

# QUALE RUOLO DELLE ISTITUZIONI PUBBLICHE NELLA PROMOZIONE DELL'INNOVAZIONE NEL SETTORE FARMACEUTICO

La misurazione del valore del farmaco:  
Quali scenari futuri?

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# Drug value



Gianni Benzi 1931-2006

# Economics is...

“... study of how societies use scarce resources to produce valuable commodities and distribute them among different people”

*Paul A Samuelson, Nobel Laureate 1970*

# Farmaco

- Valore per la salute dei pazienti
- Valore come settore industriale
- Valore per la competitività

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# Che cosa conosciamo

- Qualità
- Sicurezza (teorica)
- Efficacia (teorica)
- “Prezzo”

# Che cosa vorremmo conoscere?

- Qualità
- Sicurezza (reale/pratica)
- Efficacia (reale/pratica)
- Utilizzo (Da chi? Per chi?)
- Valore

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## The burden of renal cell cancer: A retrospective longitudinal study on occurrence, outcomes and cost using and administrative claims database

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**Table 1 – Population characteristics**

Variable	With metastases	Without metastases	Difference/OR/(95% CI)	Difference/OR/(95% CI) <sup>a</sup>
Age (years)	69.8	66.7	-3.1 (-4.63/-1.46)	
Sex				
Male	156	700	1.12 (0.84/1.47)	
Female	100	402		
	256	1102		
Length of follow-up (d)	382.14	857.81	475.66 (409.57/541.56)	
Mortality	0.76	0.21	5.8 (4.79/7.04) <sup>b</sup>	5.5 (4.52–6.64) <sup>b</sup>

a Adjusted for age and sex.

b Hazard ratio.

