

Barriers to Innovation in Medical Devices

Restrictions in health care budgets –
the view of the industry

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Chair Economic Affairs Group, Eucomed





Society

Healthcare

DRG

Hospital

Hospital Procurement is moving to become more centralised and more professionalised. As result, short-term focus on price is increasing, at the expense of a full eVALUation.

Impact of intensified focus of purchasing on device cost

The German example

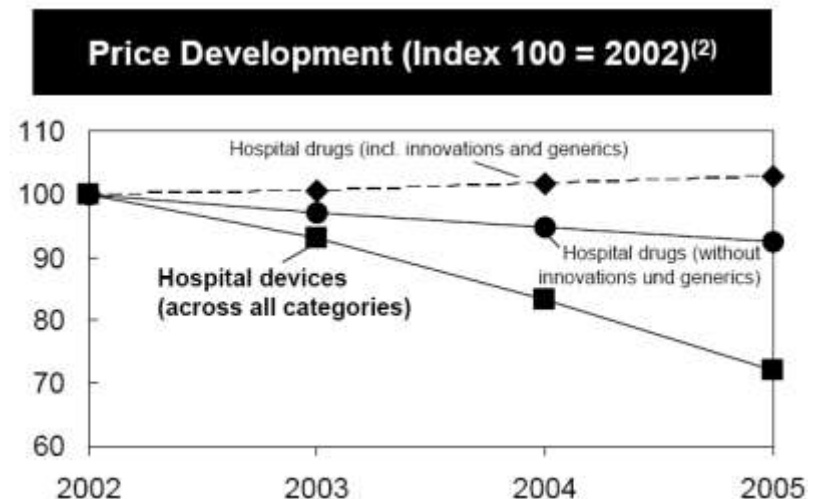
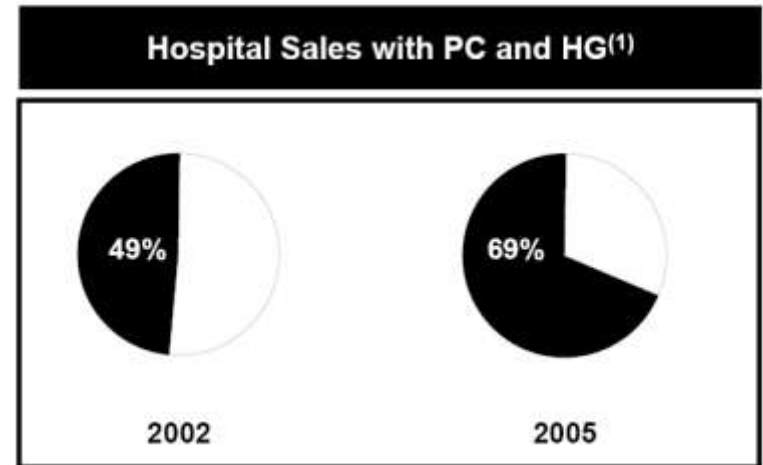
- Intensified business through purchasing consortiums and hospital groups (2009: 70%)
- Hospital devices price erosion of 30% in 3 years ('02-'05 about 10% p.a.)

Preliminary conclusion:

- It pays off.

More balanced conclusion:

- Reduced competition leads to decreased offerings (e.g. Helios -> de facto 1 interested supplier only for CRM)
- PC/HG have delayed access to latest technologies (so reduction in patient's access to innovations)
- Reduced investments in service, training & education organized by industry
- Lowered DRG of CRM devices causes downward spiral affecting profitability as since 2007 no more price gains
- As a consequence, intensified focus on other costing elements to sustain profitability



Source: SK&P report for BVMed, 2005



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Economic Affairs 2011


Value Based Purchasing Project Team

Objectives

- Improve Med Tech Industry understanding of the current use of HTAs or health economic arguments in purchasing decisions of medical devices.

Activities 2011

- Research proposal
 - Follow up with the Commission on our submission
 - Proposal to Assobiomedica to set up a pilot of the research in e.g. A region in Italy
- HELP Workshop: “What is the role of Health Economics and “micro-HTA” in purchasing decisions of medical devices?”
 - Set up a second workshop in Q1 of 2012. It could be with speakers from regional procurement, GPOs, end-users etc.
 - Input for the EAG activity at the Medtech Forum 2011: Focus on the iTAPP project?
- EC Public consultation on the modernisation of the European Public Procurement Market
 - Participate in the consultation of the green paper
- Collaboration/coordination with the new Procurement Group at Eucomed
 - Attend meetings in the Procurement Group
 - Consider if we need a new name for our WG: Purchasing and Health Economics?



Shaping the relationship between providers and manufacturers: the role of medical devices purchasing consortia

Giulia Cappellaro
Università L. Bocconi

European Health Technology Institute for Socio Economic
Research



Background: EHTI research on procurement

DIMENSIONS OF ANALYSIS


- ✓ What are the main characteristics of price regulation/setting/negotiations?
- ✓ At which level are prices set, regulated or negotiated?
- ✓ Is it possible for a manufacturer to get different prices/payments from different service providers and/or goods distributors?
- ✓ Which actors are involved in the establishment of prices?
- ✓ Is there central procurement?




