

**La prevenzione cardiovascolare efficace:  
la distanza fra evidenze scientifiche e realta' clinica.**

**Una proposta per il SSN**

Firenze, 12 settembre 2011

Simposio

“Le evidenze scientifiche”

Il rapporto costo-beneficio nell'EBM

*Ezio Degli Esposti*

# “Ricerca clinica”, “pratica clinica”, “farmacoeconomia”, “economia sanitaria”

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**Studi osservazionali**

Fattore causale

Incidenza di eventi

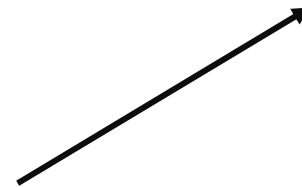
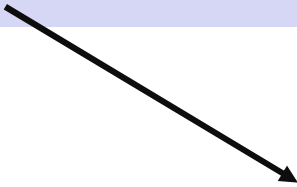


**Ricerca clinica**

**Pratica clinica**

Studi fisiopatologici  
Studi di intervento  
Studi clinici controllati  
Studi  
farmacoeconomici

Valutazioni di esito  
Sostenibilità finanziaria  
Appropriatezza d'uso  
Popolazione target  
Indicazioni d'uso



**Linee guida**

# Malattia cardiovascolare: storia naturale e interventi possibili

Interventi possibili:

prevenzione

identificazione precoce

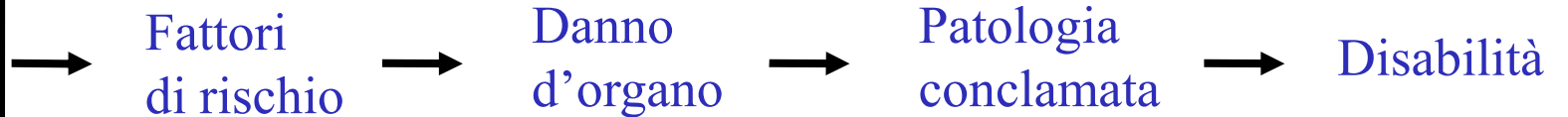
trattamento appropriato risolutivo

trattamento appropriato conservativo

trattamento palliativo

Determinanti  
genetiche

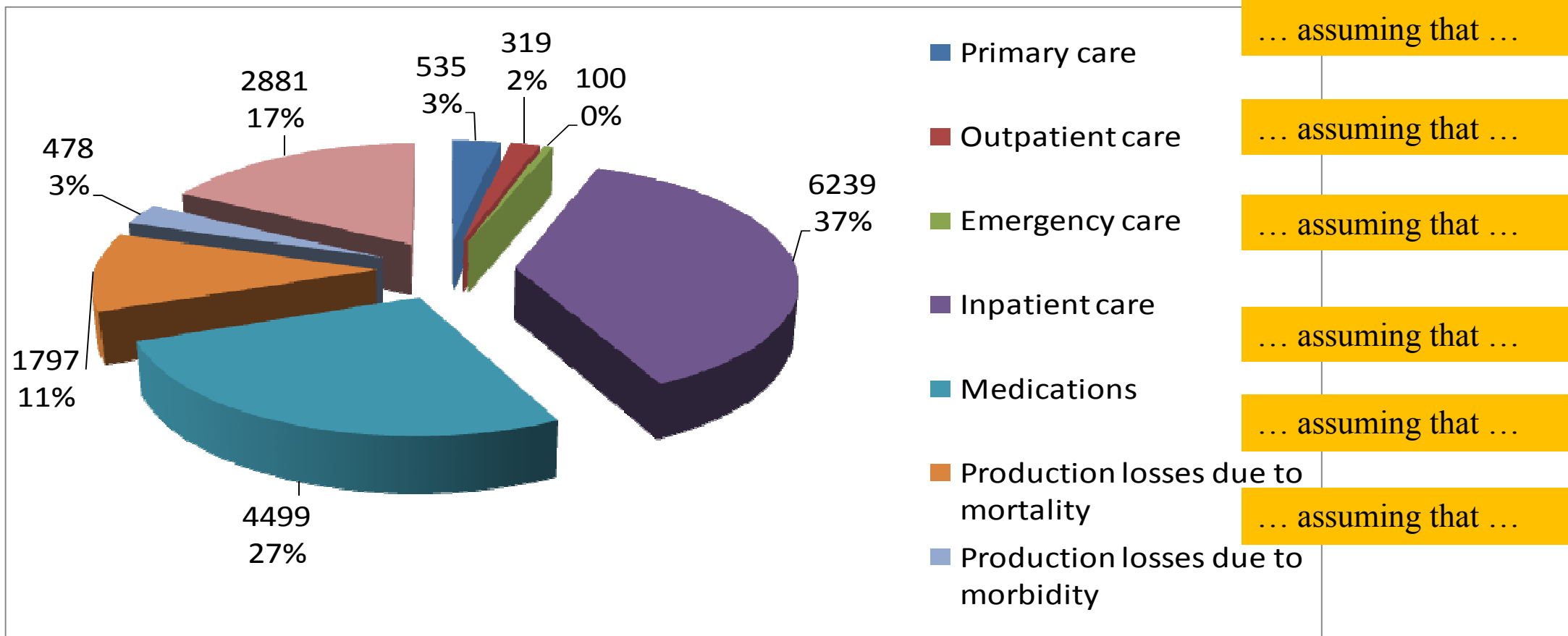
Determinanti  
ambientali



Numero di soggetti coinvolti

Costo per soggetto coinvolto

# Le conseguenze per il SSN: costo per malattie CV in Italia



Il costo totale stimato per malattie CV in Italia nel 2003 è stato di 16848 milioni di € (pari al 22,1% del FSN) di cui 11692 milioni di € (pari al 69.4%) per spese sanitarie e 5156 milioni di € (pari al 30.6%) per spese non sanitarie

# Definizioni

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## *Analisi di costo-efficacia (cost-effectiveness)*

Studio di valutazione economica nel quale le conseguenze di differenti interventi sono misurate valutando un singolo esito (morti evitate, infarti evitati, anni di vita guadagnati, ecc.). I differenti interventi sono quindi messi a confronto in termini di costo per unita' di efficacia.

## *Analisi di costo-utilita'*

..... i benefici sono espressi in anni di vita guadagnati corretti per la qualita' della vita. (QALYs)

## *Analisi di costo-beneficio*

..... i benefici sono espressi in termini monetari.

*Costi:* diretti, indiretti (o costi di produttivita'), intangibili.

*Interventi:* indipendenti, reciprocamente esclusivi.

*Rapporto incrementale di costo-efficacia:*

$$ICER = \frac{\text{differenza in costo fra programma 1 e 2}}{\text{differenza in esiti di salute fra programma 1 e 2}}$$

# Efficiacia del trattamento farmacologico con statine

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There is evidence from placebo-controlled studies to suggest that statin therapy is associated with a statistically significant reduction in the risk of:

- all-cause mortality, fatal and non-fatal MI, and a composite end-point of CHD death plus nonfatal MI, in both primary and secondary prevention
- stable angina in primary prevention
- cardiovascular mortality, CHD mortality, nonfatal stroke, PAD, unstable angina and coronary revascularisation in secondary prevention.

# Revisiting Rose: strategies for reducing coronary heart disease

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No of deaths from coronary heart disease avoided\*

