11ª Reunión Científica
de la Asociación Española de Evaluación de Tecnologías Sanitarias (AEETS)

Racionamiento y priorización: dos estrategias que reclama la Evaluación de Tecnologías Sanitarias

13 y 14 noviembre 2014

Métodos para desarrollar la ETS

Carlos Campillo Artero

10 regulatory problems

Regulation: evidence-based, self-improving, timely, stakeholders?

Not associated with market failures (capture)

Shortcomings & heterogeneity of appraisal, coverage, pricing

Innovation: real vs commercial (incentives)

HTA: does it make up ex post for deficiencies ex ante? Flaws in HTA

Waste of knowledge

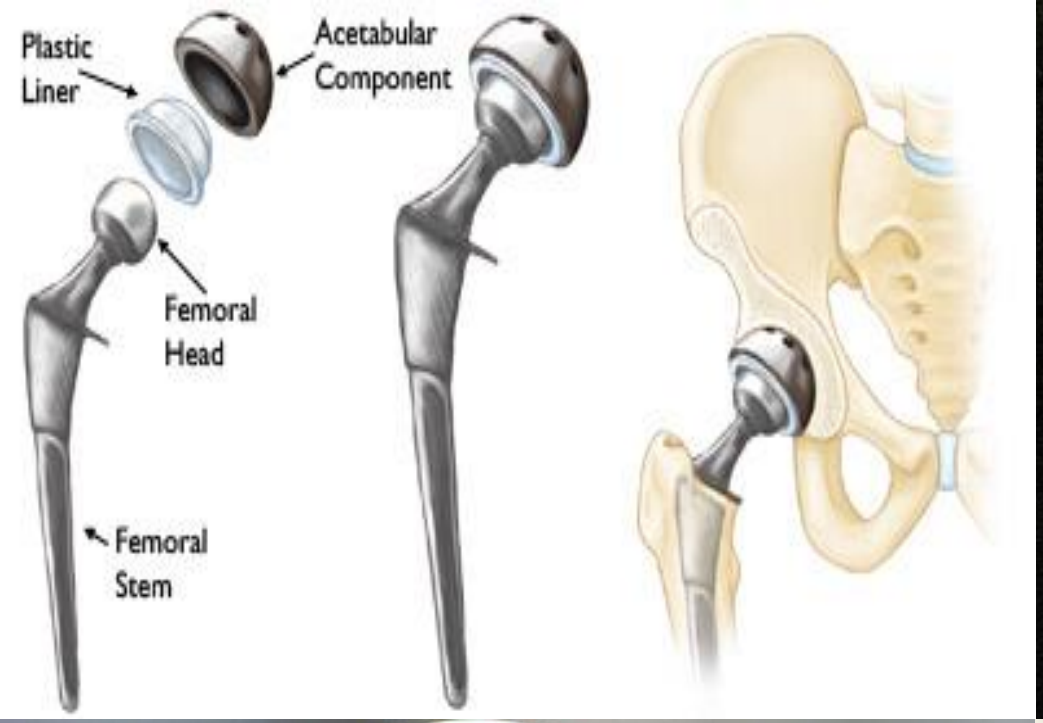
Inappropriate resources for management & postmarket surveillance

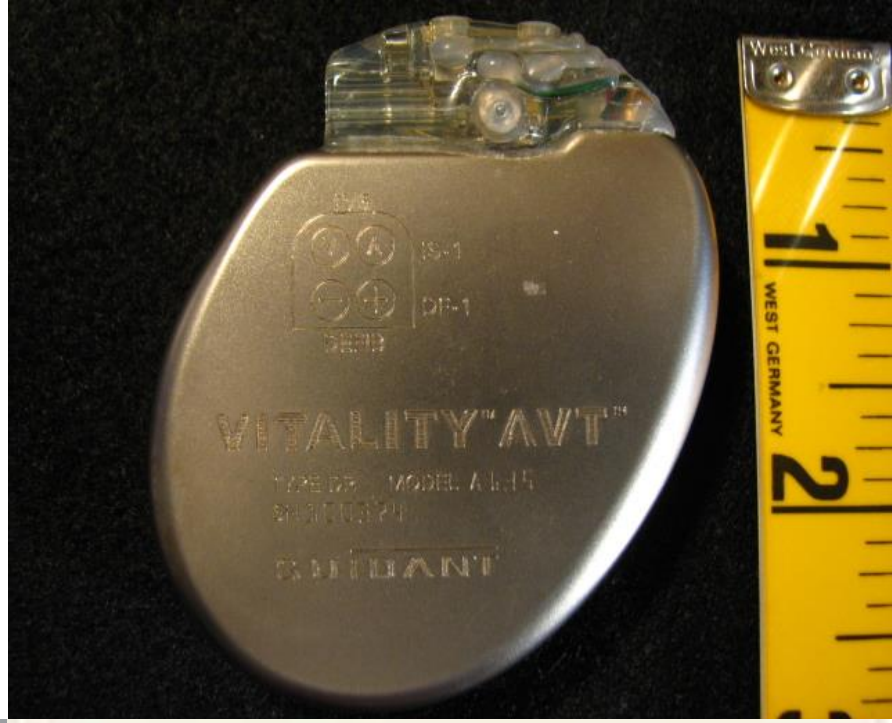
Virtually nonnexistent disintvestment

Incentives for regulatory overhaul scanty

Externalities, inefficiency, opp costs

Regulatory ladder


Plastic Liner
Acetabular Component
Femoral Head
Femoral Stem


VITALITY AVT
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Check out our coverage
MORCELLATION DEBATE

