicians' backing a technology that counts with "sufficient" clinical benefit and outcomes evidence

- Most reimbursement pathways start essentially with a willingness to adopt based on "**sufficient" evidence of clinical outcomes and benefit**



Strong health economic and clinical outcomes evidence is required to meet the challenges of coverage restrictions



"HTA is a multi-disciplinary field of policy analysis studying the medical, economic, social and ethical implications of the development, diffusion and use of health technologies" (INAHTA)

Just happened: EU medical Device Regulation and In Vitro Device Regulation provide stricter pre-market control of high risk devices

- Regulations published in 2017, entered into force 2018
  - 3 year transition period
- Objective:
  - Stricter pre-market controls: increased protection of public health and safety
  - EUDAMED database of medical devices
  - Unique device identifyer
  - “Implant Card” for patients
  - Financial mechanism for patient compensation

- Manufacturers will need to demonstrate clinical benefit “defined as a positive impact on the health that should be measured using patient-relevant clinical outcomes”

Health Technology Value assessment – HTA´s across Europe

Spain →

grouped into the Spanish Network of Health Technology and Services Evaluation

AETS - ISCIII	National
UETS-ALE	Madrid
AETSA	Andalucia
Avalia-T	Galicia
AIAQS / AATRM	Cataluña
SESC	Canary Islands
OSTEBA	Basque Countries
IACS	Aragon

European HTA Map

European HTA Projects:

- Cross-Border Directive on Patient Rights
- HTA Network
- Joint Action -1,
- Joint Action -2
- FP-7 Research