Conclusions:

Which generalisations can be drawn from the analysis?

Lesson 1: ECONOMIC DIMENSION

- 
- Savings are mainly achieved in the **short run**
 - Decrease in purchasing price does not represent a sustainable competitive advantage

Lesson 2 and 3: ORGANISATIONAL DIMENSION

- 
- Strategies for members' staff reduction should be carefully considered and not be the exclusive aim of consortia
 - Strengthen Technical Committees working on criteria for tenders (and including members' representatives) in order to achieve:
 - ✓ Higher commitment and social acceptance
 - ✓ Higher specialisation and focus on quality criteria for devices (rather than price)



Conclusions:

Which generalisations can be drawn from the analysis?

Lesson 4: STRATEGIC DIMENSION

- Products: **not all MD are suitable to standardised purchases**: need to carefully plan in advance the type of devices object of centralised strategies
- Supply market: need to enforce strategies to avoid negative repercussions on local SME;
- Need to ensure a certain degree of independence of the consortium from political cycles:



Consortia can achieve positive results only if their long term sustainability is guaranteed.

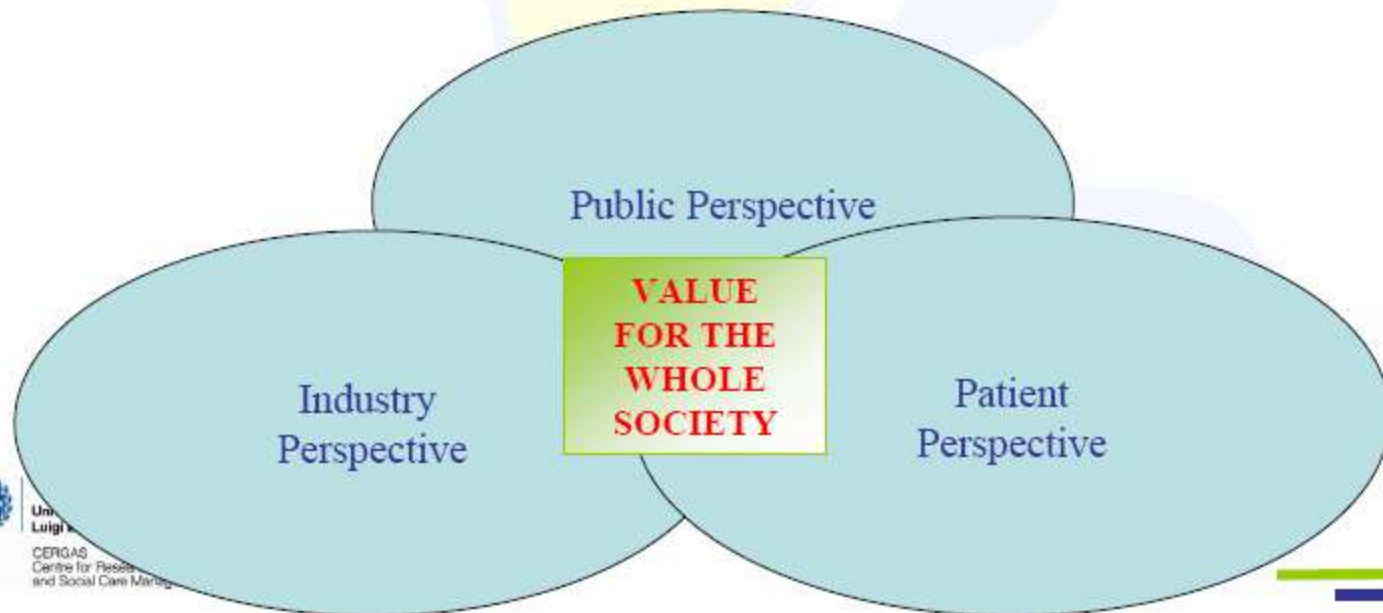


Future perspectives

The current analysis has investigated the implications of purchasing consortia for the public sector



- Which implications for the industry?
- Which impacts for the patients?



Many physicians loose their influence in the procurement process to the administrators and to new roles of professional purchasing staff inside the hospital

SJM « Nordic Clinical Advisory Board » Recommendations

The procurement process:

1. «Nurses are central in the purchasing process, but often not educated well enough on the clinical and economic value of devices. Develop tools that will help to reach out to them.»
2. «Often the doctors are not part of the procurement process. Can industry request that they are heard? Develop a cross-industry set of recommendations/best practise in procurement that could serve as gold standard at Eucomed or ESC/EHRA level.»
3. «There is a communication gap between physicians and administrators. Help us to overcome this by giving us material in the shape and formate that they need and understand.»
4. «The physical process of formulating and submitting requests for new devices to the administration is tedious and burdensome for doctors.»