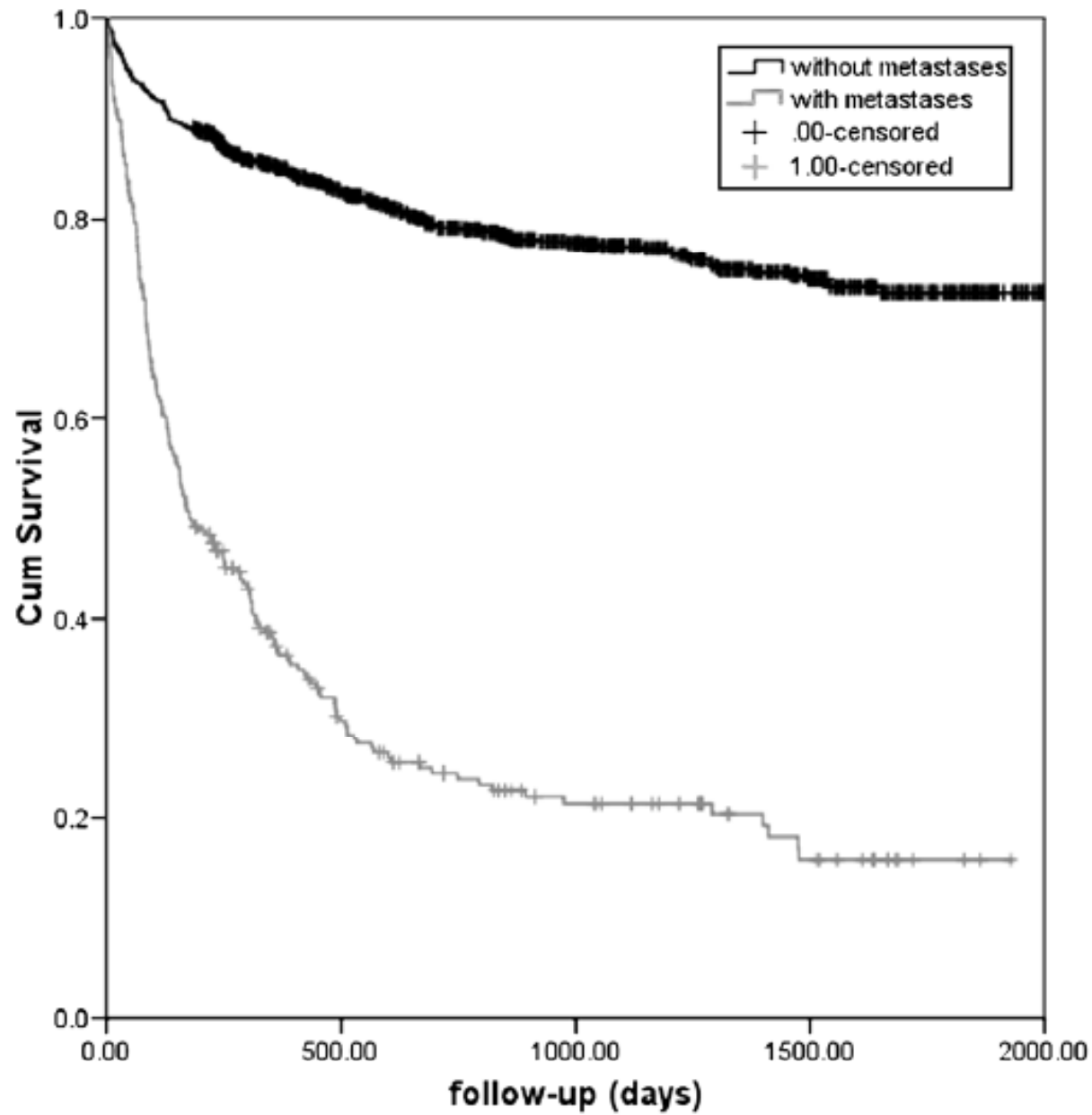


Fig. 1 - Kaplan-Meier survival curves of individuals with diagnosis of RCC with and without metastases.

**Table 2 – Cost per patient during entire follow-up period**

Variable	With metastases (N = 256)	W/O metastases (N = 1102)	Difference (95% CI)	Difference (IC 95%) <sup>a</sup>
Cost of hospitalisation	14238.30	11424.69	2813.61 (1112.47/4514.76)	2928.97 (1326.35/4531.58)
Cost of drugs	1431.34	1719.29	-287.96 (-673.42/97.51)	-285.62 (-663.53/92.29)
Cost for outpatient care	1986.38	2946.36	-959.99 (-1744.41/-175.56)	-817.14 (-1560.39/-73.89)
Total health care cost	17656.02	16090.35	1565.67 (-664.21/3795.55)	1826.20 (-223.72/3876.12)

a Adjusted for age and sex.