Proteína C reactiva

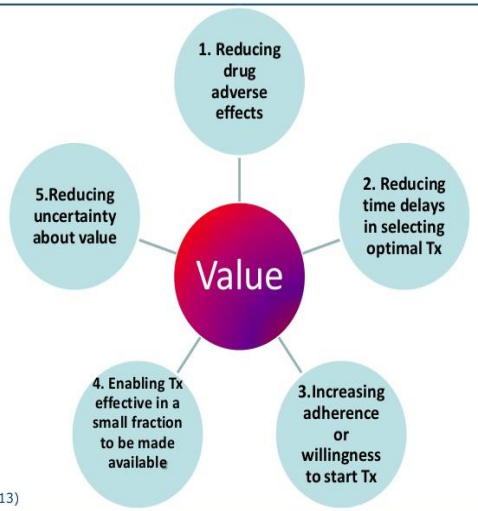
CEA, AFP

Procalcitonina

CK MB, Troponina

CK, mioglobina, rabdo-IRC

Framework to assess value of diagnostic test technologies in the context of treatment



Source: Garau et al. (2013)

Office of Health Economics
Research & Consulting

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Decision-Analytic Modeling to Evaluate Benefits and Harms of Medical Tests: Uses and Limitations

Thomas A. Trikalinos, MD, Uwe Siebert, MD, MPH, MSc, ScD, Joseph Lau, MD

Medical Tests—White Paper Series

Proposals for a Phased Evaluation of Medical Tests

PERSPECTIVE

nature biotechnology

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Frank D Sistare[1], Frank Dieterle[2], Sean Troth[1], Daniel J Holder[1], David Gerhold[1], Dina Andrews-Cleavenger[3], William Baer[4], Graham Betton[5], Denise Bounous[6], Kevin Carl[2], Nathaniel Collins[7], Peter Goering[8], Federico Goodsaid[8], Yi-Zhong Gu[7], Valerie Guilpin[9], Ernie Harpur[9], Alita Hassan[4], David Jacobson-Kram[8], Peter Kasper[10], David Laurie[2], Beatriz Silva Lima[11], Romaldas Maciulaitis[10], William Mattes[12], Gérard Maurer[2], Leslie Ann Obert[13], Josef Ozer[13], Marisa Papaluca-Amati[10], Jonathan A Phillips[14], Mark Pinches[5], Matthew J Schipper[4], Karol L Thompson[8], Spiros Vamvakas[10], Jean-Marc Vidal[10], Jacky Vonderscher[15], Elizabeth Walker[12], Craig Webb[4] & Yan Yu[1]

Genome-Based Diagnostics: Clarifying Pathways to Clinical Use

Workshop Summary

Steve Olson and Adam C. Berger, *Rapporteurs*

Roundtable on Translating Genomic-Based Research for Health
Board on Health Sciences Policy

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the understanding that interpretations of genomic information may evolve as research unravels the meaning of gene–gene and gene–environment interactions and the roles of noncoding DNA

Risks of Presymptomatic Direct-to-Consumer Genetic Testing

Justin P. Annes, M.D., Ph.D., Monica A. Giovanni, M.S., C.G.C., and Michael F. Murray, M.D.

Table 1. Measures for improving and integrating the regulation of drugs, medical devices, diagnostic tests, and surgical innovations.

Area of improvement	Drugs	Medical devices	Diagnostic tests	Surgical innovations
Principles governing regulation	Regulation should be evidence-based, self-improving, timely, and achieve participation of all stakeholders			
Assessment, appraisal, coverage, pricing, reimbursement	Coordinate and harmonise these functions and assign them to public, independent, technically competent agencies, that include expert clinicians and foster cross-fertilisation among all stakeholders			
Governance	Apply relevant Governance criteria to regulation: voice and accountability, government effectiveness, regulatory quality, rule of law, control of corruption			
Unequivocal identification of technology	ATC codes	ICD codes	ICD codes	ICD codes
Risk classification	All technologies should be accurately and reliably classified on the basis of the risks they pose to health			
Decision criteria on approval, coverage, reimbursement, disinvestment	Relative efficacy, safety, and effectiveness, and incremental cost effectiveness	Relative efficacy, safety, and effectiveness, and incremental cost effectiveness	Relative efficacy, safety, effectiveness, and incremental cost effectiveness, as well as analytical validity, clinical validity, and clinical utility. Biomarkers should be validated and qualified before approval. Apply a phased evaluation based on principles of randomised controlled trials	Relative efficacy, safety, and effectiveness, and incremental cost effectiveness. Apply a phased evaluation based on recommendations included in the Innovation, Development, Exploration, Assessment, Long-term follow-up (IDEAL) model
Insufficient evidence	Use conditional approval schemes and selective reimbursement, and make them contingent upon notification			
Postmarket surveillance	Strengthen surveillance systems in all steps of development and post-adoption, and foster the study of clinical variations and comparative effectiveness			
Value-based principles	Value-based assessment and pricing models ought to be further developed and gingerly applied in tandem, considering new theoretical developments			
Social efficiency	Minimise social costs and inefficiencies due to externalities, send unequivocal signals regarding innovation, social values and willingness to pay, bring incentives into line and make them consistent with the objectives of regulatory overhaul			