



**IFCC GENERAL CONFERENCE**  
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# The health economic value of laboratory diagnostics

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# What is value?



## Dimensions of health care quality (WHO)

- Effective
- Efficient
- Accessible
- Acceptable & patient-centered
- Equitable
- Safe

World Health Organization (2006) Quality of care : a process for making strategic choices in health systems.

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## Better health

- Save life years
- Reduce morbidity
- Improve Quality of Life



## Better management

- Detected infections / cases
- Guide treatment

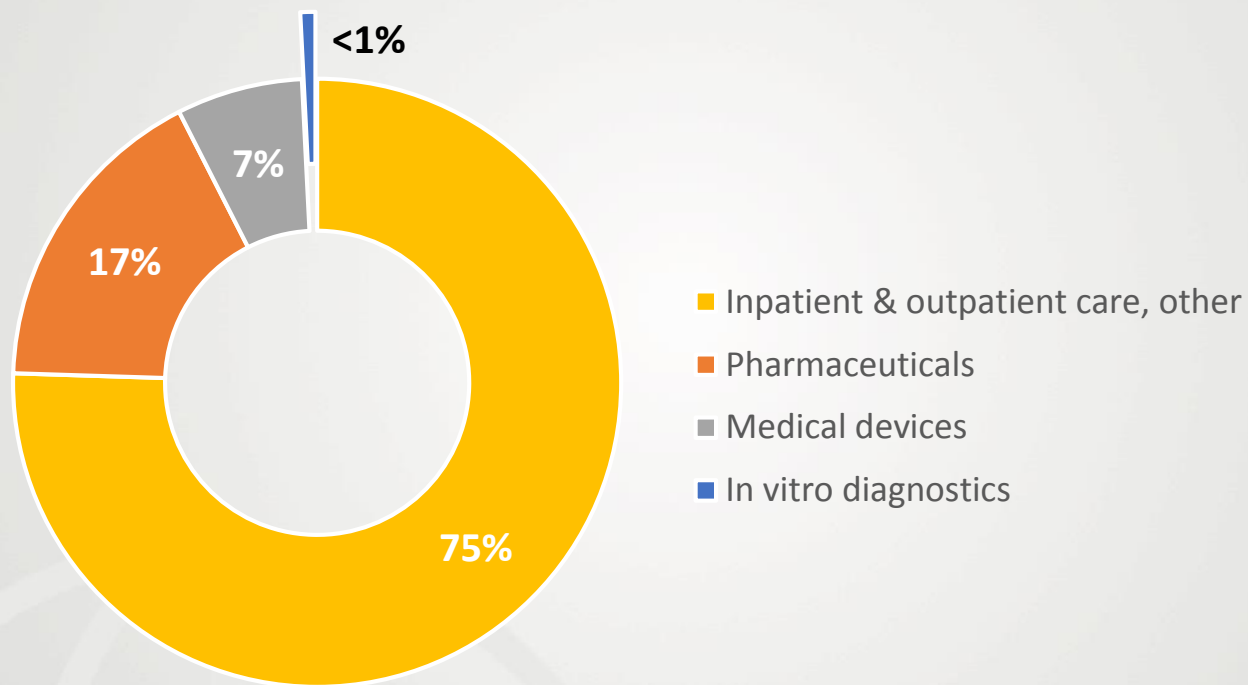


## Better service

- Streamline processes
- Relieve other resources



# Is IVD regarded as valuable?



The European Medical Technology Industry, MedTech Europe  
[http://www.medtecheurope.org/sites/default/files/resource\\_items/files/01012014\\_MTE\\_The%20European%20medical%20technology%20industry%20in%20figures\\_Industrydata.pdf](http://www.medtecheurope.org/sites/default/files/resource_items/files/01012014_MTE_The%20European%20medical%20technology%20industry%20in%20figures_Industrydata.pdf). Accessed: 18 Oct 2017

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**“IVD guides 60-70% of clinical decisions”**

**Overutilization and underutilization** of testing are widespread issues

Besides medical motives, **test-ordering** is influenced by **non-medical factors**

**Perception of value:**  
Diluted by lack of clarity or inappropriateness?

Rohr UP et al. PLOS One 2016; 11(3):e0149856.  
Epner PL, et al. BMJ Qual Saf. doi:10.1136/bmjqs-2012-001621  
Zhi M, et al. PLOS One 2013; 8(11):e78962.  
Van der Horst A, et al. Clin Chem Lab Med 2017; 55(10): 1523-1529.