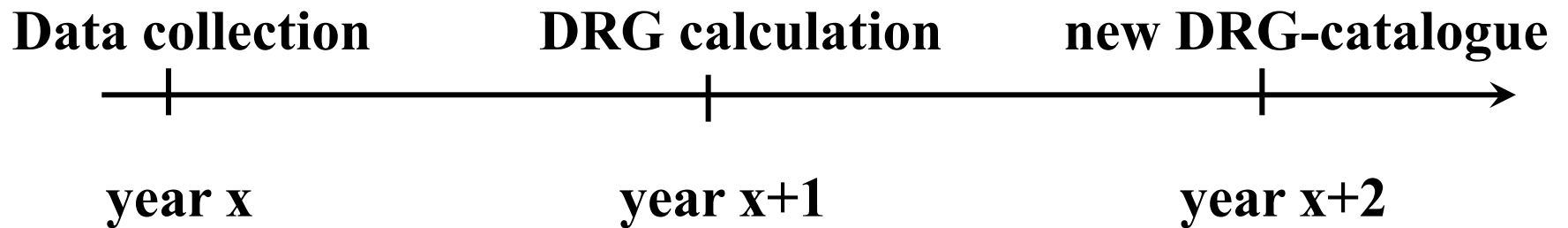


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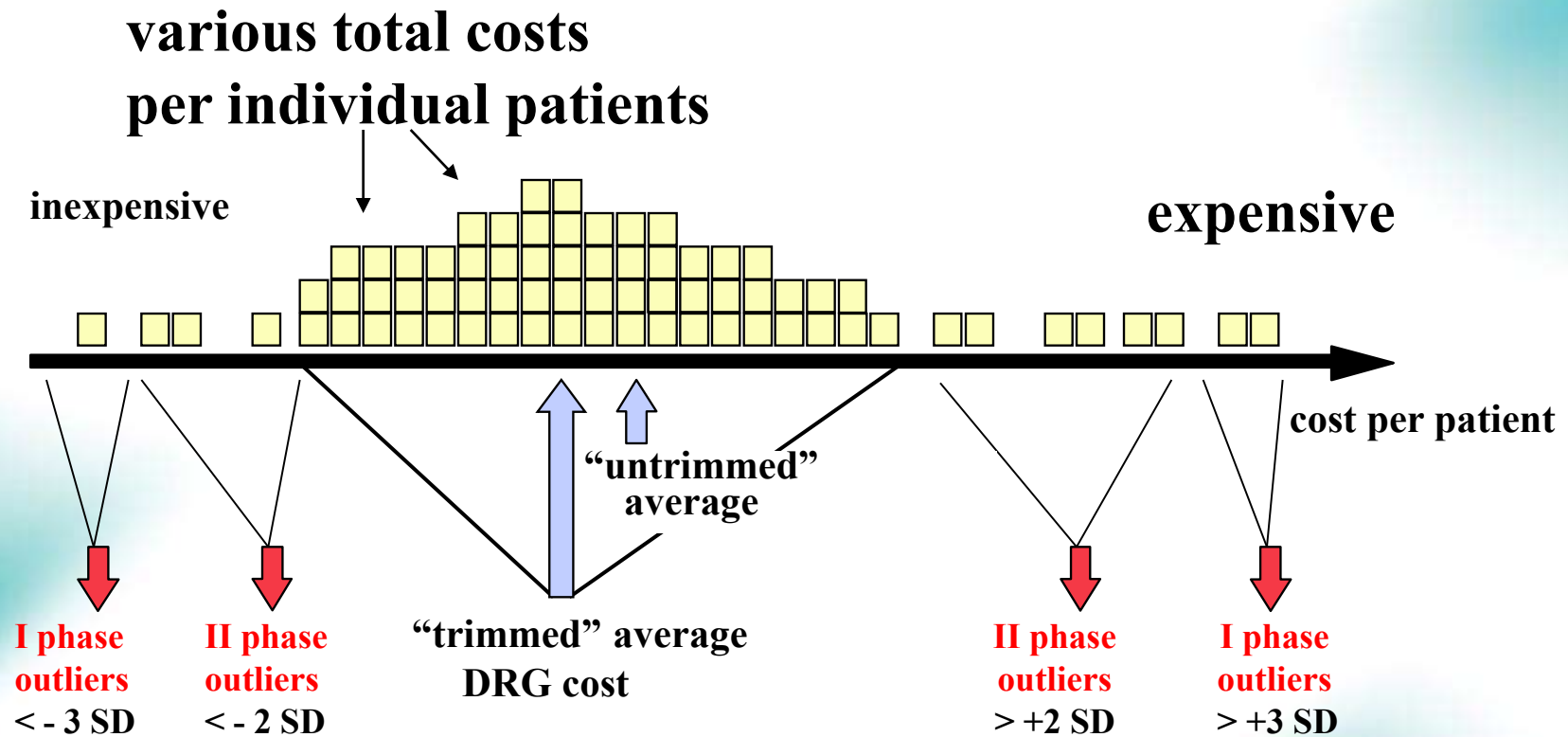
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Countries are moving to DRG, thus introducing market mechanism. DRG systems are inherently backward-looking with a negative impact on innovation.