eunethta

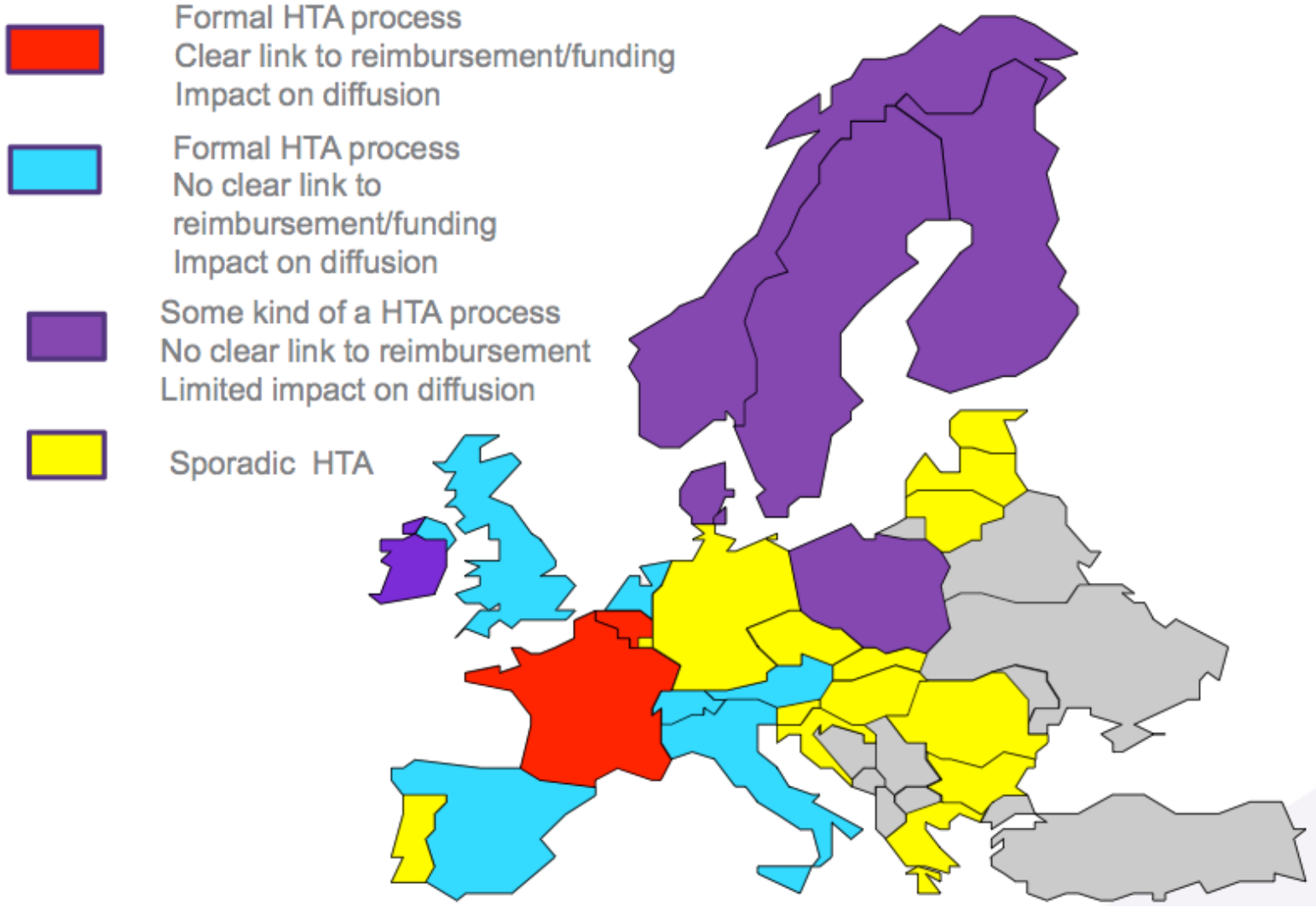
INTEGRATE-HTA

Advance HTA

MedtecHTA

AdHopHTA

To Date: The use and impact of HTA´s vary amongst European countries



About to happen: Common EU HTA Evaluation brings new rules for clinical evaluations of medical technology in 2018

- EU Directive 2011/24/EU set to be modified during 2018
- Reason: **Market access of medical devices and sustainability of healthcare systems is plagued by difficulties due to high prices of innovations which do not always go hand in hand with significant therapeutic advances**
- Philosophy: **"new technologies should not only be safe and effective, it should be clinically better than existing technologies"**
- Establishment of a **common EU evaluation committee** made up of Evaluation Agencies of the member states
  - To carry out **clinical evaluation and determine relative efficacy compared** to existing drugs, medical technologies, high risk medical devices and most innovative technologies and/or with a significant impact on public health
  - **Economic evaluations remain within authority of member states**
- Member states should adhere to the conclusions, but may carry out additional evaluation if justified within national / regional context
- Possible next step: Legislation on standardized methodology for economic evaluations
  - Would facilitate exchange of information between member states which would facilitate introduction of innovations

There is an ever increasing demand for health economic evidence

Evidence Requirements (EU)

	HTA Agency	Safety Data	Efficacy Data	Volume / Cost Forecast	Simple Cost Benefit	Cost Effectiveness / Utility
Belgium	KCE	✓	✓	✓	✓	✓ (New)
UK	NICE	✓	✓	✓	✓	✓
France	HAS	✓	✓	✓	✓	✓(New)
Germany	G-BA and IQWiG	✓	✓	✓	✓	
Spain	AETS and Regional HTA Groups	✓	✓	✓	✓	✓(New)

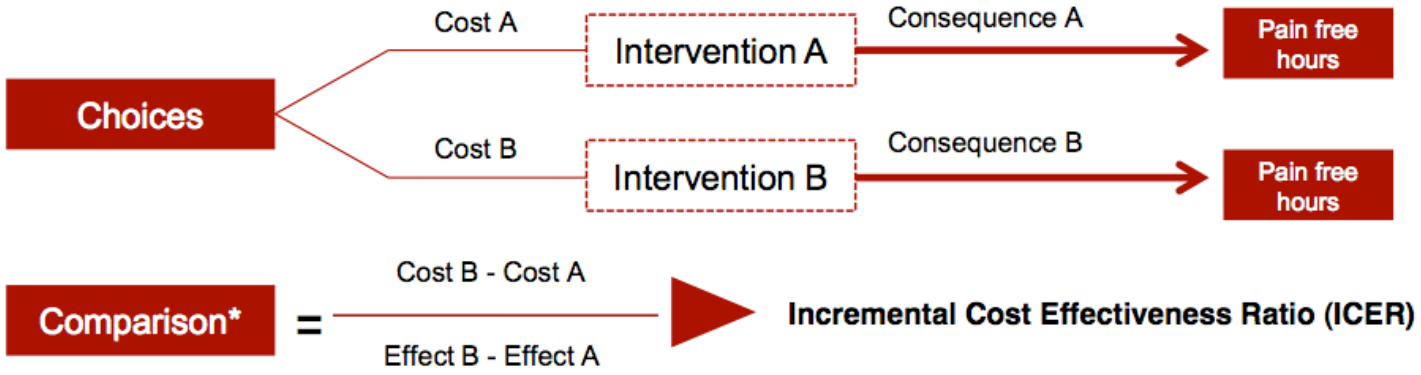
- HTA Bodies exert an enormous amount of influence on reimbursement decisions.
- HTA Bodies (UK, Germany) **expect medical device companies to prove the superiority** of their products.
  - Equivalence or non-inferiority compared with the gold standard is not sufficient anymore for new applications!