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**Is it safe?**

Safety

**Does it help?**

Effectiveness

**Is it worth?**

Cost-effectiveness

**Is it affordable?**

Budget impact

Centered around the clinical pathway





## Critical factors for value assessment and decision making

### Hospital manager

- Clinical effectiveness (72%)
- Economics (72%)

### Guideline developers

- Patient related outcomes
- Clear test treatment

### Physicians

- Clinical utility and cost-effectiveness

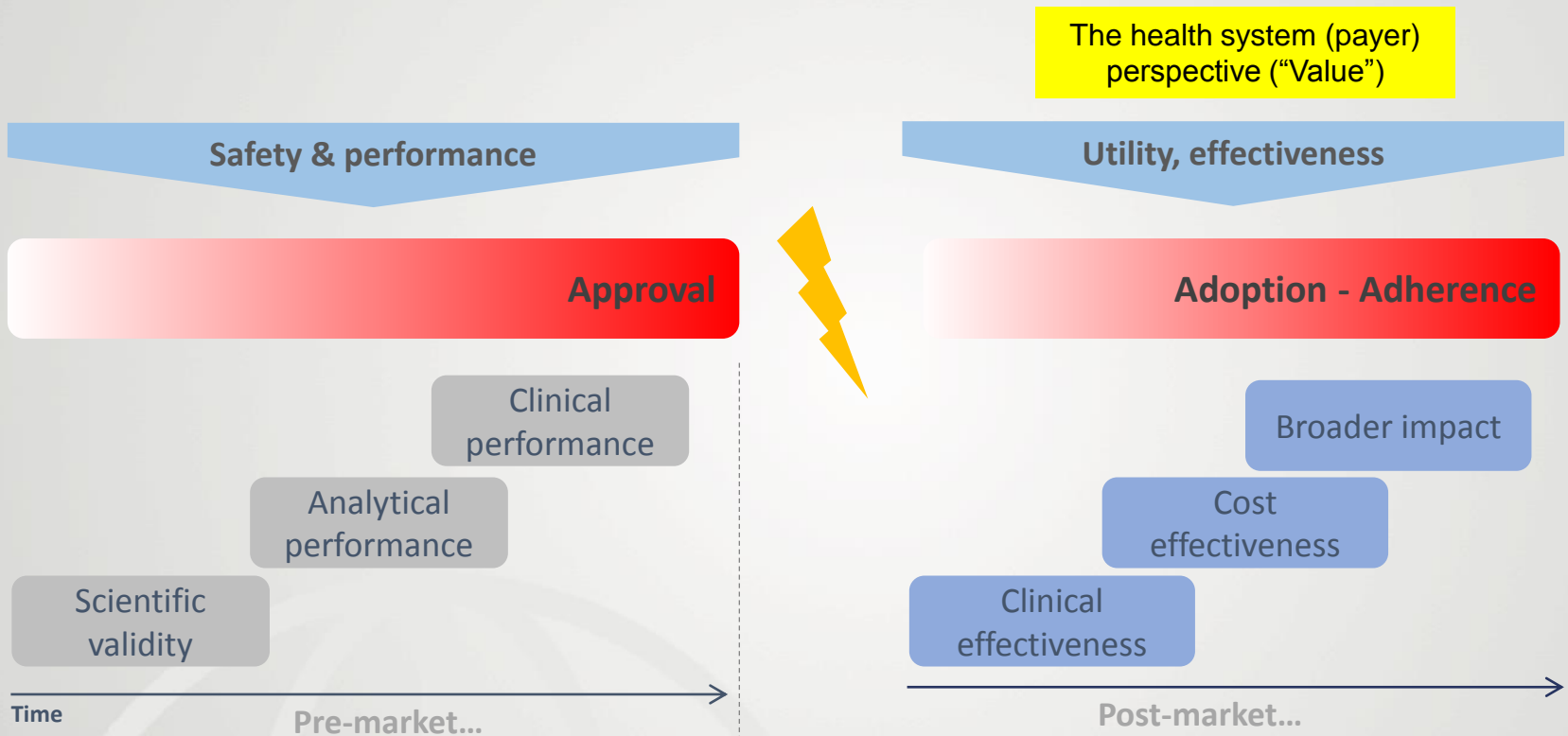
### Laboratorians

- Data, education and communication to facilitate
  - Appropriateness & result interpretation
  - Impact / clinical research studies
- “look outside the lab”

**Perception of value:  
Skewed by lack of understanding?  
Biased by lack of information (data)?**