Why DRGs are not good for innovation



Determination of the average DRG cost (-> billing price, DRG weight)



Most countries offer supplemental payments – but eligibility can require substantial evidence

Country	System	Exclusions?	Additional Payment?
Germany	G-DRG	Yes	Yes- Innovation Clause (NUB)
UK	HRG	Yes	Yes – Innovation Payment
France	GHS	Yes	Yes – Supplements
Italy	DRG	Yes	Yes
Portugal	DRG	Yes	TBD



8° Congresso Nazionale AIAC, 15-17 Aprile 2010

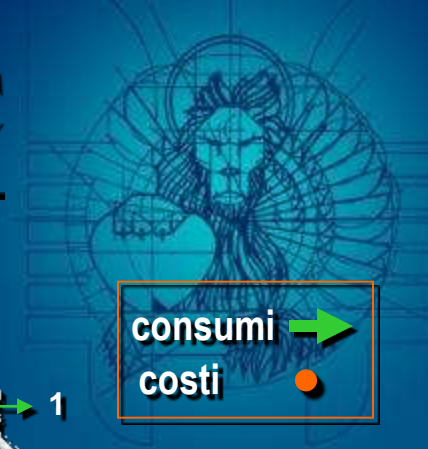


Documento AIAC di “Health Technology Assessment” della terapia ablativa della Fibrillazione atriale

Dr Sakis Themistoclakis

Dipartimento Cardiovascolare, Ospedale dell'Angelo, Mestre-
Venezia

I Centri della Survey AIAC



- ◆ 52/87 Centri hanno fornito le risposte al questionario sui consumi
- ◆ 4 Centri hanno partecipato all'analisi di costing delle risorse