Example France: HTA mandatory requirement as part of market access

Evidence should be gathered with an understanding of the target indication in a reimbursement and health economic context

"The comparative analysis of alternative courses of action in terms of both their costs and consequences in order to assist policy decisions" (Drummond et al)

Always comparative analysis | **Comparison of both costs and Consequences**



ICER should be below the Willingness-To-Pay of each payer (e.g. in UK it is 30,000 £ / QALY)

*Assuming B as a new intervention and having more costs and effects

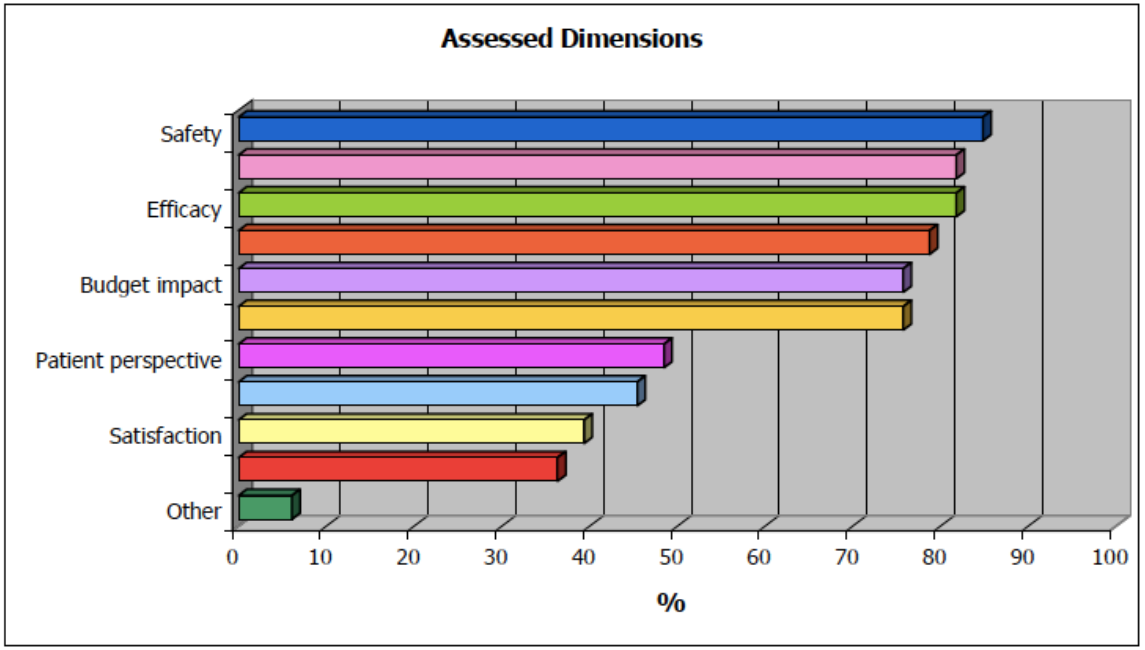
NICE committees apply an evidence evaluation framework *in the context of each different type of review it carries out.*

Nice establishes acceptance criteria based on the availability and strength of **published clinical and economic evidence.**

Evidence Level	Type of Evidence
1++	• RCTs with *very low* risk of bias • High Quality meta-analyses
1+	• RCTs with *low risk* of bias • Well conducted meta-analyses
1-	• RCTs with a *high risk* of bias • Meta-analyses
2++	• *High quality* systematic reviews of case-control or cohort studies with *low risk* of bias
2+	• *Well conducted* case-control or cohort studies with *low risk* of bias
2-	• Case-control or cohort studies with *high risk* of bias
3	• Non-analytic studies (case reports, case series)
4	• Expert opinion, formal consensus