translate test statistics into a clinical perspective

Kidholm K, et al. Health Policy 2015; 119:1424-1432.  
 Gopalakrishna G, et al. BMJOpen 2016; 5:e010549.  
 Rohr UP et al. PLOS One 2016; 11(3):e0149856.  
 Hallworth MJ, et al. Clin Chem. (2015) 61(4): 589-599.



Horvath AR, et al. Clin Chim Acta 2014; 427:49-57.

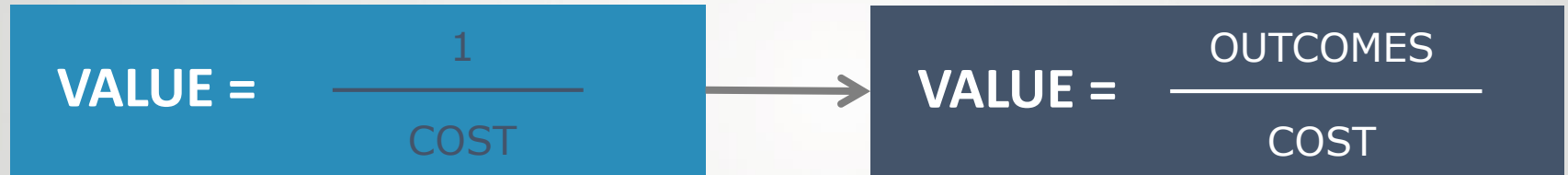
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If we can't **demonstrate**  
and **quantify** how IVD  
contributes to the overall  
**health care goals**,  
we will not have a seat at  
the table...



A minor part?

A leading part?



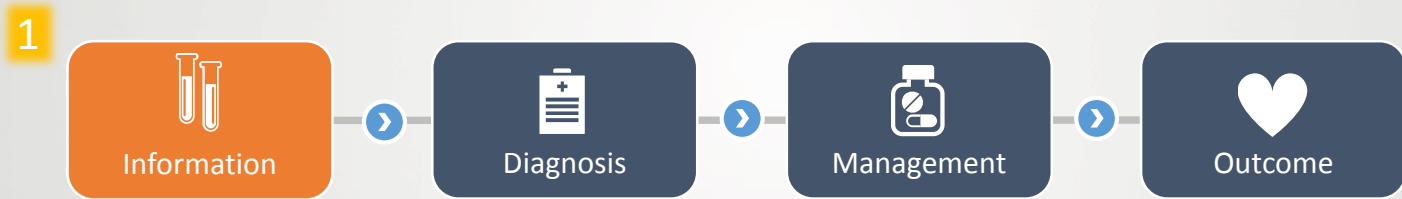
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## Patients benefit from pathway improvement, not from the test



- High technological and methodological complexity
- Indirect impact of testing on outcome