Costo INTRAOSPEDALIERO

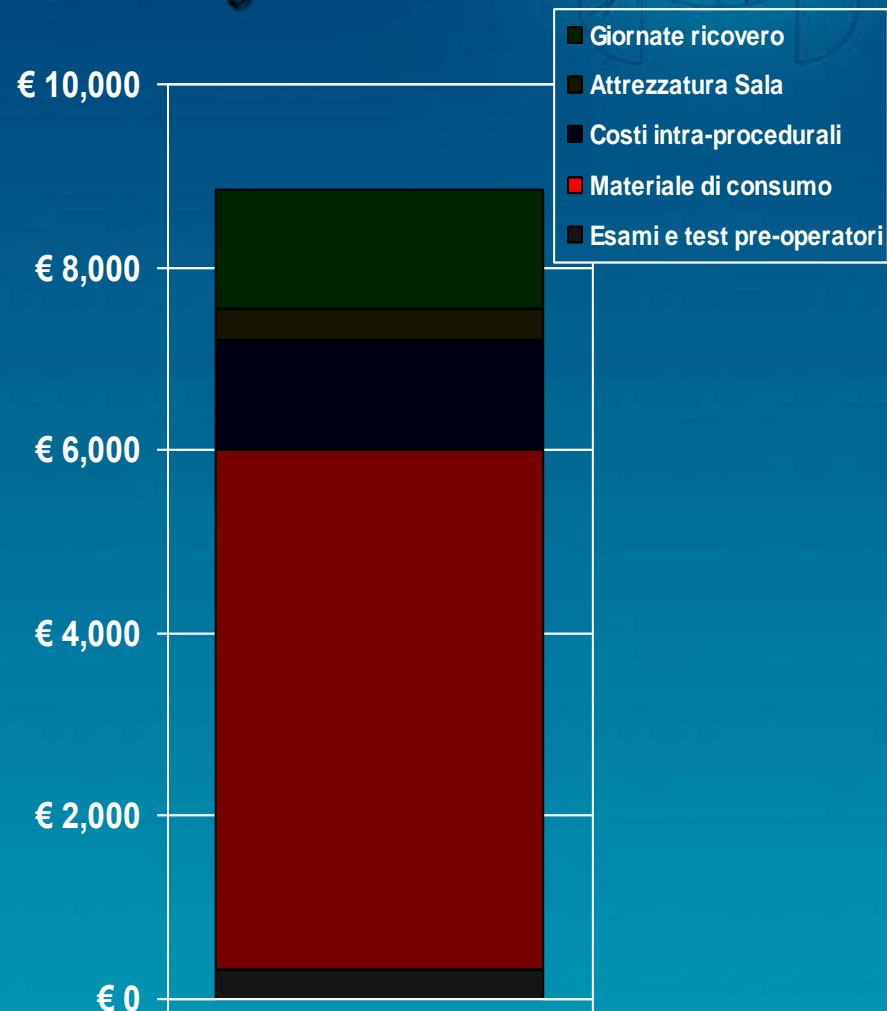
dell'ablazione

Costo medio di produzione pesato in funzione della

casistica: € 8.848,8

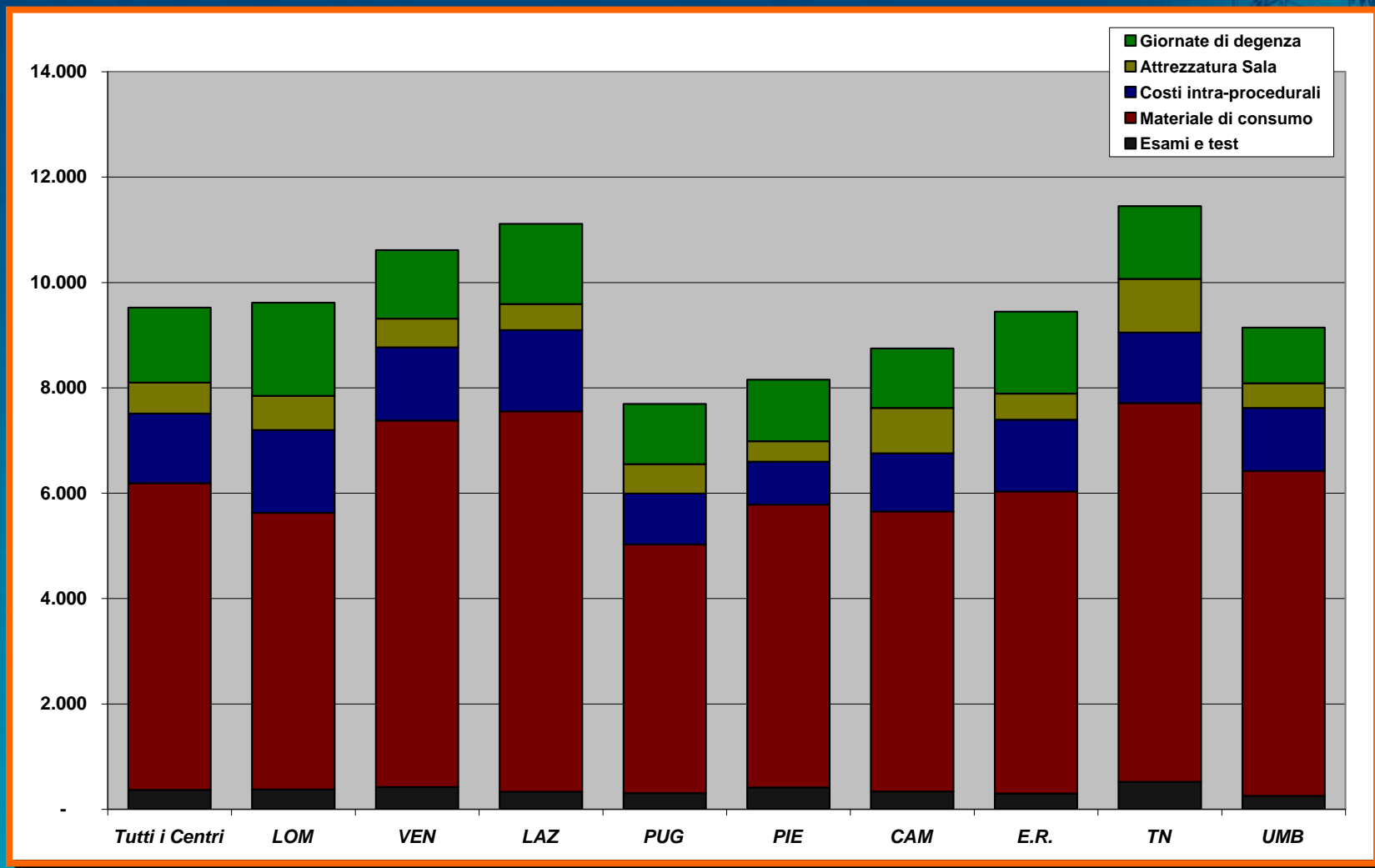
Voci di costo più significative:

- Materiali di consumo: 59 %
- Degenza: 13 %
- Occupazione sala e personale: 12%
- Attrezzatura Sala: 3,6%
- Esami: 3,4%



