Farmaci Innovativi e Medicina Generale

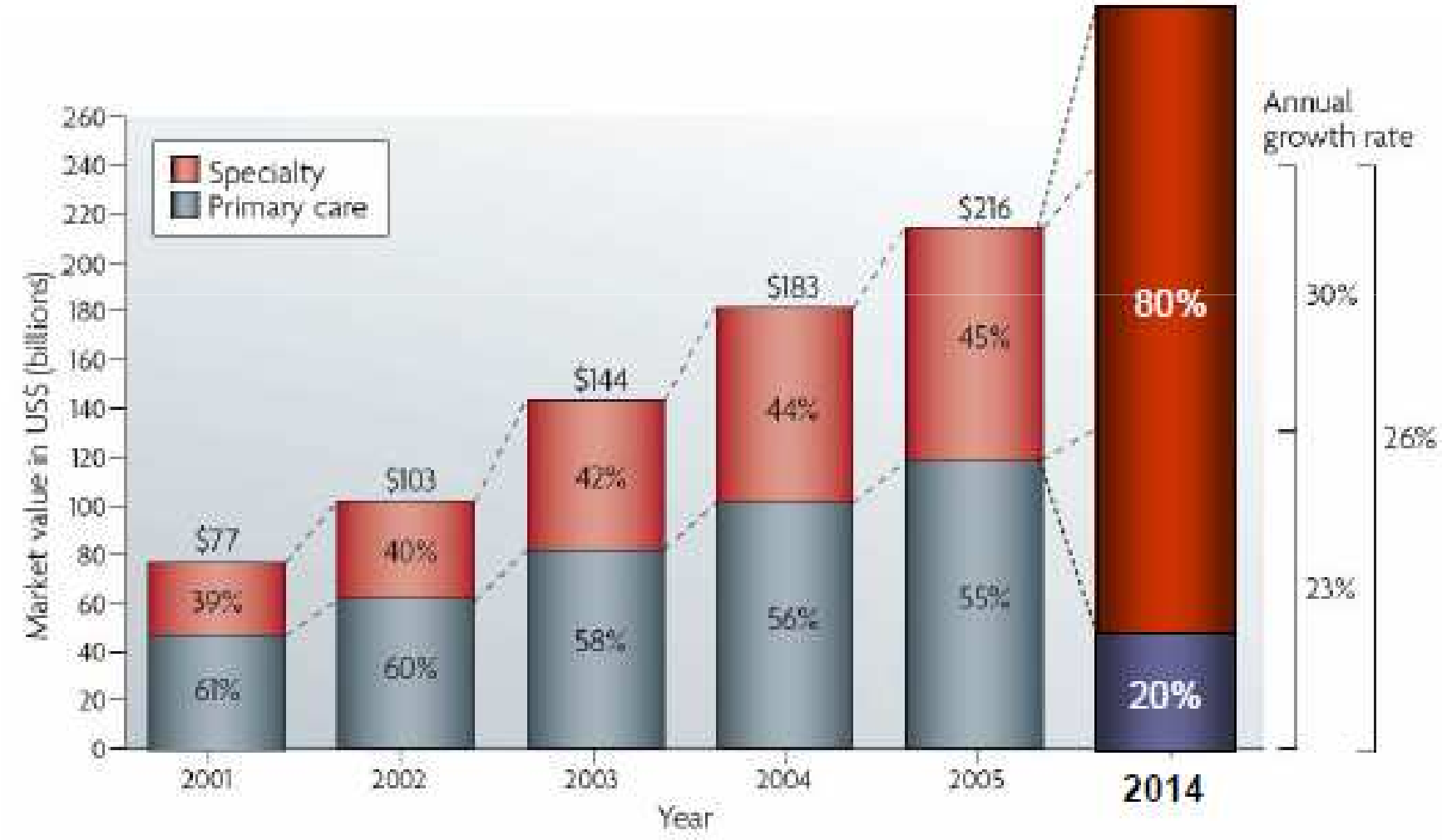
Roma 9 ottobre 2009

Claudio Cricelli
Presidente
Società Italiana Medicina Generale

Quale innovazione possiamo permetterci

- I Bisogni della popolazioni
- Quali sono le priorità del sistema
- Come allocare le risorse
- A chi affidare le risorse
- Come verficare il buon uso delle risorse
- Come liberare risorse
- Come governare il sistema sanitario
- La governance del farmaco e la MG

Spesa Territoriale e specialistica



Sanità. Il bilancio dell'Aifa sui conti nel primo semestre 2009 conferma la frenata dei consumi in farmacia