1 Make sure that the information is accurate, reliable, and efficient

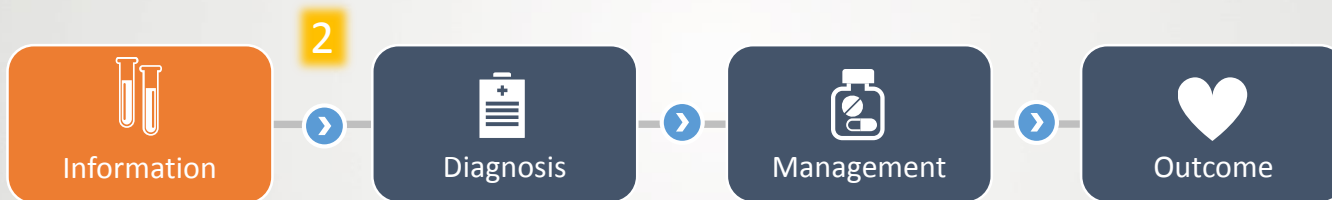


SYSTEMATIC REVIEW

**The Role of Measurement Uncertainty in Health Technology Assessments (HTAs) of In Vitro Tests**

Alison F. Smith<sup>1,2</sup> · Mike Messenger<sup>2,3</sup> · Peter Hall<sup>4</sup> · Claire Hulme<sup>1,2</sup>

Smith AF, et al. PharmacoEconomics 2918; 36:823-835.



**2 Make sure that requests are appropriate and clinically indicated, and information is meaningful**

Epner PL, et al. Graber ML. *BMJ Qual Saf.* 2013;22 Suppl 2:ii6-ii10.  
Hallworth MJ, et al. *Clin Chem.* 2015;61:589-99.








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3 Evaluate the impact on the cascade of care, management, organizational factors, and KPIs

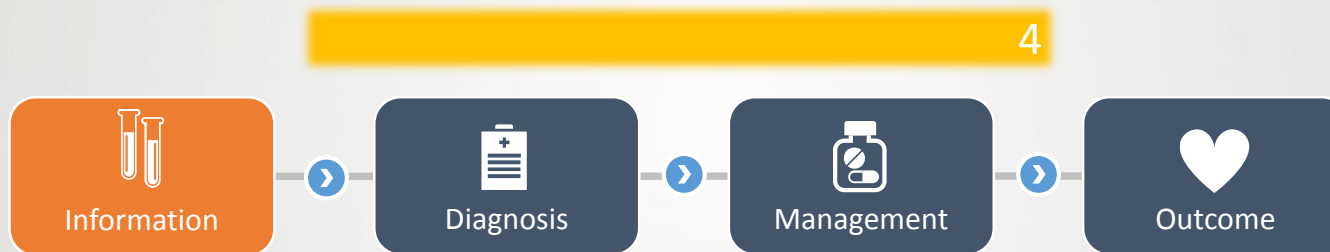


## CLINICAL & ORGANIZATIONAL EFFICIENCY

 Clinical	 Service	 Team	 Process	 Economics	 Image / Reputation
Mortality	Patient satisfaction	Staff satisfaction	Length Of Stay	LoS	Hospital Marketing
Morbidity		Employee	Occupancy Rate	Resources	Referral Rate
Complic	 <b>Evaluate the impact of lab information on hospital performance metrics</b>				ation
Pain, Qua Life					Profitability
Compliance				...	...
...				...	