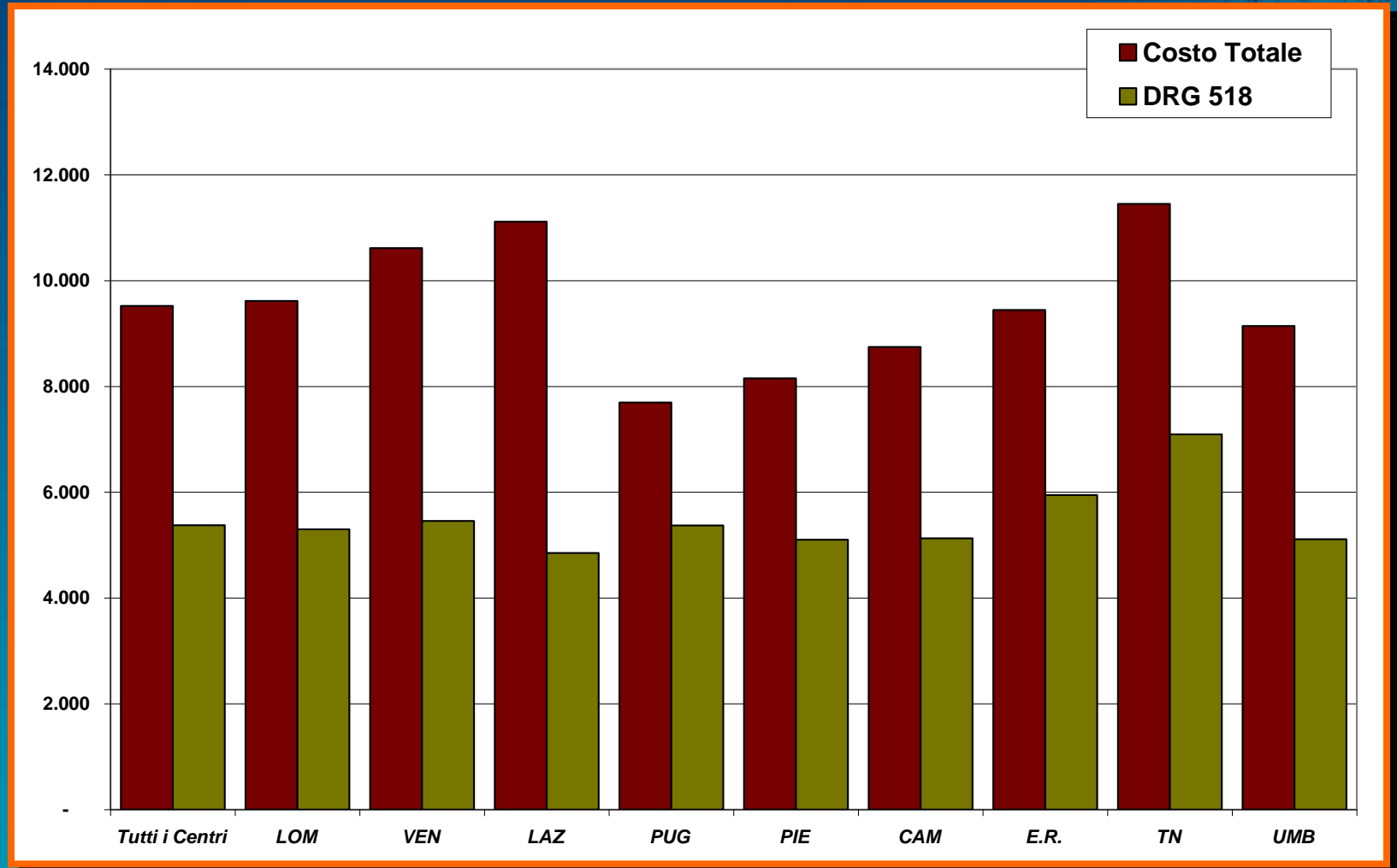
Costo Intraospedaliero della procedura

ablative *Analisi Regionale per voci di costo:*



Confronto Costo medio di Procedura e

Analisi Regionale: DRG

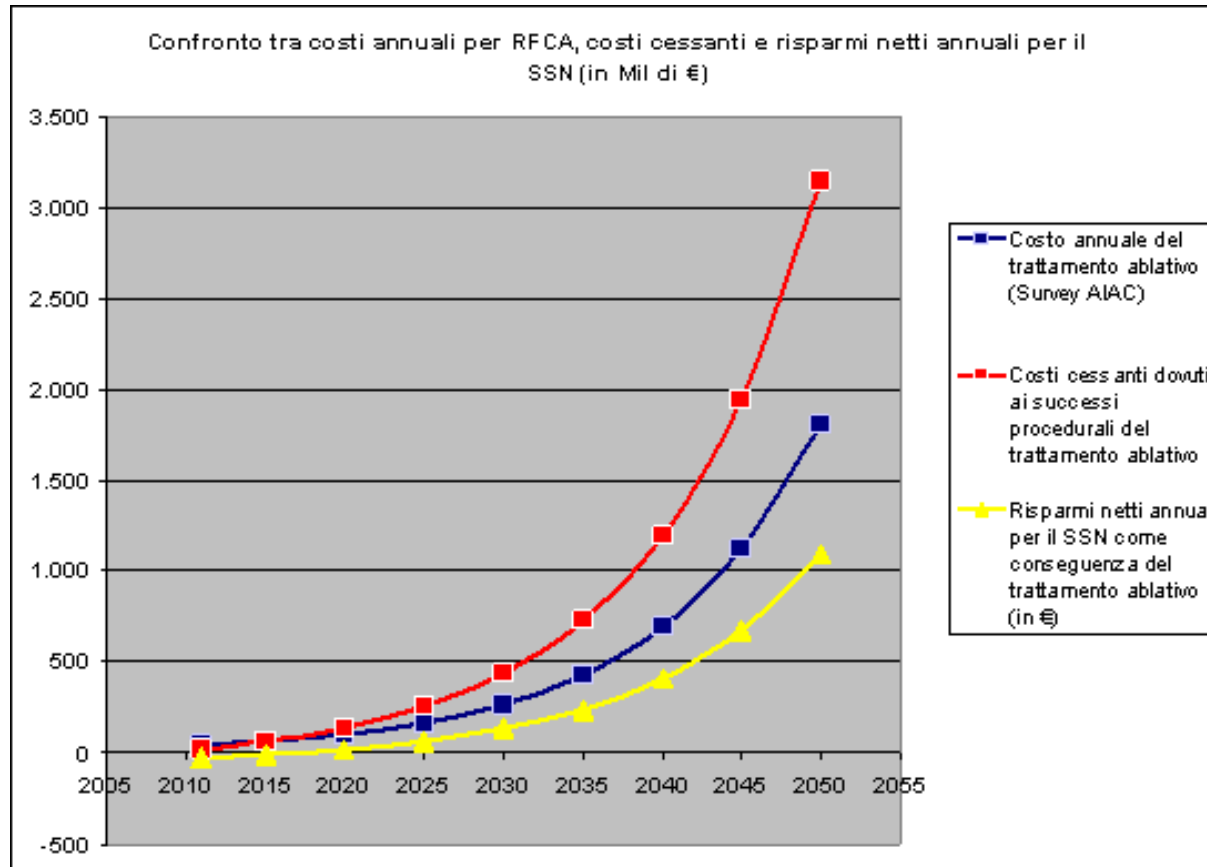


Conclusioni



- ◆ La FA, considerata la sua epidemiologia, morbilità e mortalità, rappresenta un significativo problema sanitario ed ha un importante impatto sociale ed economico che richiede più attenzione e risorse rispetto a quelle destinate finora.

Budget Impact Analysis AF ablation Italy



Blue line: total costs for AF ablation

Red line: total savings from AF ablation

Yellow line: Net savings from AF ablation

HTA is here to stay in an increasing amount of markets and we see increasing level of European and international collaboration on methods, structures and results. The impact of HTA on market access and reimbursement is increasing.

Health Technology Assessment is already here to stay





Economic Affairs 2011

HTA Project Team

Theme

- European HTA Collaboration

Objectives

- Strengthen our position as trusted stakeholders for international HTA networks, local agencies as well as other stakeholders connected to those networks in the field of HTA.

Deliverables

- EUnetHTA
 - Involvement in the Stakeholder Forum
 - Involvement in WPs 4, 5 and 7
 - Involvement in the development of the second Joint Action.
- European Commission
 - 2012 high-level conference on HTA (to be prepared in Q3 – Q4 2011);
 - Cross-border directive
 - Transparency directive
- Events
 - HTAi 2012 (Bilbao)
 - Workshop for NAs and/or presentations during meetings