**Table 3 – Cost per patient in the first year of follow-up**

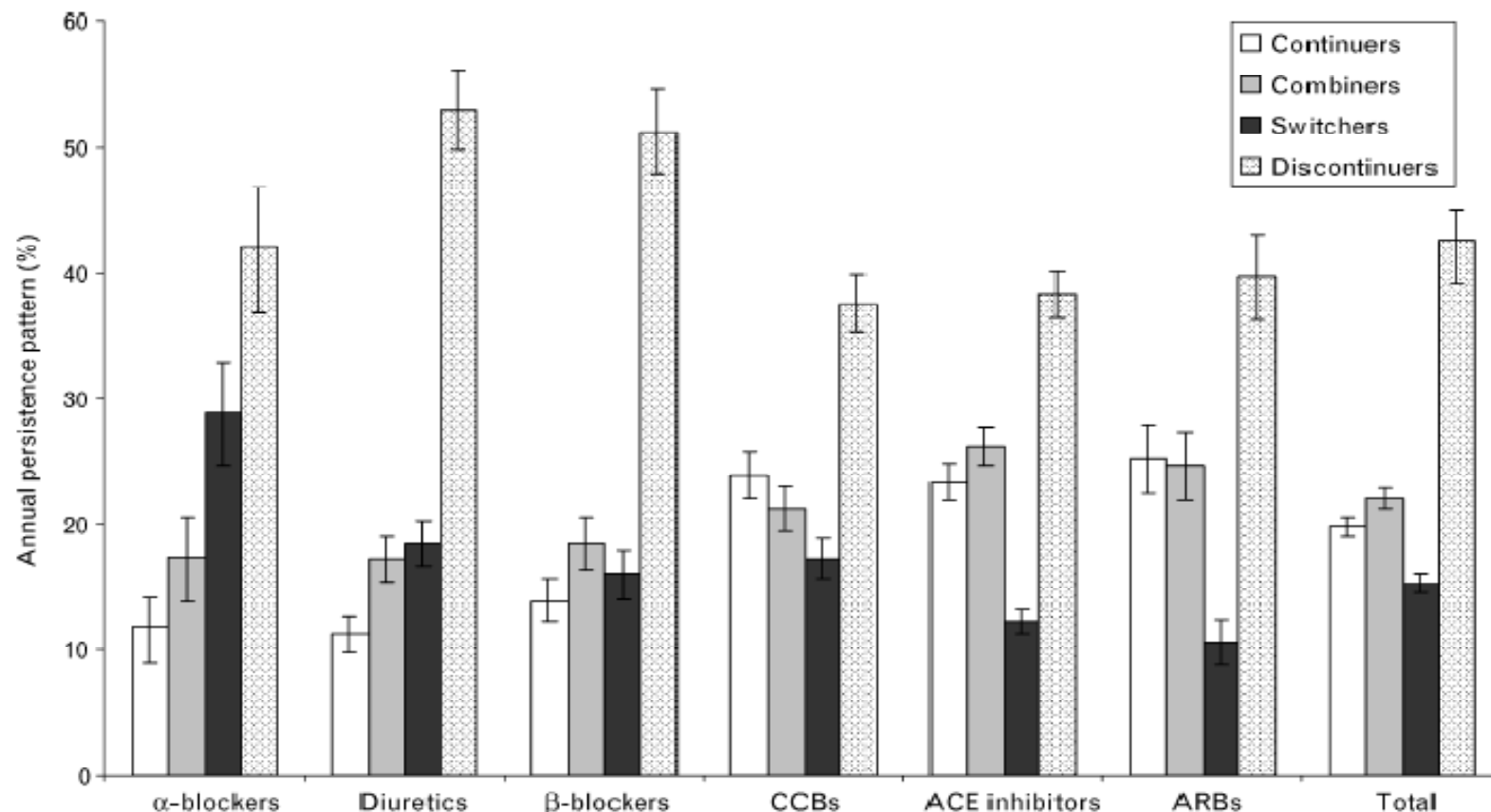
Variable	With Metastases (N = 256)	W/O metastases (N = 1102)	Difference (95% CI)	Difference (IC 95%) <sup>a</sup>
Cost of hospitalisation	11670.12	8859.47	2810.65 (1681.76/3939.54)	2920.42 (1872.69/3968.15)
Cost of drugs	875.38	597.52	277.86 (27.62/528.09)	283.28 (24.09/542.47)
Cost for outpatient care	1147.18	1045.36	101.83 (-229.11/432.76)	159.59 (-160.55/479.73)
Total health care cost	13692.68	10502.34	3190.34 (1857.88/4522.79)	3363.29 (2172.48/4554.11)

a Adjusted for age and sex

# Patterns of persistence with antihypertensive medications in newly diagnosed hypertensive patients in Italy: a retrospective cohort study in primary care

Giampiero Mazzaglia<sup>a,c</sup>, Lorenzo G. Mantovani<sup>c</sup>, Miriam C.J.M. Sturkenboom<sup>e</sup>, Alessandro Filippi<sup>b</sup>, Gianluca Trifirò<sup>d</sup>, Claudio Cricelli<sup>b</sup>, Ovidio Brignoli<sup>b</sup> and Achille P. Caputi<sup>d</sup>