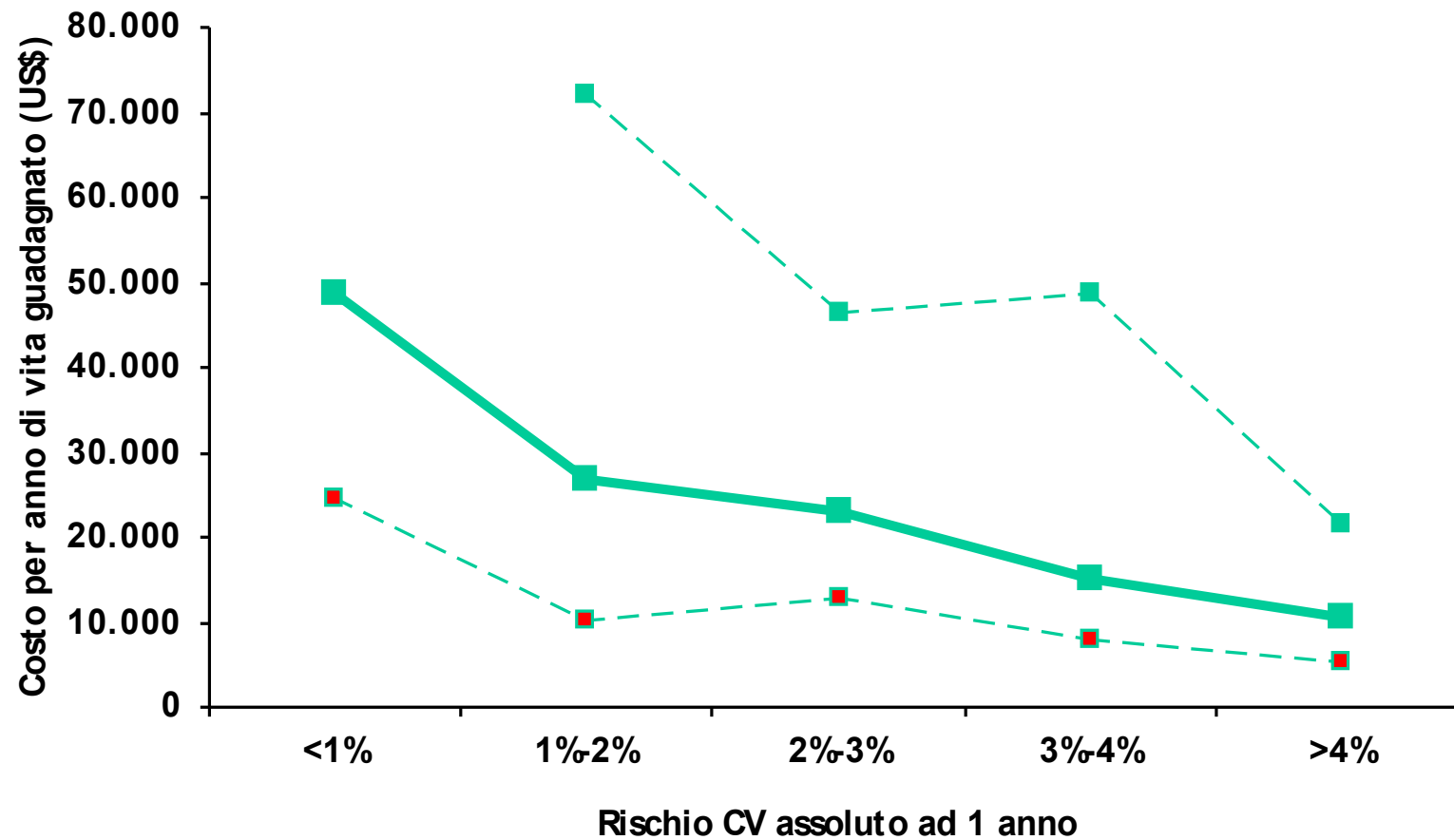
Strategy	N° (%) of population treated	Over 10 years	Per 100000 population	Low adherence
Population health (Rose)	12300000 (100)	5160	42	
Single risk factor	1370000 (11.1)	15500	125	5160**
High baseline risk	1590000 (12.9)	35800	290	5160***

\* assuming 100% community effectiveness for the single risk factor and high baseline risk strategies and a 2% total cholesterol reduction for the Rose strategy.