 - MedTech Forum

EHRA Committee on Health Economics and Outcomes 2009-2011

Chair	Giuseppe Boriani (IT)
Co-chair	Nikos Maniadakis (GR)
Members	Frieder Braunschweig (SE)
	Haran Burri (CH)
	Giovanni Fattore (IT)
	Joseph Kautzner (CZ)
	Werner Jung (DE)
	Francisco. Levya (UK)
	Andrej Lubinski (PL)
	Lorenzo Mantovani (IT)

Initiatives of our Committee

A “focus issue” of Europace
CARDIAC ELECTROPHYSIOLOGY: WHY AND HOW TO
APPROACH HEALTH ECONOMICS?

Sponsors: Device companies

Available November 2010-Spring 2011 (to be discussed)



Home

Press Room

Innovation Union

+ Why?

+ Key initiatives

+ What it means to me

Key documents

Innovation made in the EU

EXPERIENCE INNOVATION

Innovation Union Lab

Augmented reality

Tales from the future

Videos

Innovation Union means
More jobs, improved lives, better society



Innovation Union, key initiatives

The Innovation Union contains **over thirty action points** including ground-breaking proposals like the European Innovation Partnerships. For example, the **pilot Partnership on active and healthy ageing** aims to add an average of two years of healthy life for everyone in Europe

The Innovation Union also introduces the strategic use of **public procurement budgets** to finance innovation, a comprehensive **Innovation Scoreboard** based on 25 indicators and a **European knowledge market for patents and licensing**.

It includes measures to **reinforce successful existing initiatives** like the **Risk Sharing Finance Facility**, which has so far levered 15 times the combined Commission and European Investment Bank contribution of over a billion euro.