Farmaci: spesa boom in ospedale

In sei mesi rosso di 900 milioni - Il deficit tutto a carico delle regioni

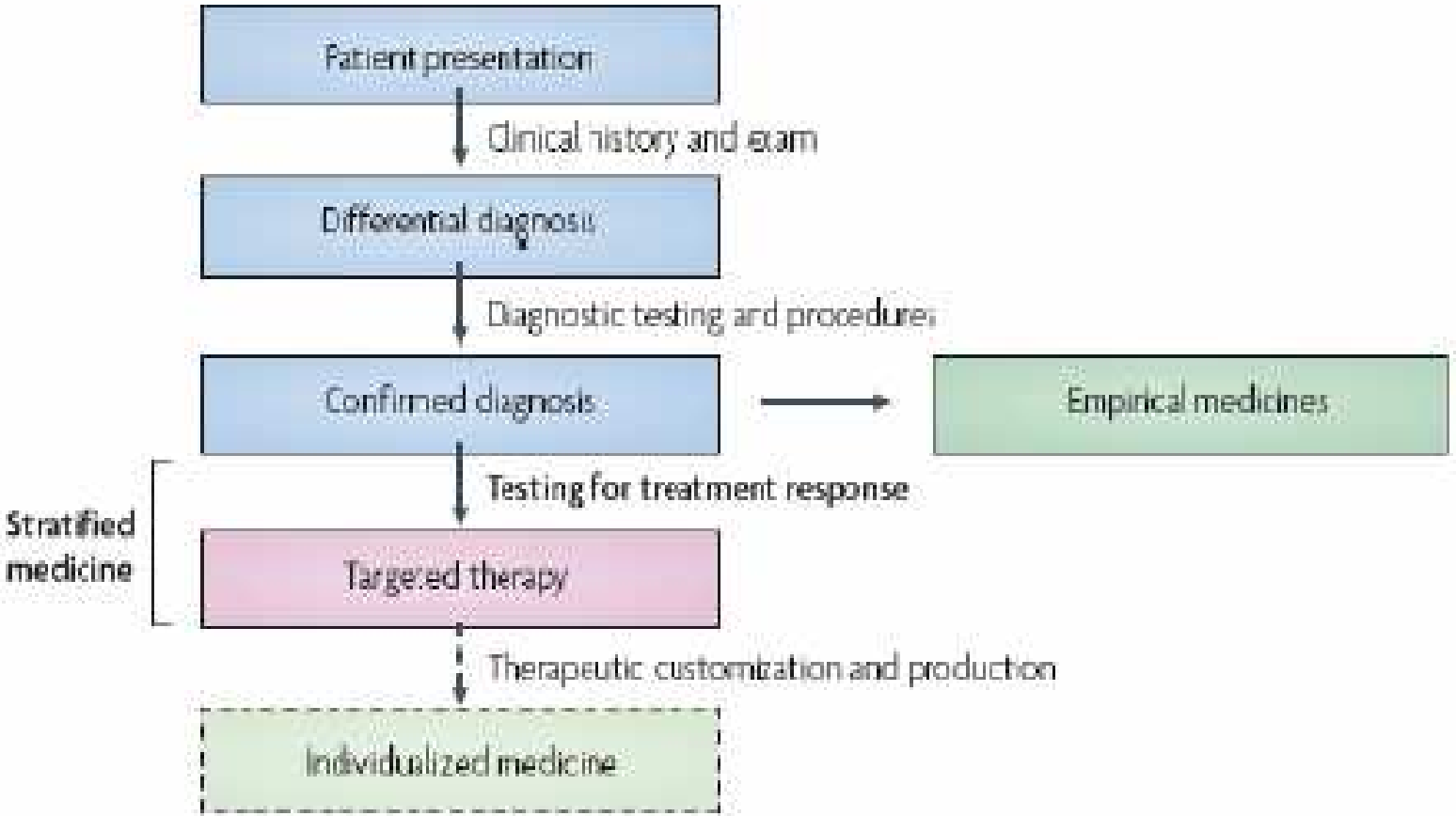


Figure 2 | **Stratified medicine in the clinical context.** In empirical medicine, a differential diagnosis is made on the basis of patient history and physical assessment, and following diagnosis confirmation from laboratory tests and clinical observation, a therapy is prescribed. Stratified medicine involves a further step in which a clinical biomarker is evaluated to associate a patient with a specific therapy. Extending this further, individualized medicine involves the customized production of the therapy (for example, using the patient's own cells).

Bisogni di Salute - Italia

Member State	Mortality			DALYs		
	Causes	Total deaths	% of total	Causes	Total DALYs	% of total
ITALY	All causes	570 710	100.0	All causes	6 789 291	100.0
	1. Ischaemic heart disease	92 928	16.3	1. Unipolar depressive disorders	464 873	6.8
	2. Cerebrovascular disease	69 075	12.1	2. Ischaemic heart disease	450 953	6.6
	3. Trachea, bronchus and lung cancer	32 114	5.6	3. Cerebrovascular disease	385 564	5.7
	4. Hypertensive heart disease	20 566	3.6	4. Alzheimer's and other dementias	304 193	4.5
	5. Chronic obstructive pulmonary disease	20 042	3.5	5. Hearing loss, adult onset	272 459	4.0
	6. Diabetes mellitus	19 335	3.4	6. Diabetes mellitus	253 447	3.7
	7. Colon and rectum cancer	17 875	3.1	7. Trachea bronchus lung cancers	238 299	3.5
	8. Lower respiratory infections	14 604	2.6	8. Alcohol-use disorders	227 530	3.4
	9. Alzheimer's and other dementias	13 627	2.4	9. Road-traffic accidents	182 555	2.7
	10. Breast cancer	11 625	2.0	10. Osteoarthritis	177 068	2.6

Member State	Deaths		DALYs	
	Risk factor	% of total	Risk factor	% of total
ITALY	1. High blood pressure	21.7	1. Tobacco	12.0
	2. Tobacco	18.8	2. High blood pressure	8.9
	3. High cholesterol	11.1	3. High BMI	8.4
	4. High BMI	10.0	4. Alcohol	5.9
	5. Physical inactivity	5.6	5. High cholesterol	5.7
	6. Low fruit and vegetable intake	3.5	6. Physical inactivity	3.
	7. Unsafe sex	0.6	7. Illicit drugs	2.2
	8. Alcohol	0.6	8. Low fruit and vegetable intake	2.0
	9. Urban outdoor air pollution	0.6	9. Unsafe sex	1.
	10. Occupational airborne particulate matter	0.5	10. Iron deficiency	0.6

Bisogni di Salute Globale - 2030

OPEN ACCESS Freely available online PLOS MEDICINE

Projections of Global Mortality and Burden of Disease from 2002 to 2030

Colin D. Mathers*, Dejan Loncar

Evidence and Information for Policy Cluster, World Health Organization, Geneva, Switzerland

Table 5. Changes in Rankings for 15 Leading Causes of DALYs, 2002 and 2030 (Baseline Scenario)