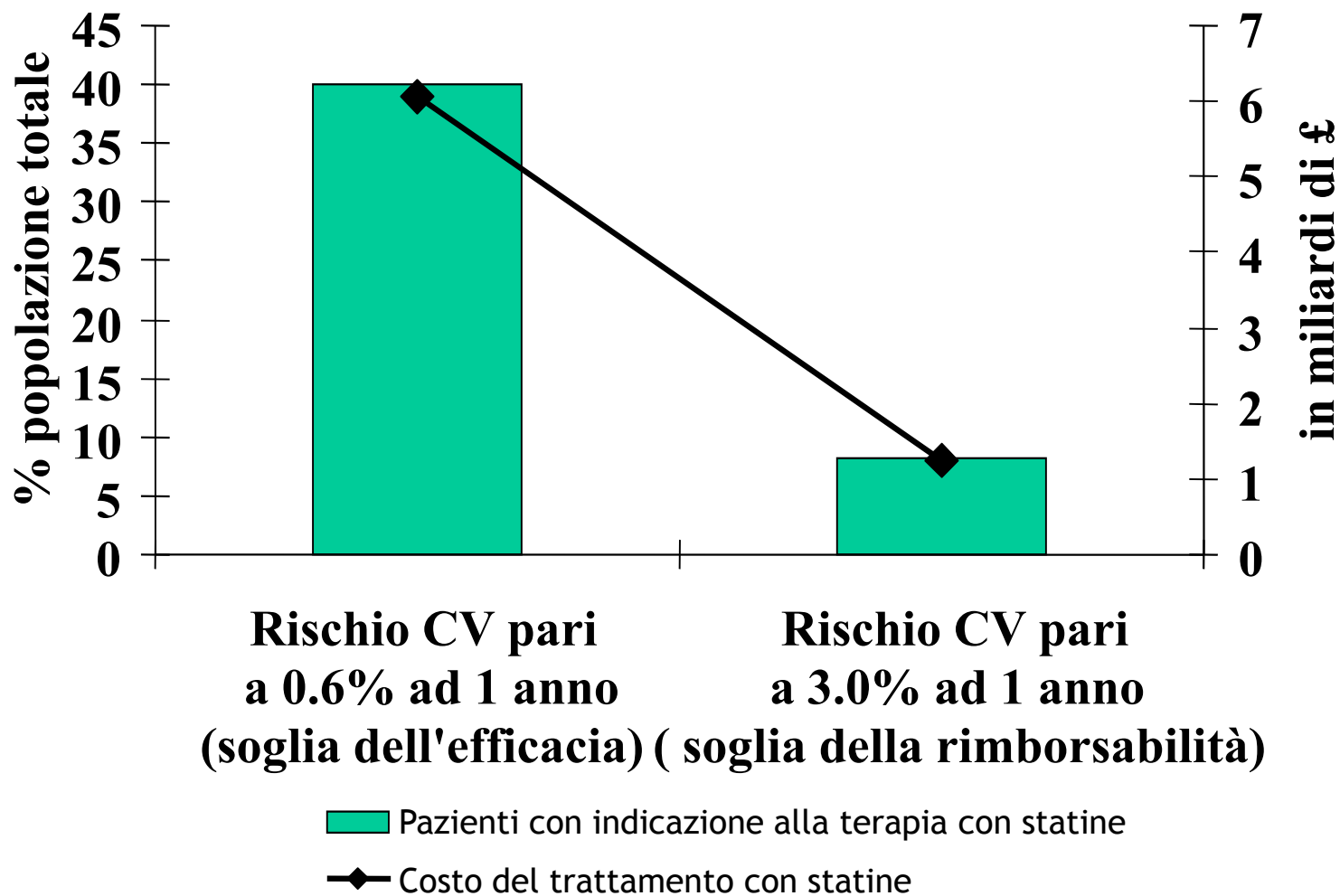
\*\* assuming 30% statin adherence

\*\*\* assuming 16% statin adherence

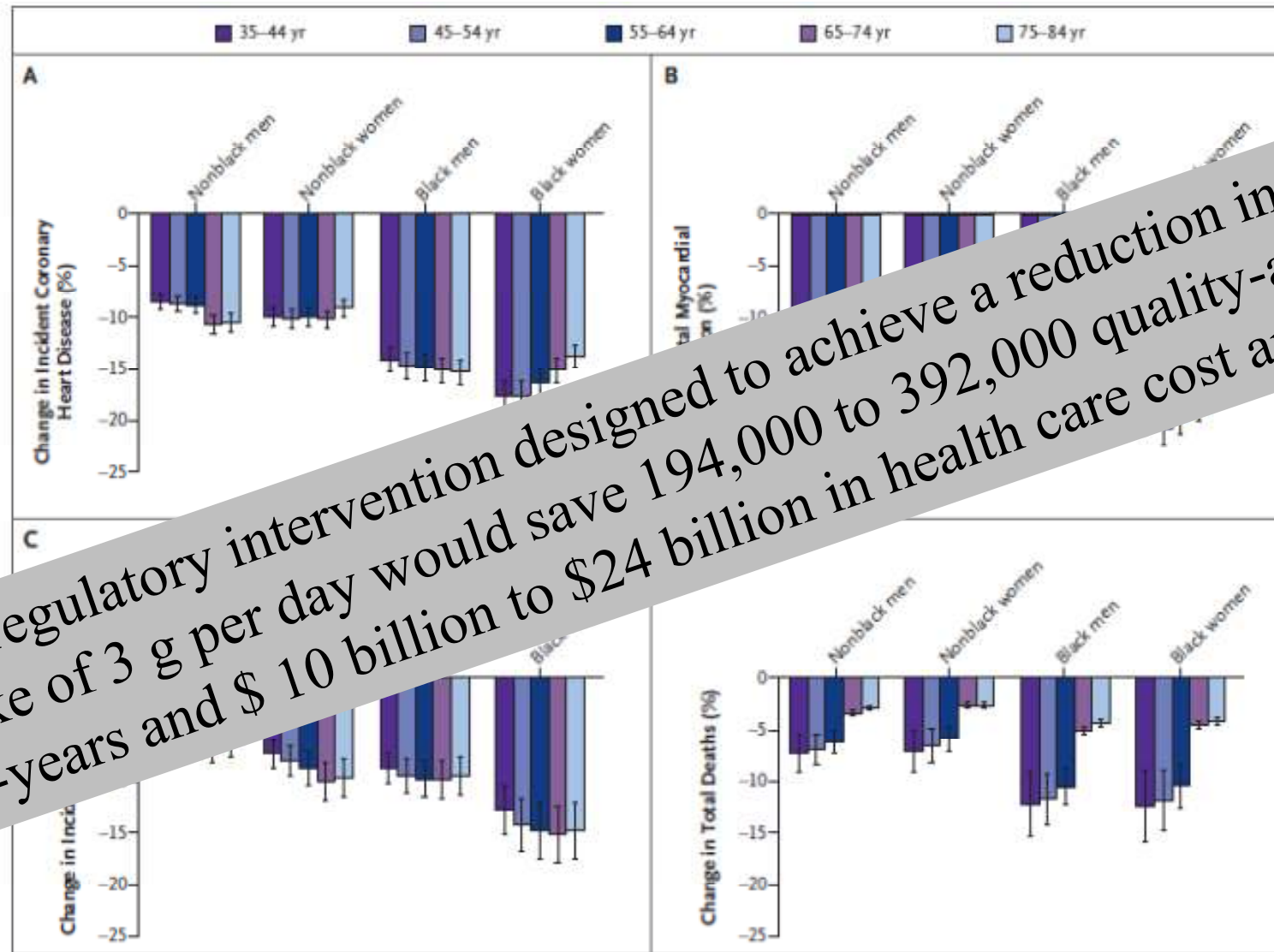
# Costo-beneficio del trattamento farmacologico con statine



# Disponibilità finanziaria per le statine



# Projected Effect of Dietary Salt Reductions on Future Cardiovascular Disease



A regulatory intervention designed to achieve a reduction in salt intake of 3 g per day would save 194,000 to 392,000 quality-adjusted life-years and \$ 10 billion to \$24 billion in health care cost annually.

Projected Annual Reductions in CVE Given a Dietary Salt Reduction of 3 g/ Day, According to Race, Gender, and Age

# Quando e quanto pagare i benefici del trattamento del paziente iperteso?

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Incremental cost-effectiveness ratio (ICER)\*:  
treated vs not treated

	Men	Women
Low risk aged 40-49 years	10315 €	9130 €
High risk aged 60-69 years	757 €	dominant strategy**

**Given the considerable costs of the program itself, any savings from avoiding long-term consequences of hypertension are likely to be offset, however.**

\*reported in Euros for the price year 2004  
and discounted at an annual rate of 3%