Fig. 1



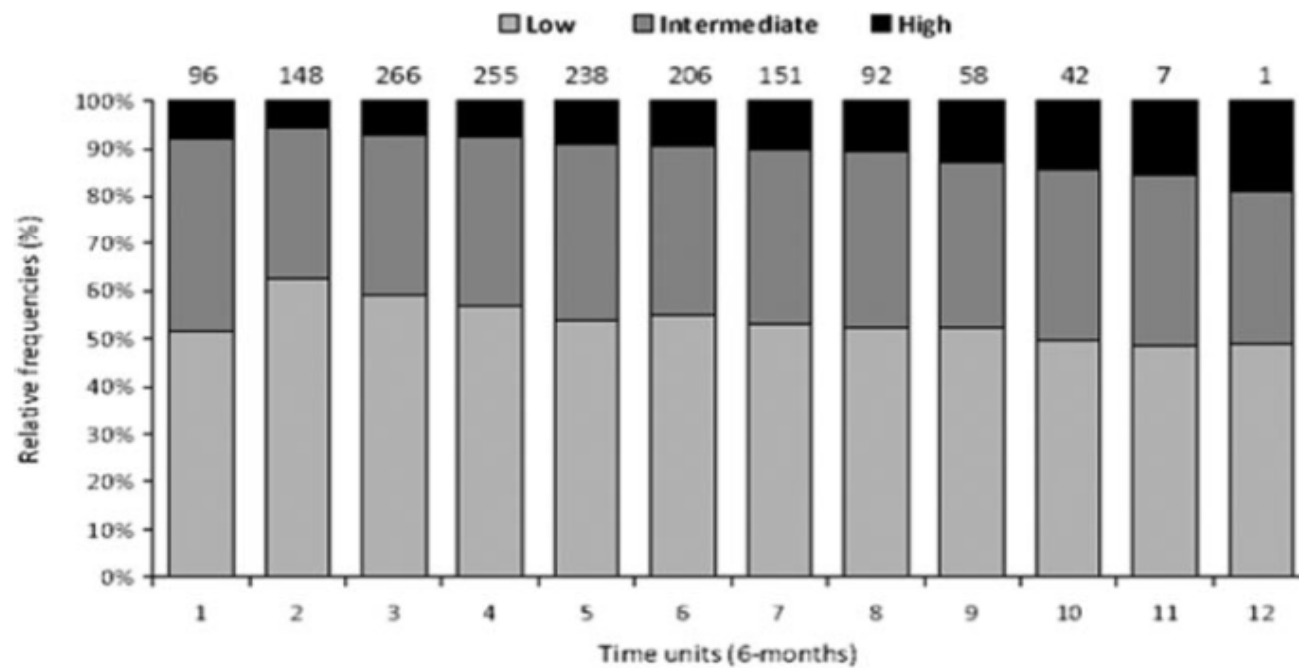
# Cardiovascular Morbidity Among Newly Diagnosed Hypertensive Patients

Giampiero Mazzaglia, MD, PhD; Ettore Ambrosioni, MD, PhD; Marianna Alacqua, MD; Alessandro Filippi, MD; Emiliano Sessa, DSc; Vincenzo Immordino, MD; Claudio Borghi, MD; Ovidio Brignoli, MD; Achille P. Caputi, MD; Claudio Cricelli, MD; Lorenzo G. Mantovani, MSc, DSc

**Background**—Nonadherence to antihypertensive treatment is a common problem in cardiovascular prevention and may influence prognosis. We explored predictors of adherence to antihypertensive treatment and the association of adherence with acute cardiovascular events.