Category	Disease or Injury	2002 Rank	2030 Ranks	Change in Rank
Within top 15	Perinatal conditions	1	5	−4
	Lower respiratory infections	2	8	−6
	HIV/AIDS	3	1	+2
	Unipolar depressive disorders	4	2	+2
	Diarrhoeal diseases	5	12	−7
	Ischaemic heart disease	6	3	+3
	Cerebrovascular disease	7	6	+1
	Road traffic accidents	8	4	+4
	Malaria	9	15	−6
	Tuberculosis	10	25	−15
	COPD	11	7	+4
	Congenital anomalies	12	20	−8
	Hearing loss, adult onset	13	9	+4
	Cataracts	14	10	+4
	Violence	15	13	+2
Outside top 15	Self-inflicted injuries	17	14	+3
	Diabetes mellitus	20	11	+9

doi: 10.1371/journal.pmed.0030442.t005

Progettazione della Innovazione

- **Indicazioni**
  - bisogni assoluti
  - bisogni residuali
- **Popolazioni**
  - selezionate
- **Variabili di Esito**
  - rilevanti
- **Confronti**
  - terapia di riferimento
  - superiorità

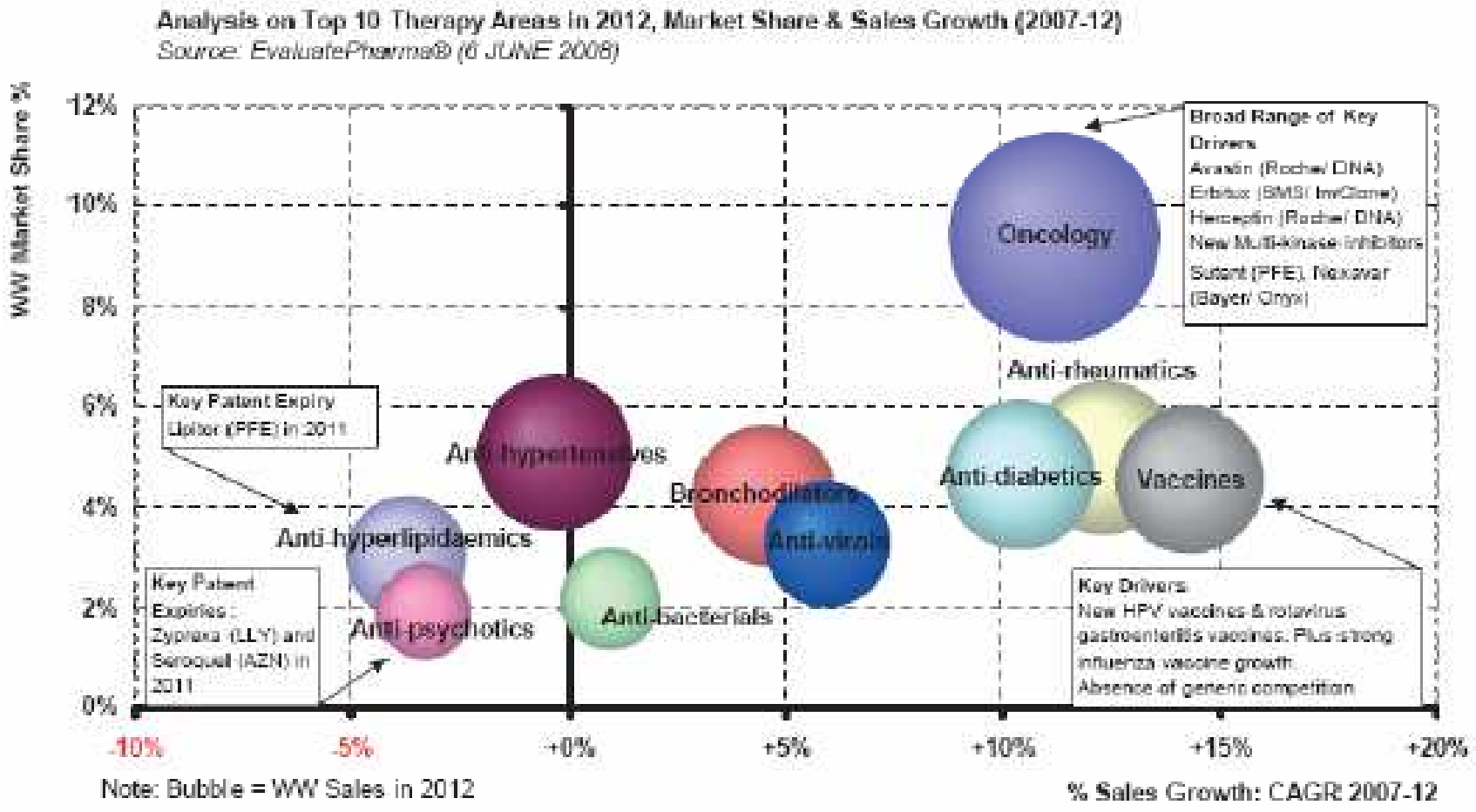

Pharmaceutical Executive

Advancing business leadership

europe

Beyond the Blockbuster: What Can Big Pharma Learn from Mid-tier and Specialty Pharma?