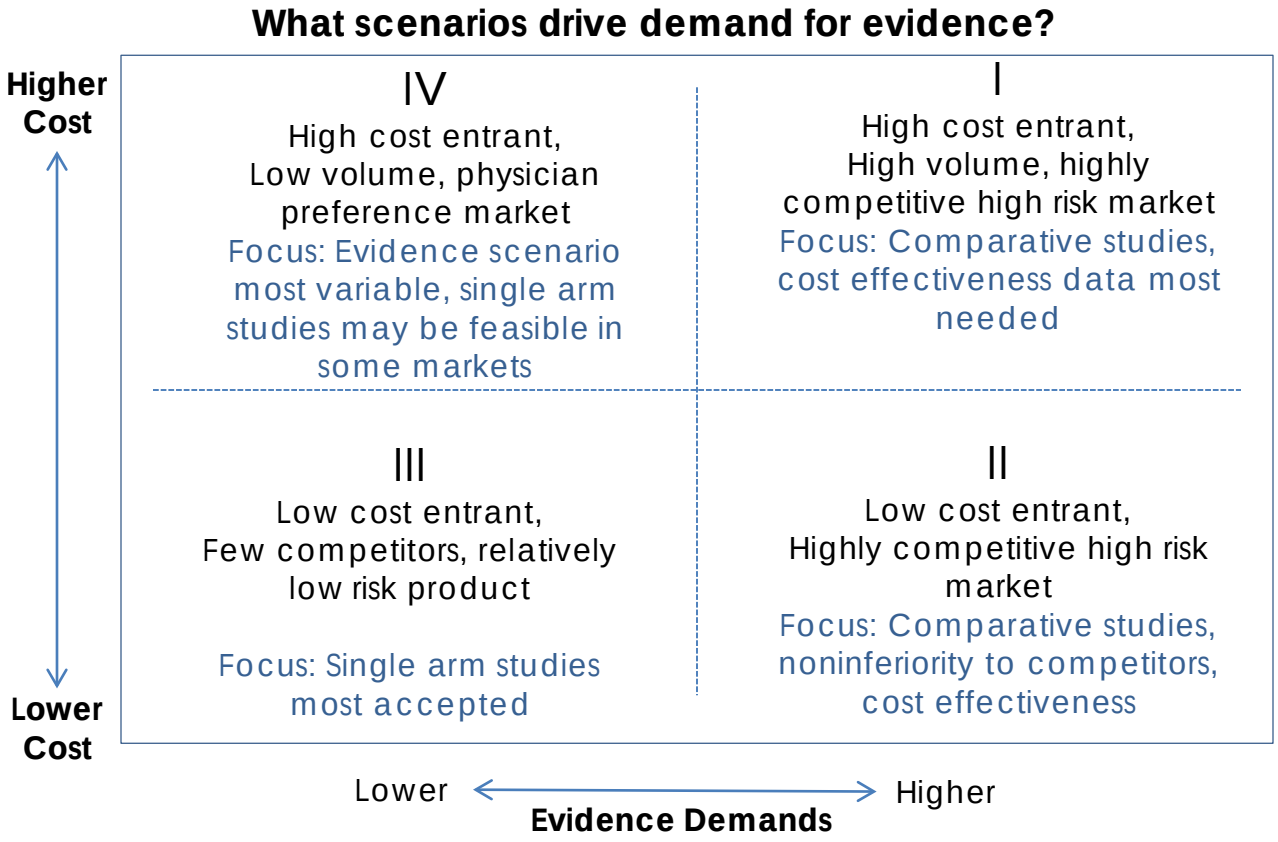
Increasingly hospital based "mini-HTA's" are used for local decision making

- Hospital based HTA – "Mini HTA" to provide hospital decision makers with a tool to assess and prioritize
  - Investment decisions
  - Improve clinical practice through innovation
  - Adapted to hospital clinical practice, comparators, organization of care
  - Uses hospital level data
  - Challenges Industry claims



Hospital Based Health Technology Assessment World-Wide Survey

Companies should be realistic about the scenario they will face in terms of demands for evidence – and plan early



General factors to bear in mind:

- Price relative to competitors
- Overall patient volume and total cost of treatment

Take Aways Market Access Tools: Clinical and Economic Evidence and Health Technology Assessments

- ✓ Market access linked to clear demonstrations of **clinical value and economic impact**:
  - Safety / Efficacy / Volume and Cost Impact / Cost Benefit and Effectiveness
- ✓ There is an ever **increasing demand for HTA´s** to inform coverage decisions
  - Analysis of society, healthcare system, payer and patient value
- ✓ HTA landscape is extremely **fragmented** at regional, national and European level but some efforts for consolidation are ongoing
- ✓ The **use and impact on coverage and payment decisions** of HTA´s varies amongst markets
- ✓ **Evidence** required to improve outcomes, expand access and optimize costs **differs per stakeholder**

Homework questions
Market Access Tools

10) What clinical outcomes and/or economic evidence will clinicians most likely require as a base to adopt your technology?