**Methods and Results**—Using data obtained from 400 Italian primary care physicians providing information to the Health Search/Thales Database, we selected 18 806 newly diagnosed hypertensive patients  $\geq 35$  years of age during the years 2000 to 2001. Subjects included were newly treated for hypertension and initially free of cardiovascular diseases. Patient adherence was subdivided a priori into 3 categories—high (proportion of days covered,  $\geq 80\%$ ), intermediate (proportion of days covered, 40% to 79%), and low (proportion of days covered,  $\leq 40\%$ )—and compared with the long-term occurrence of acute cardiovascular events through the use of multivariable models adjusted for demographic factors, comorbidities, and concomitant drug use. At baseline (ie, 6 months after index diagnosis), 8.1%, 40.5%, and 51.4% of patients were classified as having high, intermediate, and low adherence levels, respectively. Multiple drug treatment (odds ratio, 1.62; 95% CI, 1.43 to 1.83), dyslipidemia (odds ratio, 1.52; 95% CI, 1.24 to 1.87), diabetes mellitus (odds ratio, 1.40; 95% CI, 1.15 to 1.71), obesity (odds ratio, 1.50; 95% CI, 1.26 to 1.78), and antihypertensive combination therapy (odds ratio, 1.29; 95% CI, 1.15 to 1.45) were significantly ( $P < 0.001$ ) associated with high adherence to antihypertensive treatment. Compared with their low-adherence counterparts, only high adherers reported a significantly decreased risk of acute cardiovascular events (hazard ratio, 0.62; 95% CI, 0.40 to 0.96;  $P = 0.032$ ).

**Conclusions**—The long-term reduction of acute cardiovascular events associated with high adherence to antihypertensive treatment underscores its importance in assessments of the beneficial effects of evidence-based therapies in the population. An effort focused on early antihypertensive treatment initiation and adherence is likely to provide major benefits. (*Circulation*. 2009;120:1598-1605.)



**Figure.** Relative frequencies (percent) of patient adherence to AHT at baseline (ie, 6 months after index diagnosis) and during follow-up.

\* The number of patients censored within each time-unit is reported above the bars.

**Table 3. Multivariable Analysis of the Association of Patient Characteristics With First-Ever Acute Cardiovascular Event Estimated by Cox Proportional-Hazards Models**

Adherence Within 6 mo After Diagnosis	HR* (95% CI)	<i>P</i>
Model 1†		
Low (PDC <40%)	1.00	<0.001§
Intermediate (PDC, 40% to 79%)	0.87 (0.73–1.03)	0.117
High (PDC ≥80%)	0.50 (0.35–0.69)	<0.001
Model 2†		
Low (PDC <40%)	1.00	<0.001§
Intermediate (PDC, 40% to 79%)	0.86 (0.71–1.03)	0.109
High (PDC ≥80%)	0.62 (0.40–0.96)	0.032

A total of 659 CVEs were considered in the models.



## **The psoriatic arthritis cost evaluation study: a cost-of-illness study on tumour necrosis factor inhibitors in psoriatic arthritis patients with inadequate response to conventional therapy**

**I. Olivieri<sup>1</sup>, S. de Portu<sup>2</sup>, C. Salvarani<sup>3</sup>, A. Cauli<sup>4</sup>, E. Lubrano<sup>5</sup>, A. Spadaro<sup>6</sup>, F. Cantini<sup>7</sup>, M. S. Cutro<sup>1</sup>, A. Mathieu<sup>4</sup>, M. Matucci-Cerinic<sup>8</sup>, N. Pappone<sup>5</sup>, L. Punzi<sup>9</sup>, R. Scarpa<sup>10</sup> and L. G. Mantovani<sup>2,11</sup> for the PACE working group**