Innovazione ed Evoluzione della Terapia



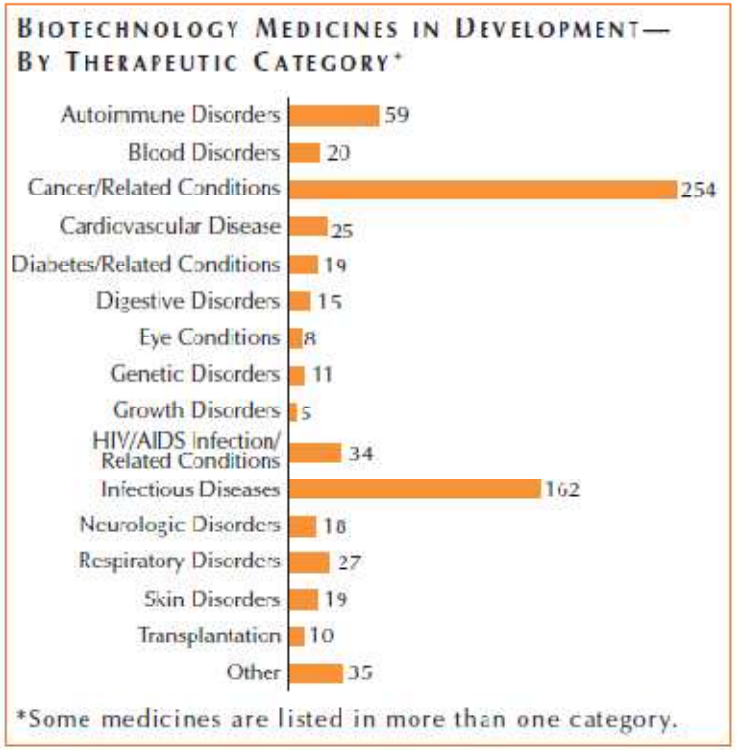
World Preview 2012

La Ricerca Del Farmaco

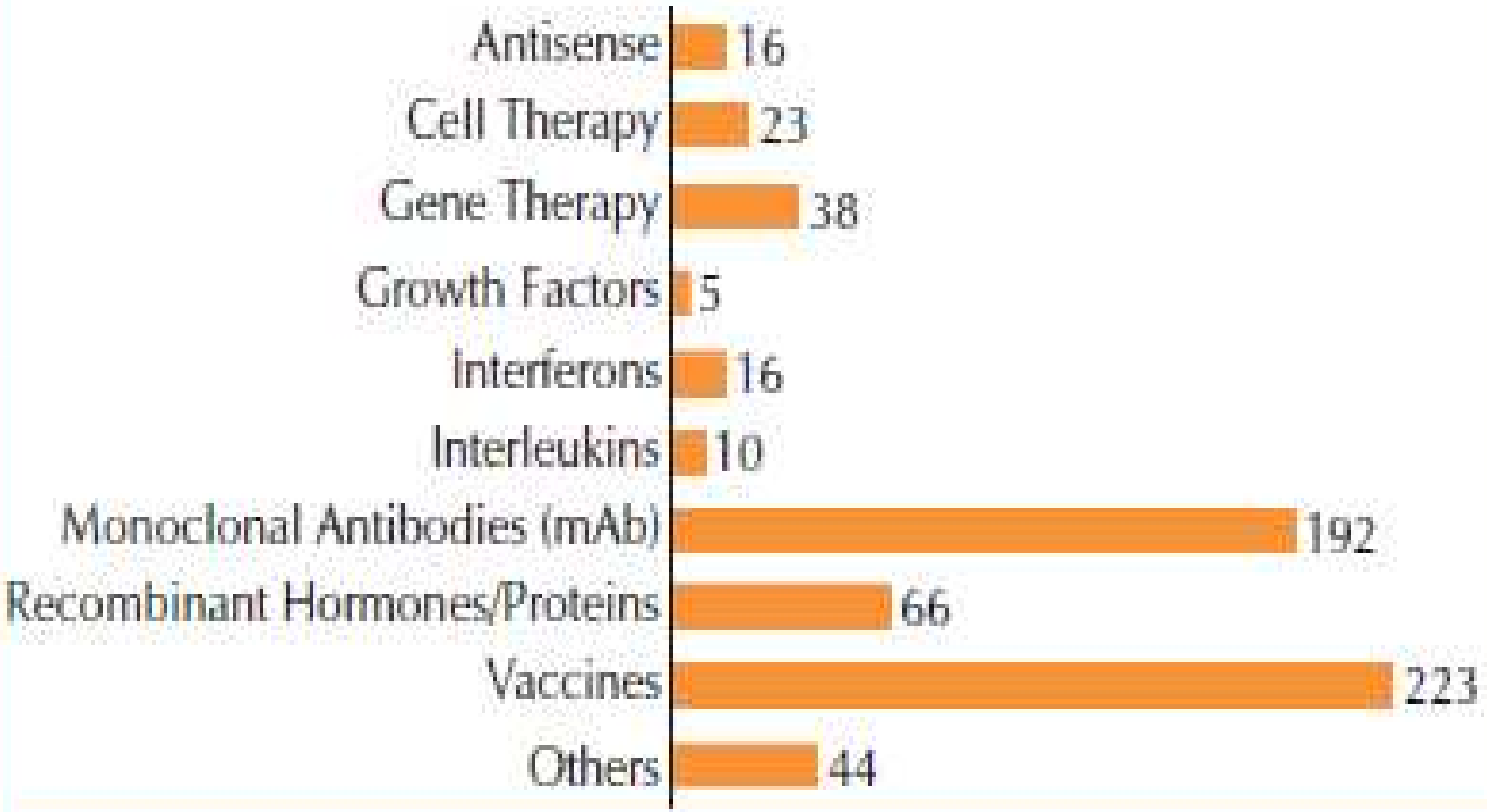
Biotechnology Research Continues to Bolster Arsenal Against Disease with 633 Medicines in Development

Millions of people have already benefited from medicines and vaccines developed through biotechnology, and a new report offers hope that in the future many more will benefit. The report found 633 biotechnology medicines in development for more than 100 diseases. These include 254 medicines for cancer, 162 for infectious diseases, 59 for autoimmune diseases, and 34 for HIV/AIDS and related conditions. These potential medicines are either in human clinical trials or under review by the Food and Drug Administration.

Approved biotechnology medicines already treat or help prevent heart attacks, stroke, multiple sclerosis, leukemia, hepatitis, rheumatoid arthritis, breast cancer, diabetes, congestive heart failure, lymphoma, kidney cancer, cystic fibrosis, and other diseases. These medicines rely on many cutting-edge technologies. For example, most early biotechnology medicines were protein drugs, produced by splicing genes into bacteria. They include recombinant insulin, human growth hormone, clotting factor for hemophilia patients, and erythropoietin to stimulate the production of red blood cells in kidney dialysis and cancer patients. Another type of biotechnology medicine, the monoclonal antibody,



Biotechnology Medicines in Development—By Product Category



The show's corresponding Web site, *www.sharingmiracles.com*, is an interactive forum for people to relate their own personal stories of hope and survival. Every patient's battle is unique, but the collective power of shared experiences can offer great help and courage to others who are fighting for their lives.