## 4 Quantify the benefits and costs of testing (Health economic evaluation)

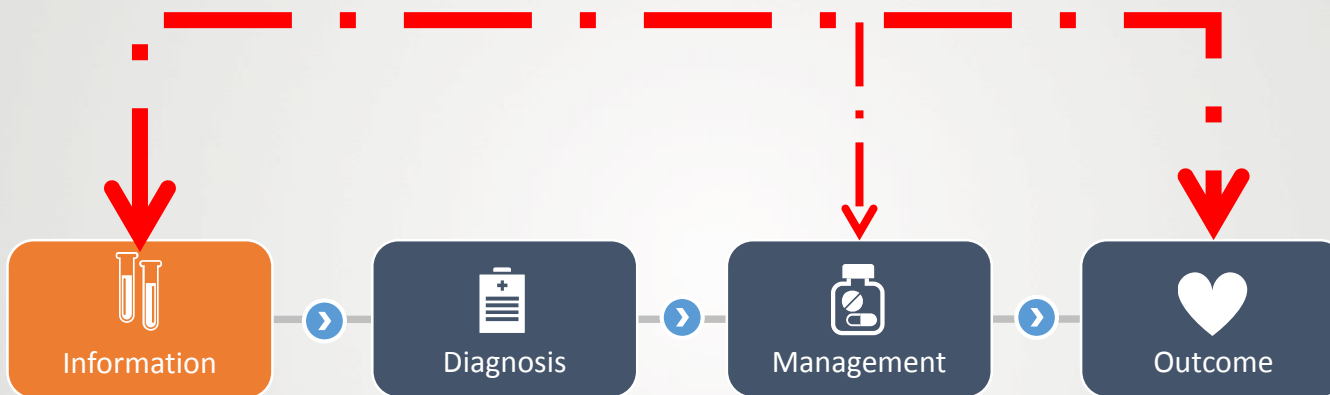
- Trial-based evidence
- Model-based evidence



- **Pathway:** Follow the patient from test results to outcomes
- **Comparator:** Costs & outcomes of new strategies to current practice
- **Results:** Dimensions depend on perspective of the audience  
Costs per Identified Case; Costs per Life Year Saved; **Costs per Effectiveness**

Fryback D, Thronsbury JR. Med Dec Making 1991; 11:88-94.  
Di Ruffano LF, et al. BMJ 2012; 344: e686.  
Di Ruffano LF, et al. BMC Medical Research Methodology 2017;17:35.

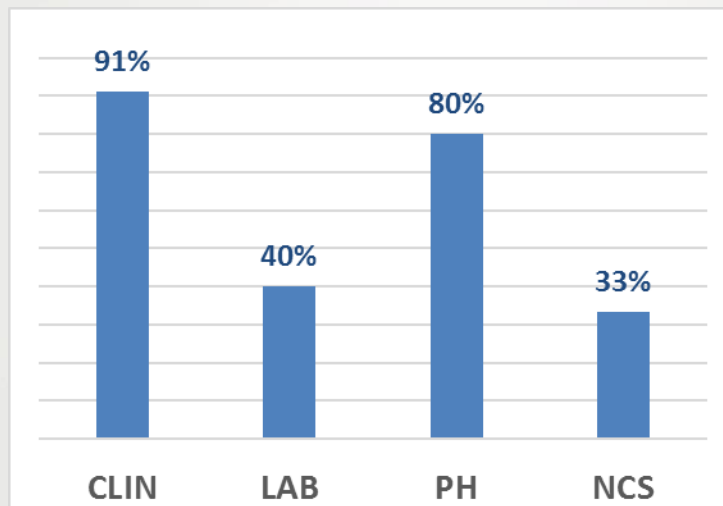
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**Access to validated clinical samples**



## Contribution



N=45 CEA studies  
CLIN Clinicians  
LAB Laboratory experts  
PH Public health experts, health economists  
NCS Non clinical scientists (e.g. statisticians)

Giusepi I, Jülicher P. 2018; manuscript in preparation

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## Guide the path built on data

### Examples:

- **Cyclical framework for test evaluation**

Evidence generation process for IVD as a **dynamic, non-linear process** of interacting stages **centered around the clinical pathway**

- **Value proposition framework**

Inform stakeholders of the **expected benefits** expressed in different dimensions

- **Provide value assessments tools**

Facilitate adoption, implementation & communication

Horvath AR, et al. Clin Chim Acta. 2014; 427:49-57.

Price CP, et al. Clin Chim Acta. 2016;462:183-6.

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- **Spread out** to stakeholders outside the lab
- **Collaborate** on value assessment processes
- **Communicate value** by means of health economic evaluations





Heidelberg



Budapest