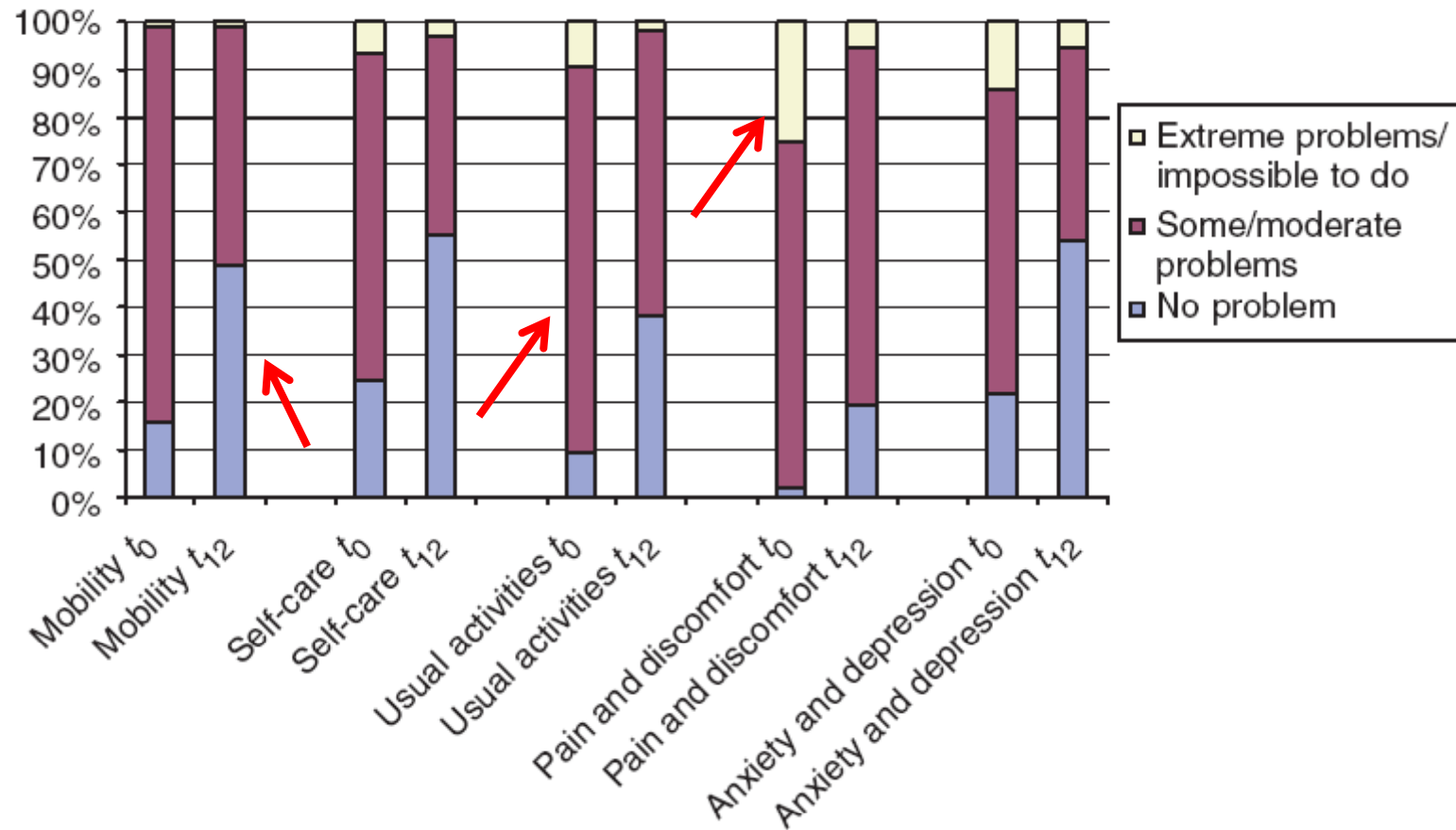


FIG. 2. EQ-5D items response frequencies before and after treatment.  $t_0$ : time of the enrolment;  $t_{12}$ : time of the second visits of follow-up.

TABLE 5. Incremental cost–effectiveness ratios of anti-TNF- $\alpha$  therapy related to comparable periods before and after anti-TNF- $\alpha$  therapy (6 months before enrolment compared with the last 6 months of the study)

Variable	Incremental cost (€) (6 months)	Utility gain (utility at final – utility at initial observations)	QALY gain (6 months)	Cost/QALY (€)
Direct cost	5052.34	0.25	0.12	40 942.78
NHS cost	5044.21	0.25	0.12	40 876.90
Social cost	4638.73	0.25	0.12	37 591.01