You can find out where *Sharing Miracles* is showing in your area and order free DVDs of the show on the web site or by calling 202-835-3460.

SHARING MIRACLES

Seven major socio-economic trends.

The burden of chronic disease is soaring.

The prevalence of chronic diseases like diabetes is growing everywhere. As greater longevity forces many countries to lift the retirement age, more people will still be working at the point at which these diseases start. The social and economic value of treatments for chronic diseases will rise accordingly, but Pharma will have to reduce its prices and rely on volume sales of such products because many countries will otherwise be unable to afford them.

Healthcare policy-makers and payers are increasingly mandating wha doctors can prescribe.

As treatment protocols replace individual prescribing decisions, Pharma's target audience is also becoming more consolidated and more powerful, with profound implications for its sales and marketing model. The industry will have to work much harder for its dollars, collaborate with healthcare payers and providers, and improve patient compliance.

Pay-for-performance The boundaries between different forms of healthcare are blurring.

Pay-for-performance is on the rise.

A growing number of healthcare payers are measuring the pharmacoeconomic performance of different medicines. Widespread adoption of electronic medical records will give them the outcomes data they need to determine best medical practice, eschew products that are more expensive or less effective than comparable therapies and pay for treatments based on the outcomes they deliver. So Pharma will have to prove that its medicines really work, provide value for money and are better than alternative forms of intervention.

The boundaries between different forms of healthcare are blurring.

The primary-care sector is expanding as clinical advances render previously fatal diseases chronic. The self-medication sector is also increasing as more prescription products are switched to over-the-counter status. The needs of patients are changing accordingly. Where treatment is migrating from the doctor to ancillary care or self-care, patients will require more comprehensive information. Where treatment is migrating from the hospital to the primary-care sector, patients will require new services such as home delivery.

The markets of the developing world, where demand for medicines is likely to grow most rapidly over the next 12 years, are highly varied.

Developing countries have very different clinical and economic characteristics, healthcare systems and attitudes towards the protection of intellectual property. Any company that wants to serve these markets successfully will therefore have to devise strategies that are tailored to their individual needs.

Many governments are beginning to focus on prevention rather than treatment, although they are not yet investing very much in pre-emptive measures.

This change of emphasis will enable Pharma to enter the realm of health management. But if it is to do so, it will have to rebuild its image, since healthcare professionals and patients will not trust the industry to provide such services unless they are sure it has their best interests at heart.

Avversione al rischio

The regulators are becoming more risk-averse.

The leading national and multinational agencies have become much more cautious about approving truly innovative medicines