\*\* cost saving and more effective

# Linee guida e analisi di costo-efficacia

Country	Source (year)	Cost or cost-effectiveness discussed in guideline	CEA performed
Australia	National Heart Foundation (2008)	Mention of costs as a factor to consider for access to medications	No
Canada	Canadian Hypertension Society (2009)	No	No
Europe	European Societies of Hypertension/Cardiology	While cost listed as consideration when choosing treatment, “cost considerations never predominate over efficacy, tolerability and protection”	No
France	Haute Autorite’ de sante’ (2005)	Diuretics and BB highlighted as “not expensive”; diuretics noted to have lowest daily cost	No
International	WHO/International Society of Hypertension (2003)	Implicit dominance of diuretics based on comparative trial data (similar effectiveness) and lower cost. Specific discussion regarding CE: more costly drugs may be cost-effective in selected patients populations	No
Japan	Japanese Society of Hypertension (2009)	Thiazide diuretics described as “inexpensive, to the advantage of pharmaco-economics”	No
United Kingdom	NCCCC (funded by NICE for NHS) (2006)	Recommendations group had access to detailed health economic analysis, which was used in conjunction with other considerations to formulate guidelines	Yes – primary economic analysis performed
United States	JNC on Prevention, Detect., Evaluat., and Treat. of High BP (2003)	Minimizing patient cost described as strategy to optimize control and minimize economic barriers. Implicit dominance of diuretics based on clinical trial data and lower drug costs.	No

# Does preventive care save money?

## Health economics and the presidential candidates

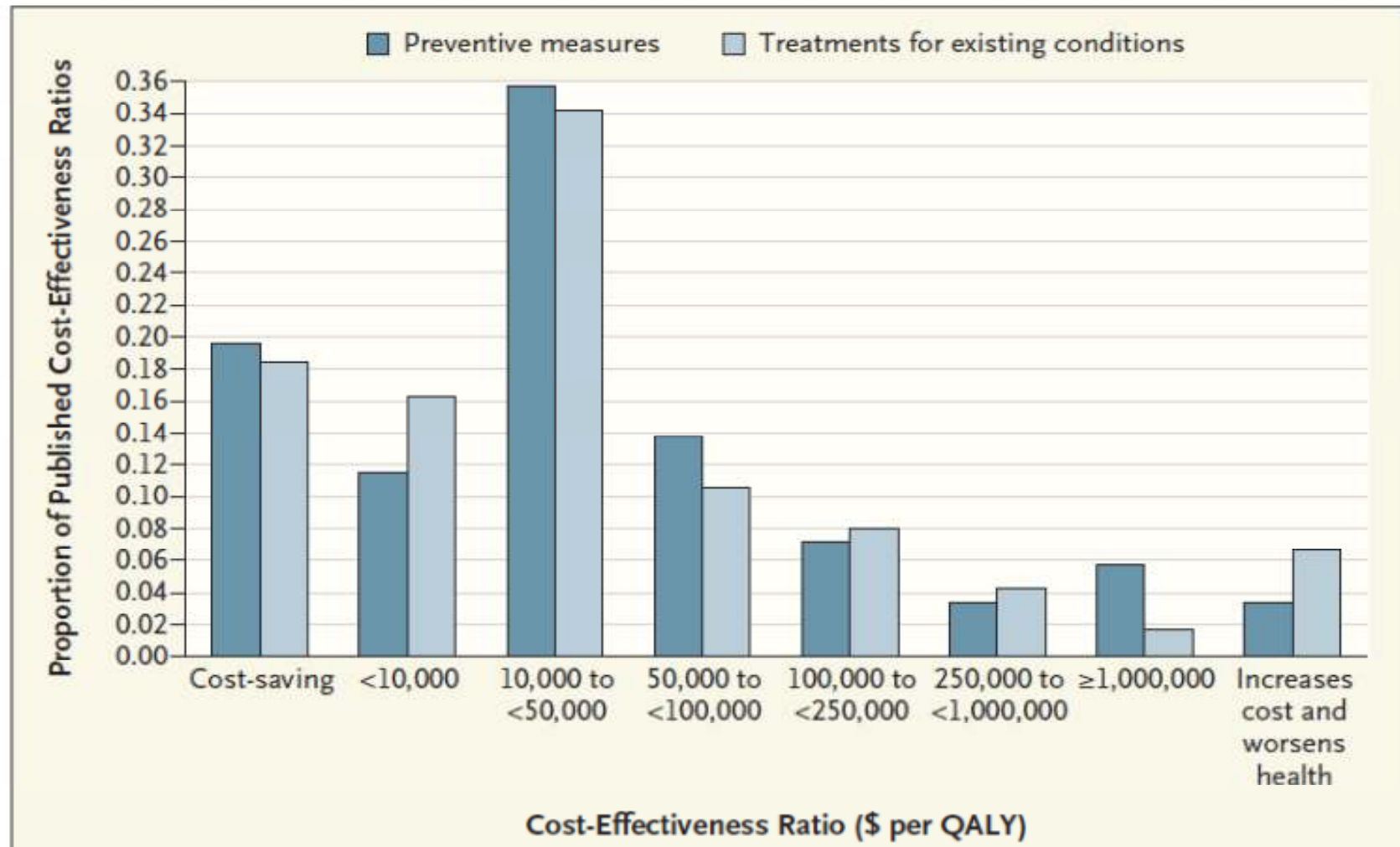
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Analisi condotta su 559 articoli pubblicati fra il 2000 ed il 2005. E' stato valutato il "cost/effectiveness ratio" che calcolato come il rapporto fra costi incrementali e l'incremento in salute quantificato in QALYs.