11) What clinical and economic evidence will likely be required by further stakeholders to support coverage and reimbursement?

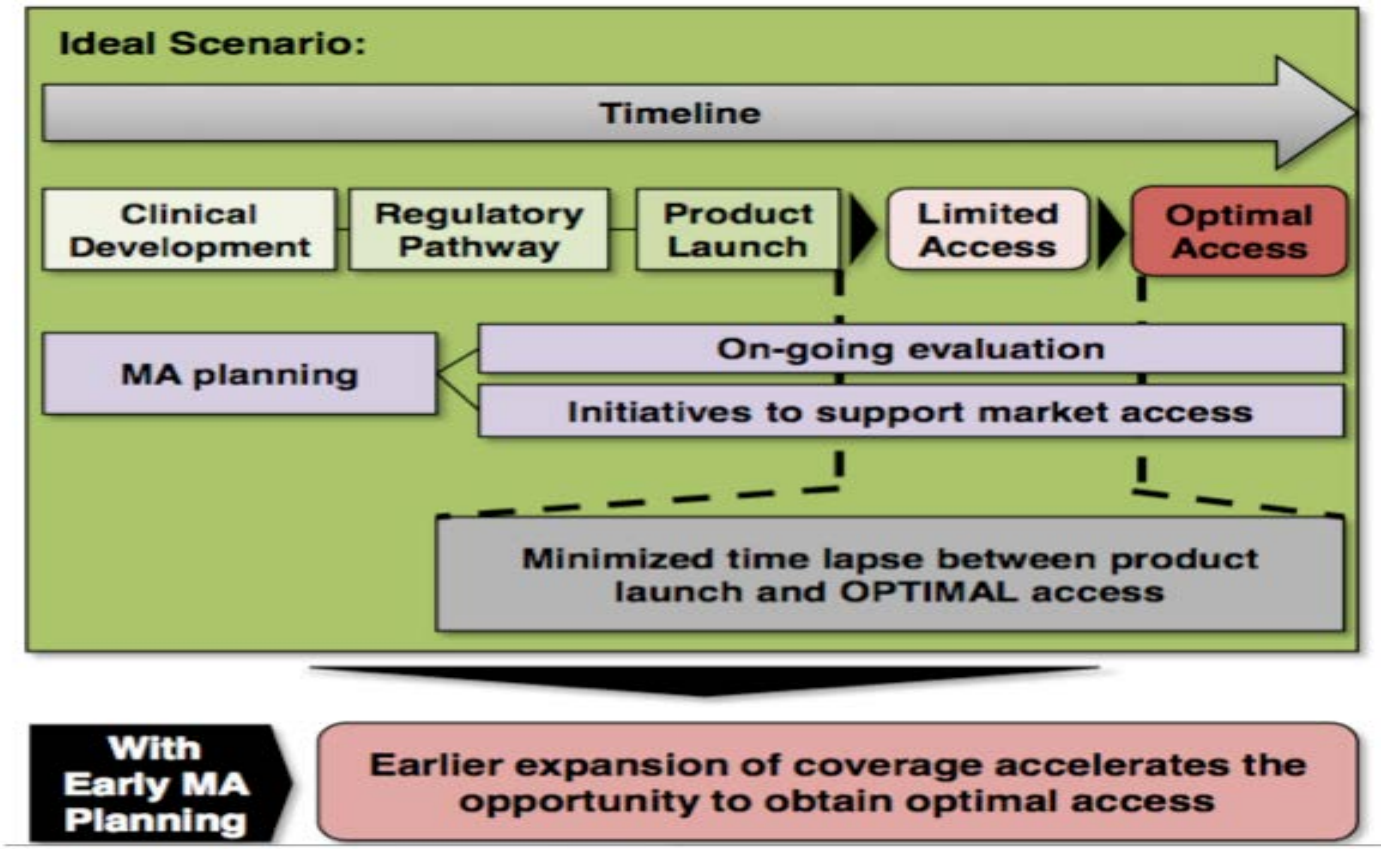
12) Has your technology, or similar technologies been subject to a HTA in your target market?