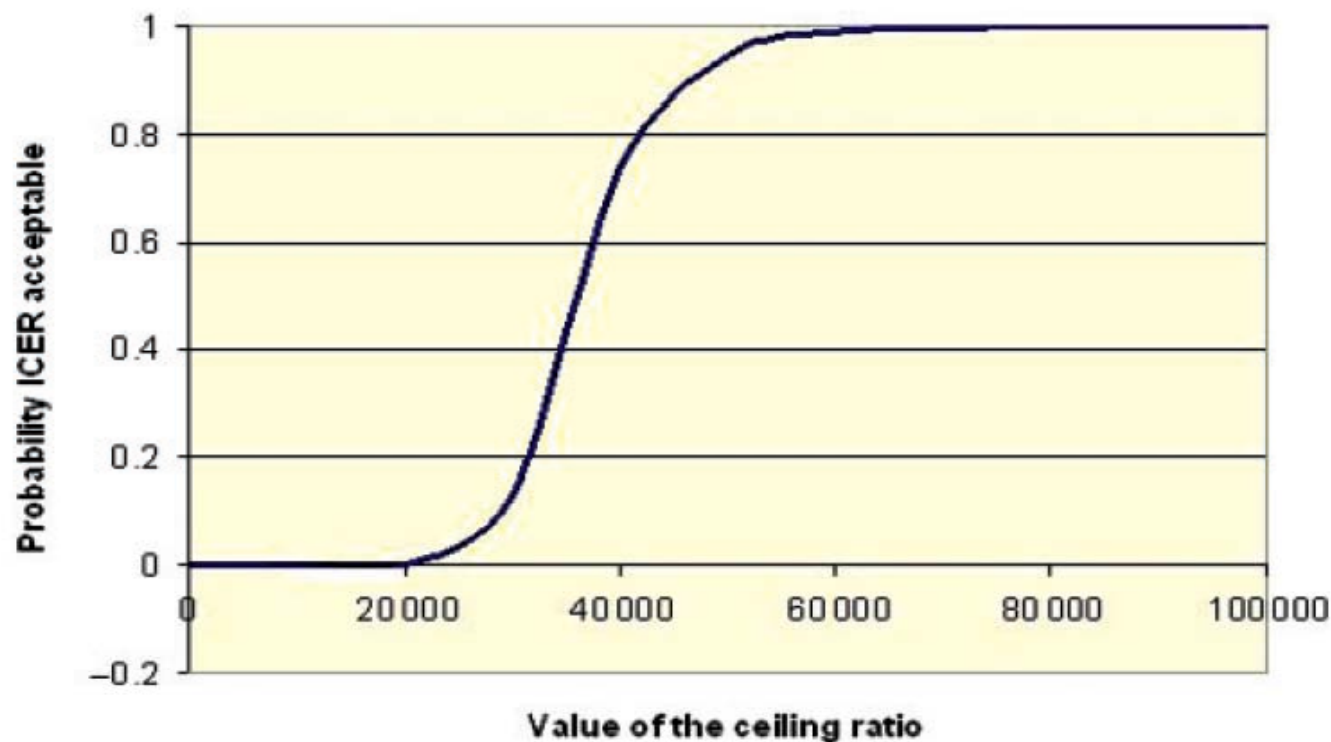


FIG. 3. Cost–effectiveness acceptability curve.

# La misurazione del valore di un farmaco

- I DB costituiscono delle miniere di conoscenza
- I DB amministrativi forniscono informazioni su ciò che accade di clinicamente ed economicamente rilevante
- I DB clinici permettono di indagare le determinanti “cliniche” di ciò che accade
- Il futuro è far dialogare i DB clinici ed amministrativi

# La misurazione del valore di un farmaco

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- I DB amministrativi forniscono informazioni su ciò che accade di clinicamente ed economicamente rilevante
- I DB clinici permettono di indagare le determinanti “cliniche” di ciò che accade
- Il futuro è far dialogare i DB clinici ed amministrativi
- **Il futuro è già iniziato...**

# **Economics is...**

“ The decision maker has a choice between optimal decisions for an imaginary simplified world or decisions that are "good enough, that satisfice", for a world approximating the complex real one more closely.”

*Herbert A Simon, Nobel Laureate 1978*