Misurare la produttività in sanità in Italia:
un progetto basato su dati di MMG

A joint CEIS Tor Vergata – SIMG Foundation project

di

V. Atella*, C. Cricelli ,**

* CEIS Tor Vergata

** SIMG

*** SIMG Foundation

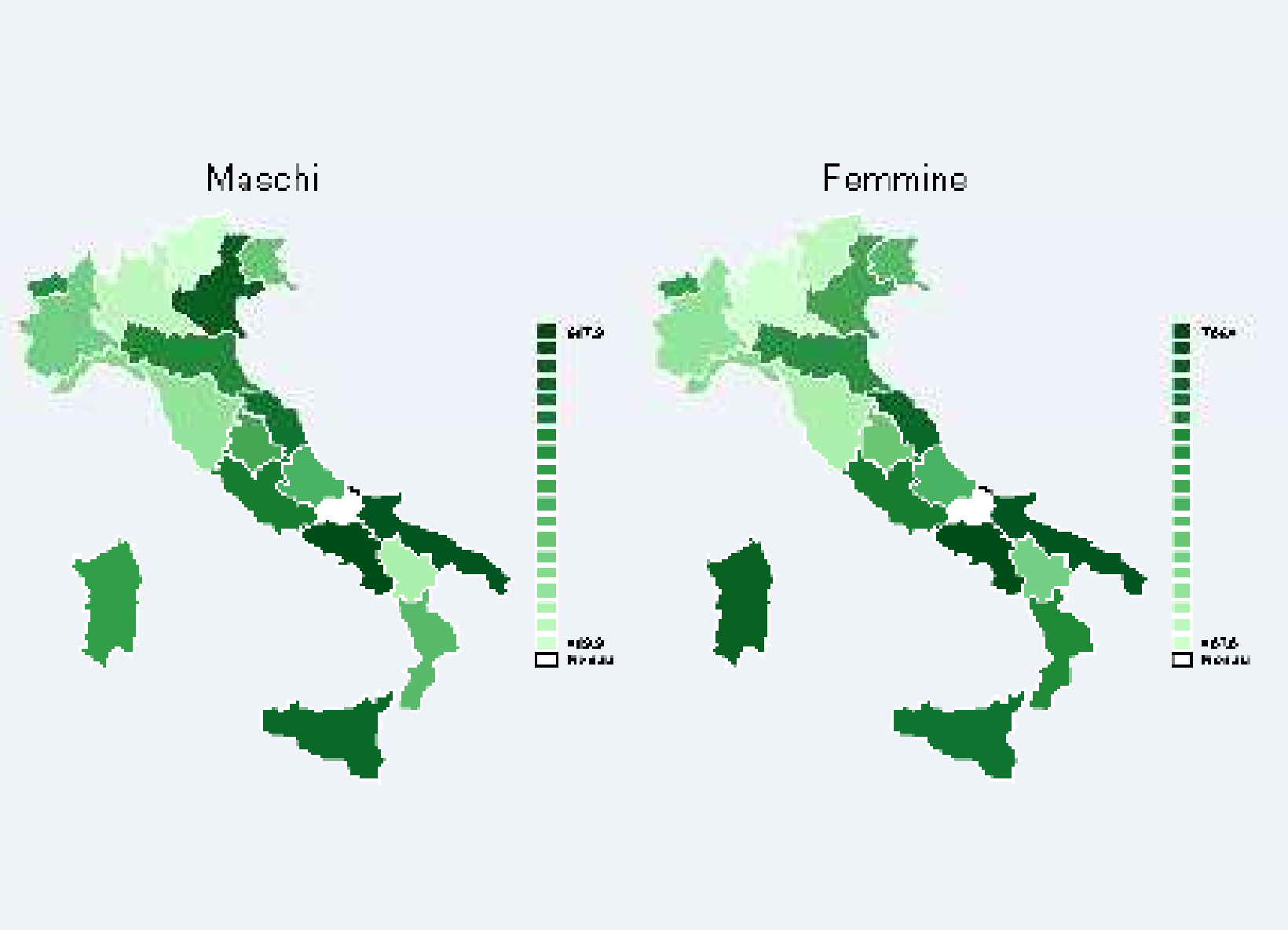
I risultati attesi dal modello

Avendo a disposizione dati raccolti a livello di singolo paziente nel tempo, si possono facilmente costruire:

- **Indici di prezzo e di quantità**
- **Indici del costo di trattamento**
- **Indici di Health Outcomes**
- **Indici di Costo-Efficacia** (∂health/∂inputs);
- **Indici di effetto di trattamento**

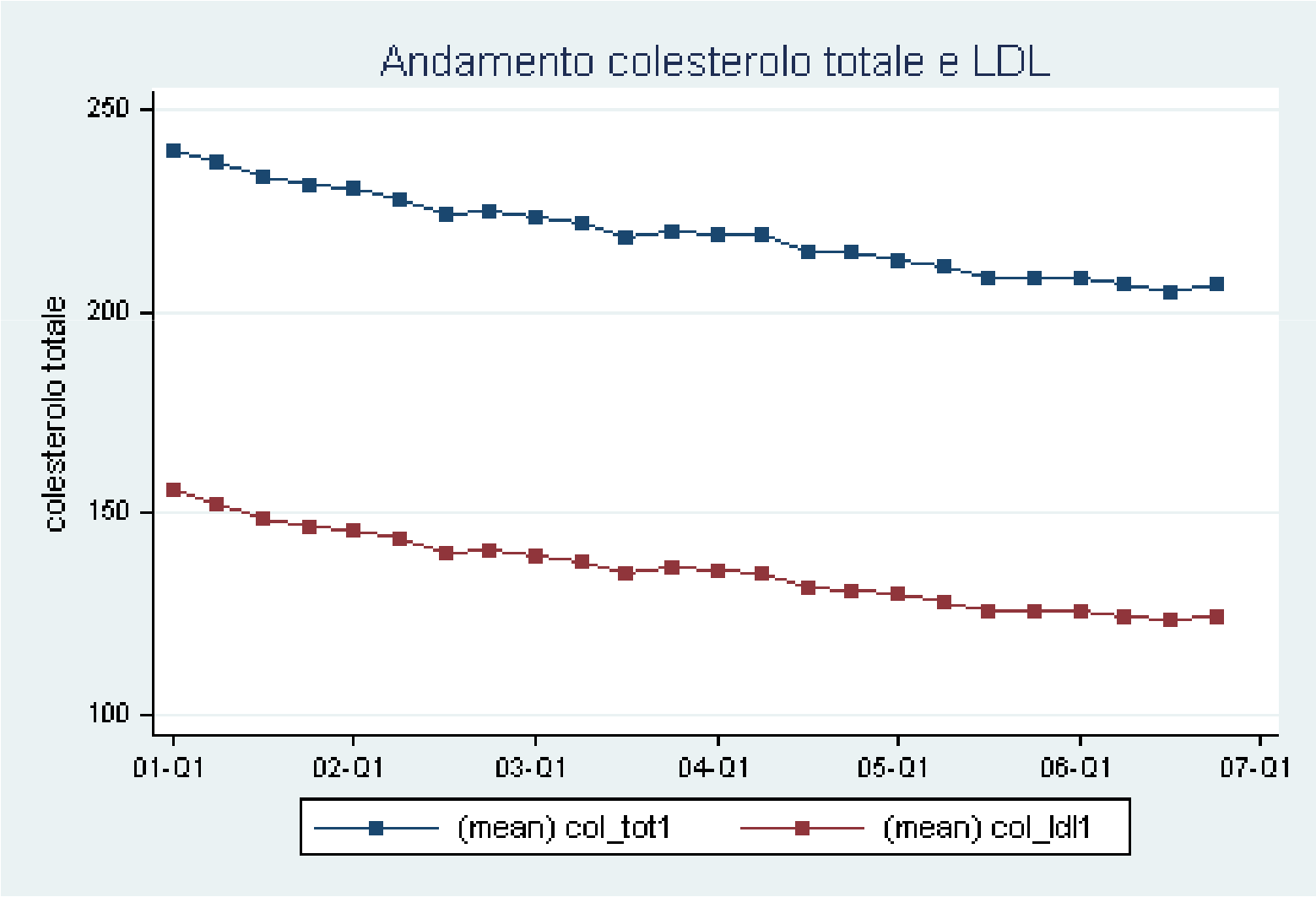
Tutti i suddetti indici possono essere prodotti per bene e servizio, gruppi di pazienti, MMG, sesso, età, regione, ASL, patologia, ed ogni possibile combinazione delle caratteristiche disponibili all'interno del dataset.