Click on the image titles below for summaries of the issues addressed in the Innovation Union Plan.

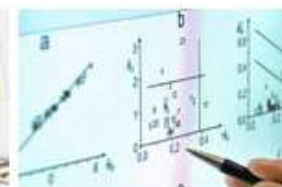
Follow this link for the [detailed list of planned initiatives](#)



Knowledge



Good ideas to market



Regional and social benefits



Innovation Partnerships



International Cooperation

Innovation Union:
Why?

Innovation Union:
Key initiatives

Innovation Union:
What it means to me

Key documents

José Manuel Durão Barroso

President of the European Commission

Europe leading social innovation

Social Innovation Europe initiative

Brussels, 17 March 2011



“Ageing of the population, and its associated health and caring costs, is indeed one of the major issues faced by governments especially at a time of fiscal consolidation. It is both a challenge and an opportunity.

It is an opportunity because the most important sectors for growth in the next decades are linked to the development of human and social capital: for example, health already represents a large share of GDP in most countries. And in many EU countries, elder care alone is due to reach 5% of GDP in a few years. It is an area where we need to maintain and even increase public investment in research and innovation. This is to invest in the future. [...]

It is also a challenge because we need to bring public and private stakeholders together to identify and deploy innovative solutions to address such an issue that is shared throughout the European Union. Together, we need for example to make the most and the best of the potential of information and communication technologies (ICTs) for improving our ability to meet those social needs, such as e-Health in healthcare. [...]

Active and healthy ageing is precisely our pilot Innovation Partnership. It will aim to give Europeans an average of two extra years of healthy life by 2020. So most of us will benefit from this innovation initiative. [...]”

Eucomed submits 4 proposals to Innovation Union

Eucomed Medical technology industry contributes to Active and Healthy Ageing Innovation Partnership consultation to overcome 'Innovation Hurdles'

Brussels, 3 February 2011 – Innovation within the European medical technology industry not only increases competitiveness, but also actively improves EU citizens' well-being. However, certain barriers to innovation still exist today which prevent Europe's innovative potential from being used to the fullest. Wanting to improve European competitiveness while tackling societal challenges, the European Commission (EC) in October 2010 launched the Innovation Union Strategy, of which the pilot Innovation Partnership on Active and Healthy Ageing is a key component. Eucomed, the European Medical Technology Industry Association, believes that the medical technology industry is uniquely positioned to contribute to these goals by continuing to drive the competitiveness and sustainability of Europe.

Eucomed answered to the EU public consultation by providing four proposals to the 'Active and Healthy Ageing Partnership' which revolve around:

- Developing procurement systems that focus on procuring innovation. UK and Sweden have developed new approaches around this objective
- Facilitating research on the parameters that influence national and local procurement decisions
- Reducing risks and hospitalisation of people with cardiac problems. Raising awareness for the benefits of remote monitoring of cardiac devices and develop appropriate funding schemes
- Avoiding hospitalisation of people through effective community care in the areas of stoma, wounds and incontinence, conditions that have high prevalence with people with any chronic conditions

Active Ageing Innovation Partnership – EC Public Consultation

Project Name: Remote Monitoring of Cardiac Implantable Device

I. General

1. What are the main barriers of innovation for you? (max. 3) Briefly explain.

a. Financial

Lack of funding and reimbursement for remote cardiac device monitoring is a strong disincentive to apply these innovative programs, preventing patients and systems to benefit from them. Current funding mechanisms (silo budgeting) are also a barrier to the implementation of solutions the costs and benefits of which are distributed across the entire care continuum.

b. Behavioral

Physicians, and nurses have not yet embraced telemonitoring

c. Organizational c. Public Authorities do not sufficiently promote the adoption of innovative solutions, nor facilitate the transformations required in the healthcare systems.

Telemonitoring and, at further stage, comprehensive disease management, involves the re-design of traditional processes of care (see b) and the application of novel solutions that can enable an overall increase in efficiency and drive improvements in the sustainability of the healthcare system with new funding models (see a).

2. How could the Innovation Partnership overcome these barriers. Briefly explain.

a. Proposing new models for reimbursement and funding that respond realistically to the new paradigms of care and to the solutions designed with a holistic approach.

b. To incorporate all stakeholders involved in the development, communication and application of these novel solutions through a partnership of collaboration.

9. Key partners for success of the programme

- Patient organisations (European and national level)
- Payers
- Healthcare professionals: European Heart Rhythm Association, European Society of Cardiology, Heart Failure Association of ESC
- Ministries of Health,

In conclusion

The impact of restricted health care budgets can be seen at various levels from hospital to society.

Industry is not shy to accept the challenge and to document the value of its technology solutions.

However a pre-requisite for that is an appropriate, holistic definition of what creates value and transparent approach of assessing value, based on full stakeholder involvement, incl industry.

Effective partnership with individual clinician-experts in their capacity as customers, but certainly also with scientific organisations is critical for medical technology innovation to stand its case.

Thank you



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