- 279 "ratio" classificati come valutazione di interventi in prevenzione primaria (finalizzati ad impedire la comparsa di malattia o di danno d'organo)
- 1221 "ratio" classificati come valutazione di interventi in prevenzione secondaria (finalizzati a fare regredire o a rallentare la progressione di uno stato clinico già presente) o in prevenzione terziaria (finalizzati a migliorare le condizioni cliniche in uno stato clinico o malattia conclamati)

# Does preventive care save money?

## Health economics and the presidential candidates



Distribution of Cost-Effectiveness Ratios for Preventive Measures and Treatments for Existing Conditions.

Data are from the Tufts–New England Medical Center Cost-Effectiveness Registry. QALY denotes quality-adjusted life-year.

# Due considerazioni

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## **Comparing Cost-Effectiveness Analyses of Anti-Hypertensive Drug Therapy for Decision Making: Mission Impossible?**

Mullins CD et al. 2002

The methodology used to measure effectiveness, the cost variables included, and the characteristics of the patient population varied significantly across studies. Due to this lack of conformity, it would be difficult, if not impossible, to compare the results and draw conclusions about the relative cost-effectiveness of different types of antihypertensive drug therapies.

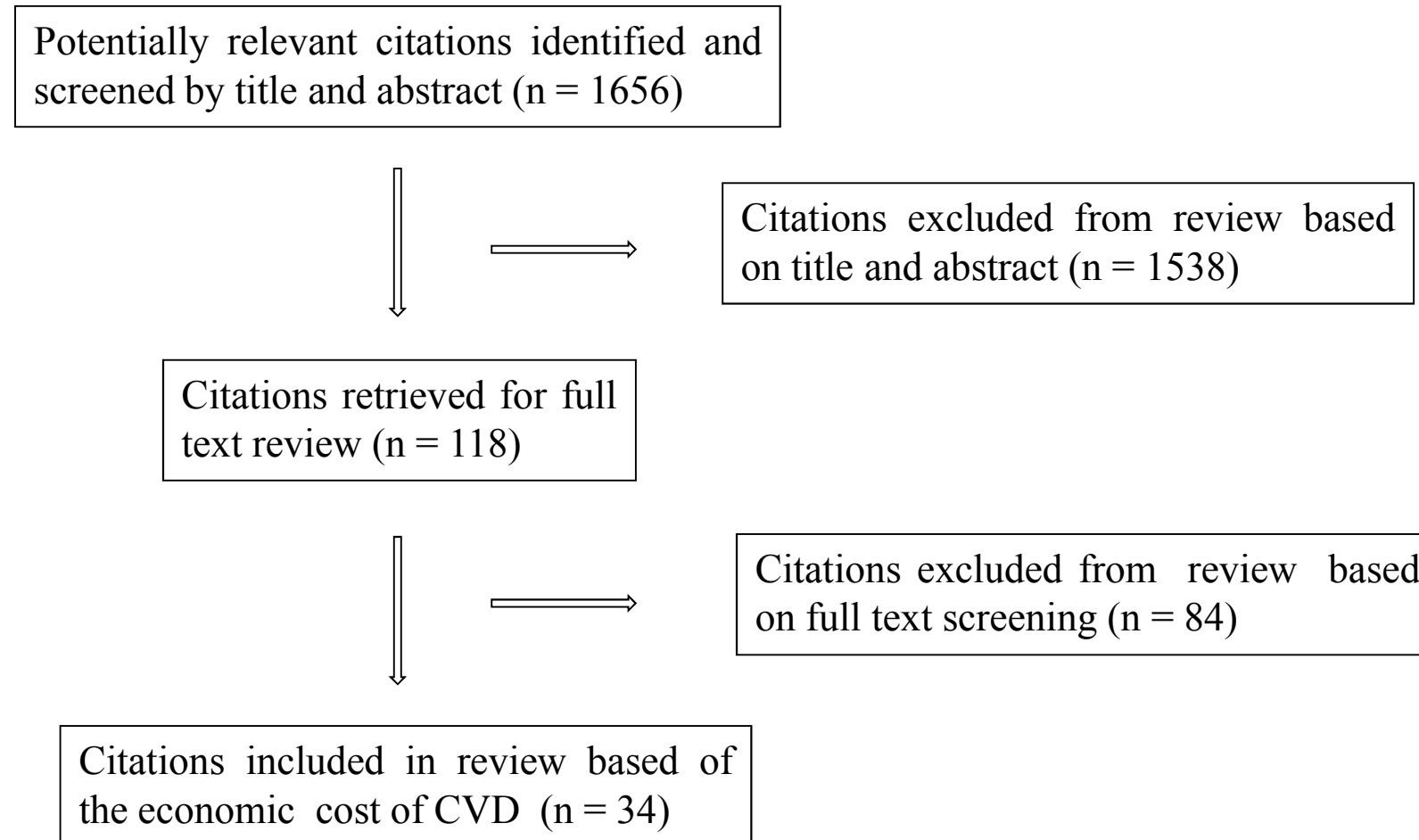
## **Effectiveness, safety and cost of drug substitution in hypertension**