Costi Standard

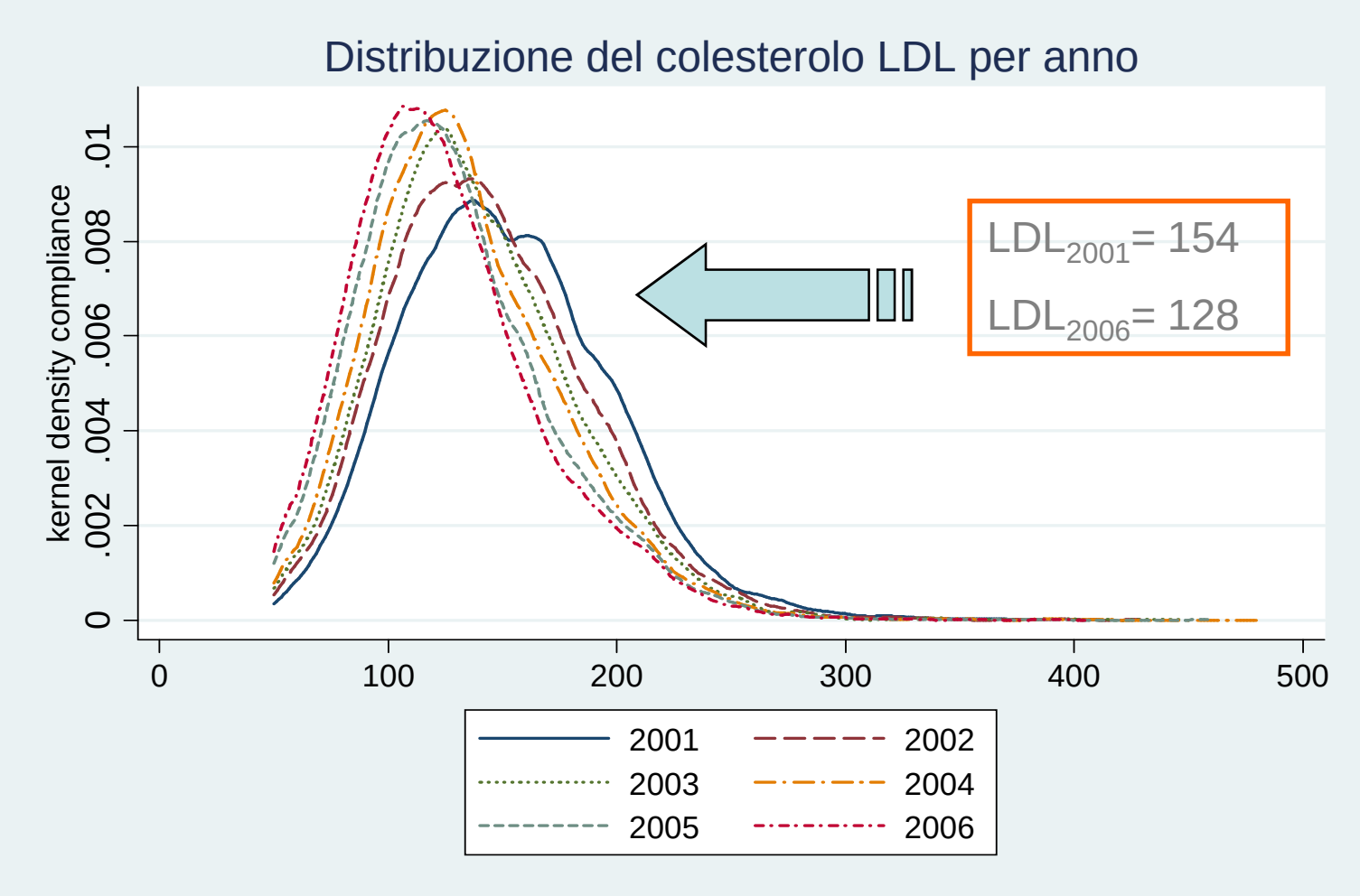


INDICATORI DI ESITO SANITARIO

Indicatori di esito sanitario:
Trend dei livelli di colesterolo (Totale e LDL) della popolazione italiana