4. Sample Steps to Market Access Strategy Development

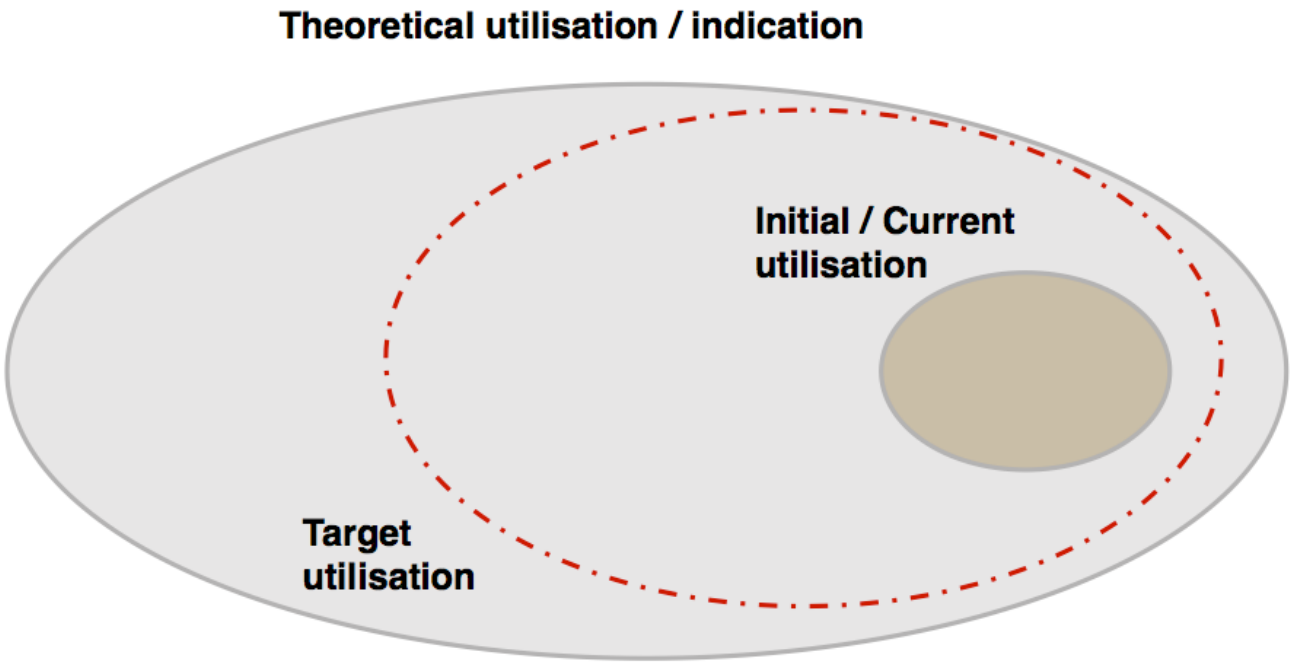
Proactive and strategic market access preparation is required to achieve optimal market access for medical devices

- Optimal strategy: market access preparation and strategic engagement of each stakeholder in the target markets at clinical development phase.

Optimal Strategic Market Access Planning for Medical Devices



What market do you wish to address, and what do you want to accomplish through your market access activities in that particular market?



Reimbursement and health economic challenges depend on the objectives set out for the technology

Establish initial utilisation

- **Establish reimbursement mechanism and payer / HTA acceptance**

  Remove formal hurdles / Require formal change in a system

Grow to Target Indication

- **Increase the utilisation of a technology**

  Convince hospitals / clinicians about the value to change in spite of the higher product cost

Grow share of use within current / evolving utilisation

- **Increase the market share within an established utilisation**

  Clinical and economic data, tools and activities may still be used from a marketing point of view

Step I of a strategic assessment takes into consideration the external market access environment

- **Objectives of the Step I assessment:**
  - Understand a market´s unique characteristics and options available
  - Identify the key players and their interaction

Patient access to Care	- Access to care? - **Setting of care?** - Funding of innovations? - Purchasing process?
Reimbursement / Funding mechanisms	- Payment Mechanism? - **Is coding linked to hospital financing?** - Timelines? - Stakeholders? - Supplemental or add-on payments available?
Reimbursement / Funding Approval Pathways	- Reimbursement approval process: frequency of updates and data required? - Centralized or decentralized approval? - Transparency of process? - **Use of HTA?** - Relation between approval and update of system?