Johnston A et al. 2010

In an ideal world, the question of whether the potential costs of drug substitution in hypertension are outweighed by its benefits would be investigated by randomized controlled trials before such policies are recommended for wide application in clinical practice. However, real-world observational studies and patient databases can also provide useful information on the possible impact of switching medications. Although the cost of treatment should always be considered, such considerations should not predominate over effectiveness and tolerability issues in any individual patient.

# A review of the cost of cardiovascular disease

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# A review of the cost of cardiovascular disease

Potentially relevant citations identified and screened by title and abstract (n = 1656)

Cost of illness of	Country							
	Usa n	Canada n	Europe n	UK n	Italy n	Finland n	Germany n	Australia n
cardiovascular disease	5	1	1					
stroke	2	3	3				1	1
hypertension	5	1			2	1		
heart failure	2							
various CAD	4	1	2	2				

Citations included in review based of the economic cost of CVD (n = 34)

# Il costo di malattia

Analisi  
verticale per  
centro di costo

<i>pazient i</i>	<i>n</i>	<i>farmac i</i>	<i>visite</i>	<i>ricoveri ospedalieri</i>	<i>accertament i</i>	<i>altro</i>	<i>costo medio paziente</i>	<i>costo totale</i>
<i>N - N</i>	<i>352</i>	<i>307.5</i>	<i>160.2</i>	<i>114.1</i>	<i>102.8</i>	<i>38.6</i>	<i>723.2</i>	<i>254566</i>
<i>N - I</i>	<i>200</i>	<i>326.3</i>	<i>166.6</i>	<i>46.9</i>	<i>100.2</i>	<i>38.9</i>	<i>678.9</i>	<i>135780</i>
<i>I - N</i>	<i>323</i>	<i>361.1</i>	<i>159.2</i>	<i>167.1</i>	<i>99.4</i>	<i>34.9</i>	<i>826.2</i>	<i>266862</i>
<i>I - I</i>	<i>776</i>	<i>393.5</i>	<i>171.2</i>	<i>112.5</i>	<i>99.1</i>	<i>35.5</i>	<i>811.8</i>	<i>629956</i>
<i>Totale</i>	<i>1651</i>	<i>595491</i>	<i>273983</i>	<i>190816</i>	<i>165223</i>	<i>61641</i>		<i>1287164</i>

Analisi  
longitudinale  
per paziente