Step 2 of a strategic assessment includes at micro level the characteristics of a device and how it fits into the market

- **Objectives of the Step 2 assessment:**
  - Evaluation of external factors that can impact support
  - Core clinical and economic value proposition

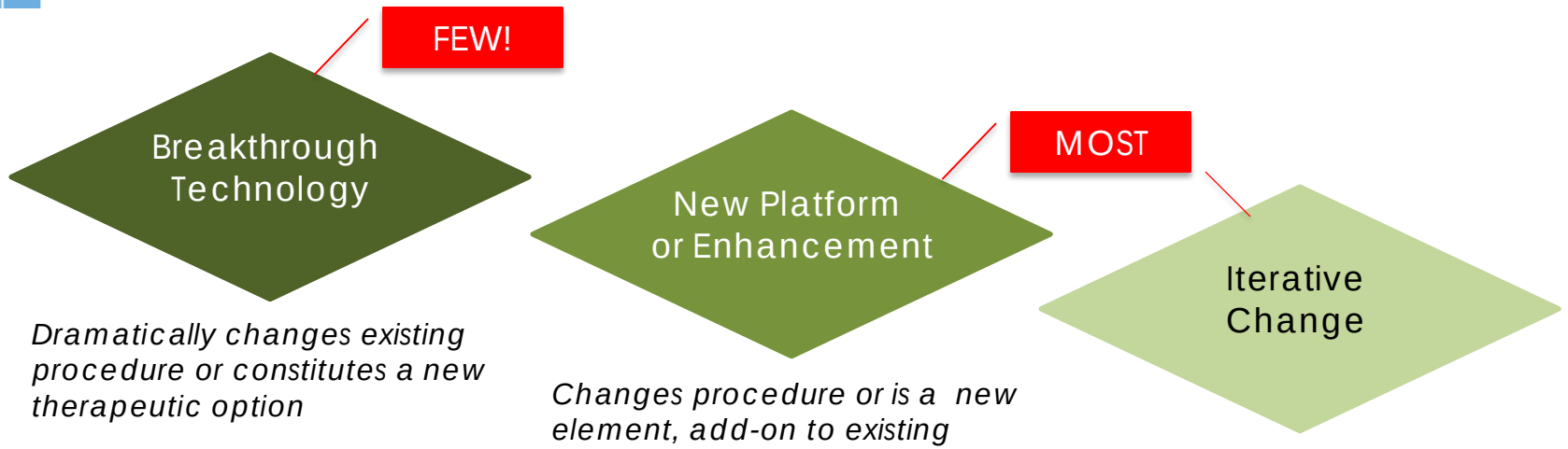
External Device/Procedure Influencers

- Therapy = key focus?
- Broad funding or narrow coverage?
- **Physician support / training?**
- Unmet clinical / economic needs?
- **Require change in treatment pathways / organization?**
- Role of clinical guidelines?

Internal Device/Procedure Influencers

- Clinical value?
- Economic value and cost–benefit?
- **Addresses unmet needs?**
- Competitive advantage?
- Value proposition relation to price?

Depending on the degree of innovation products face different demands for market access support



Dramatically changes existing procedure or constitutes a new therapeutic option

Changes procedure or is a new element, add-on to existing therapy

Does not significantly change the procedure or patient outcome

HIGH LEVEL SUPPORT

- **Requires coverage policy and new coding / reimbursement**
- **Clinical and economic evidence pre-requisite**
- **Advocacy with clinicians, payers, health tech assessment entities**

MODERATE / COMPLEX SUPPORT

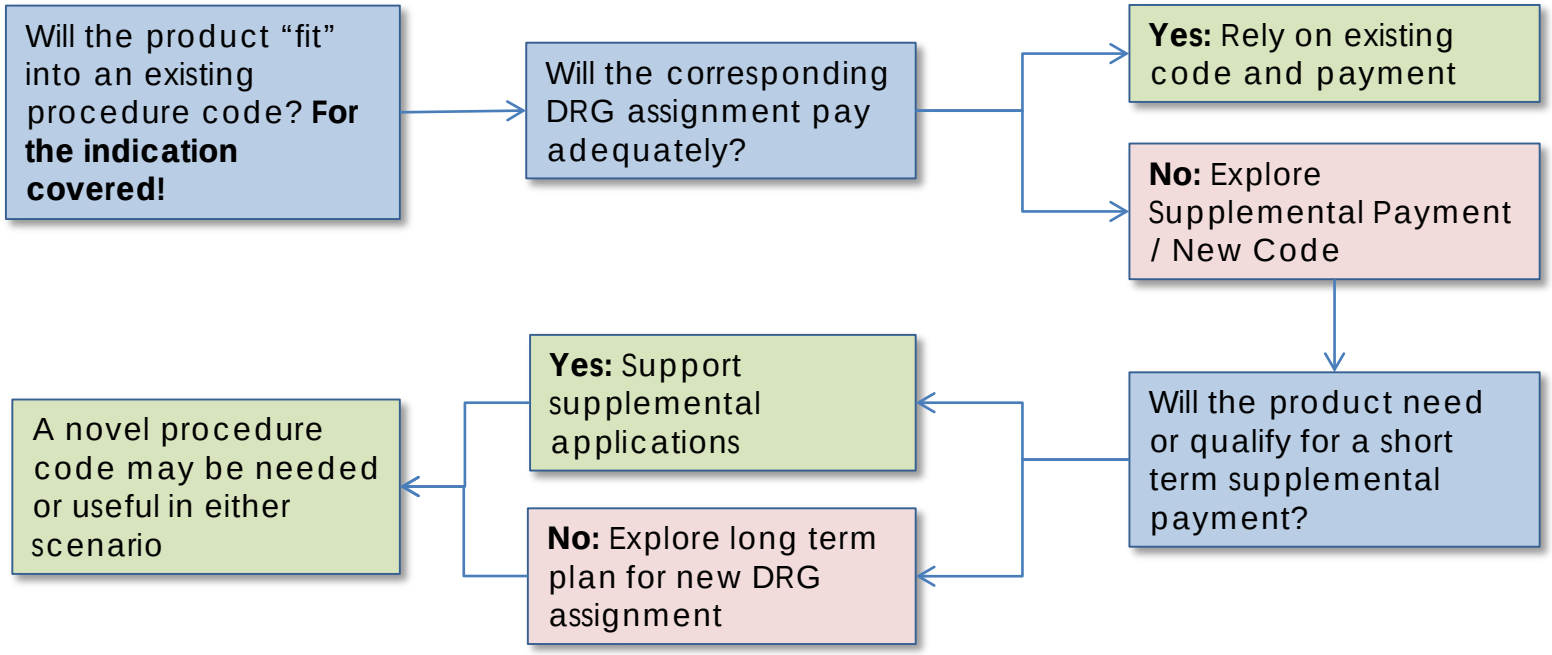
- **Likely need for new codes**
- **New tools on clinical, economic, and QALY?**

MINIMAL SUPPORT

- **No need for new coding/reimbursement strategy**
- **Clinical and economic evidence essential to convey value.**

Unclear Stakeholder Influence

The availability of existing procedure codes remains one of the key questions to explore for all levels of innovation



- Does the technology addresses an unmet clinical need that physicians would be willing to support internally?
- What tools / evidence is required to support adoption and reimbursement?

Take Aways
Market Access Strategy Development

- ✓ **Focus strategy on theoretical market, target market and core group early adopters:**
  - Establish initial utilisation -> Grow to target indication -> Grow to utilisation witin current/evolving utilisation
- ✓ **Take into account the level of innovation and stages of the product lifecycle:**
  - High level of innovation leads to short leadtime to product launch
  - Reimbursement processes are less developed and transparent than for Pharma
  - Ongoing product improvements require ongoing evidence gathering and adaption of market access strategies to target populations as product matures
- ✓ **Step 1: Assessment of external market factors:**
  - Patient access to care and reimbursement / funding / approval
- ✓ **Step 2: micro level assessement**
  - External and Internal device / procedure influencers

Homework Questions

Market Access Strategy Development

13) What is the degree of innovation of your technology?

14) What is the theoretical and target market for your device?

15) Does the technology addresses an unmet clinical need that physicians would be willing to support internally?

16) What is the core clinical and economic value proposition?

    a. Vis a vis competitors and standard of care?

17) Who are the stakeholders for adoption of your product?

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