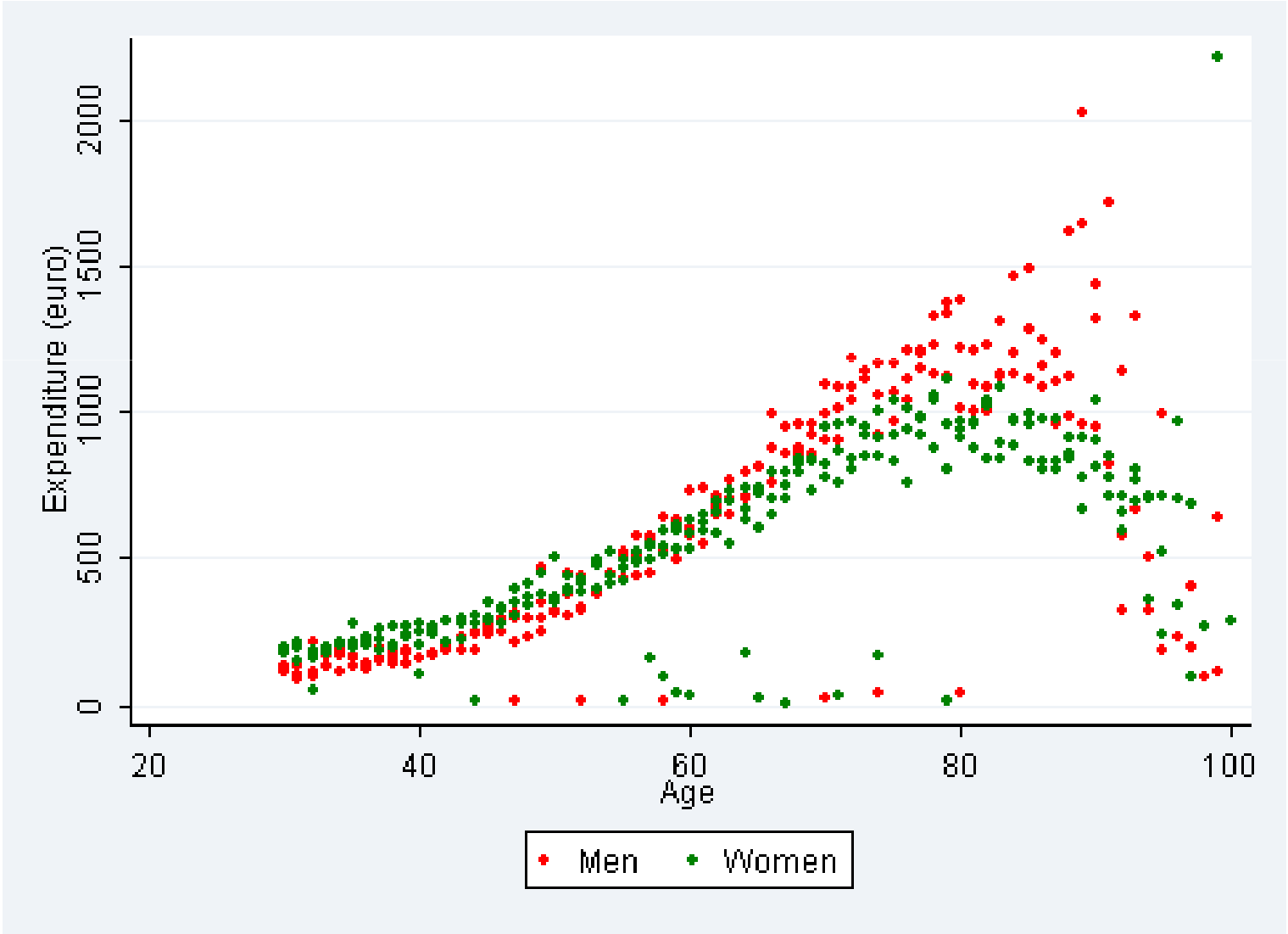


Indicatori di esito sanitario:
Distribuzione livelli del colesterolo LDL per anno

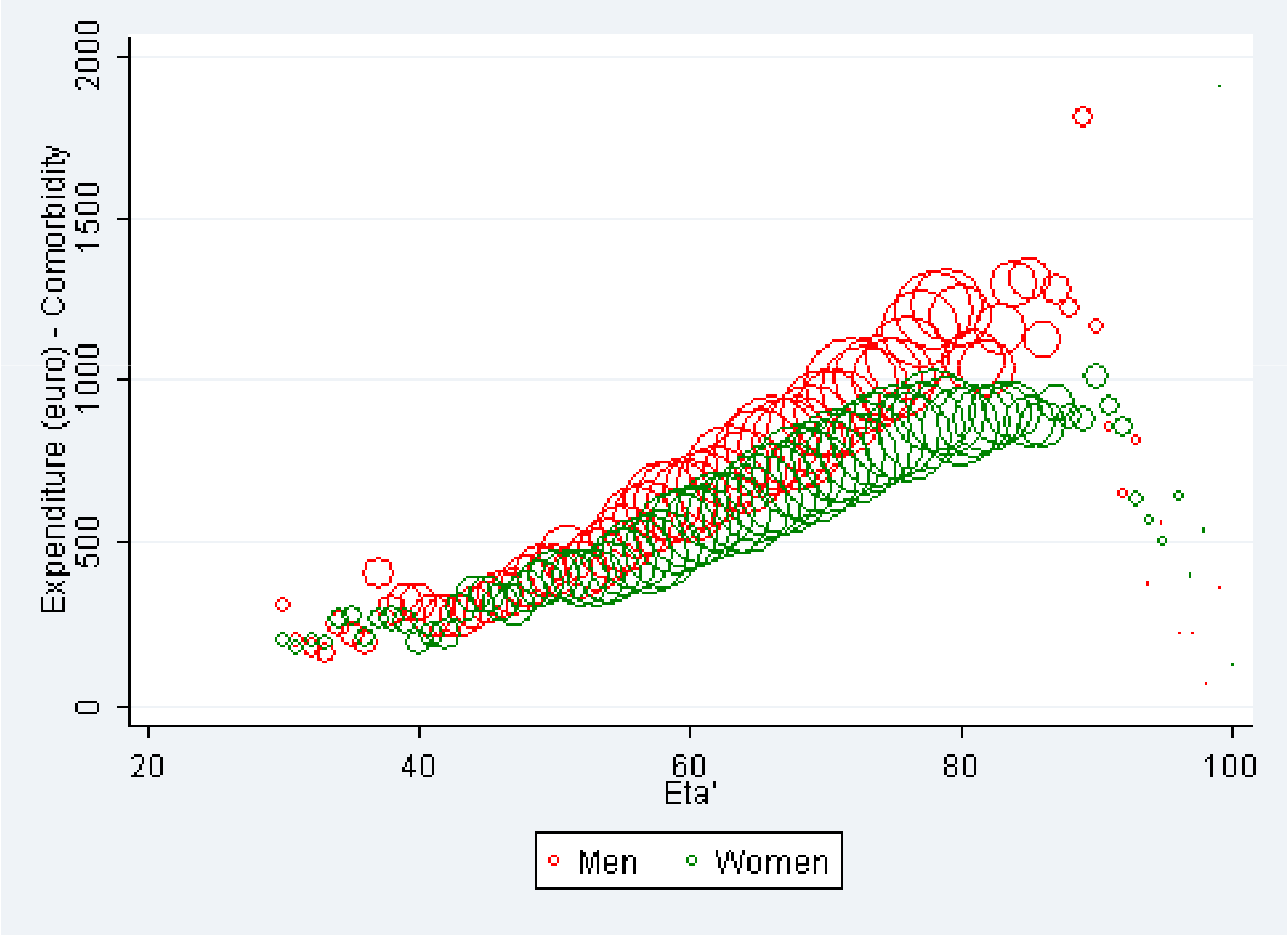


INDICATORI DI COSTO

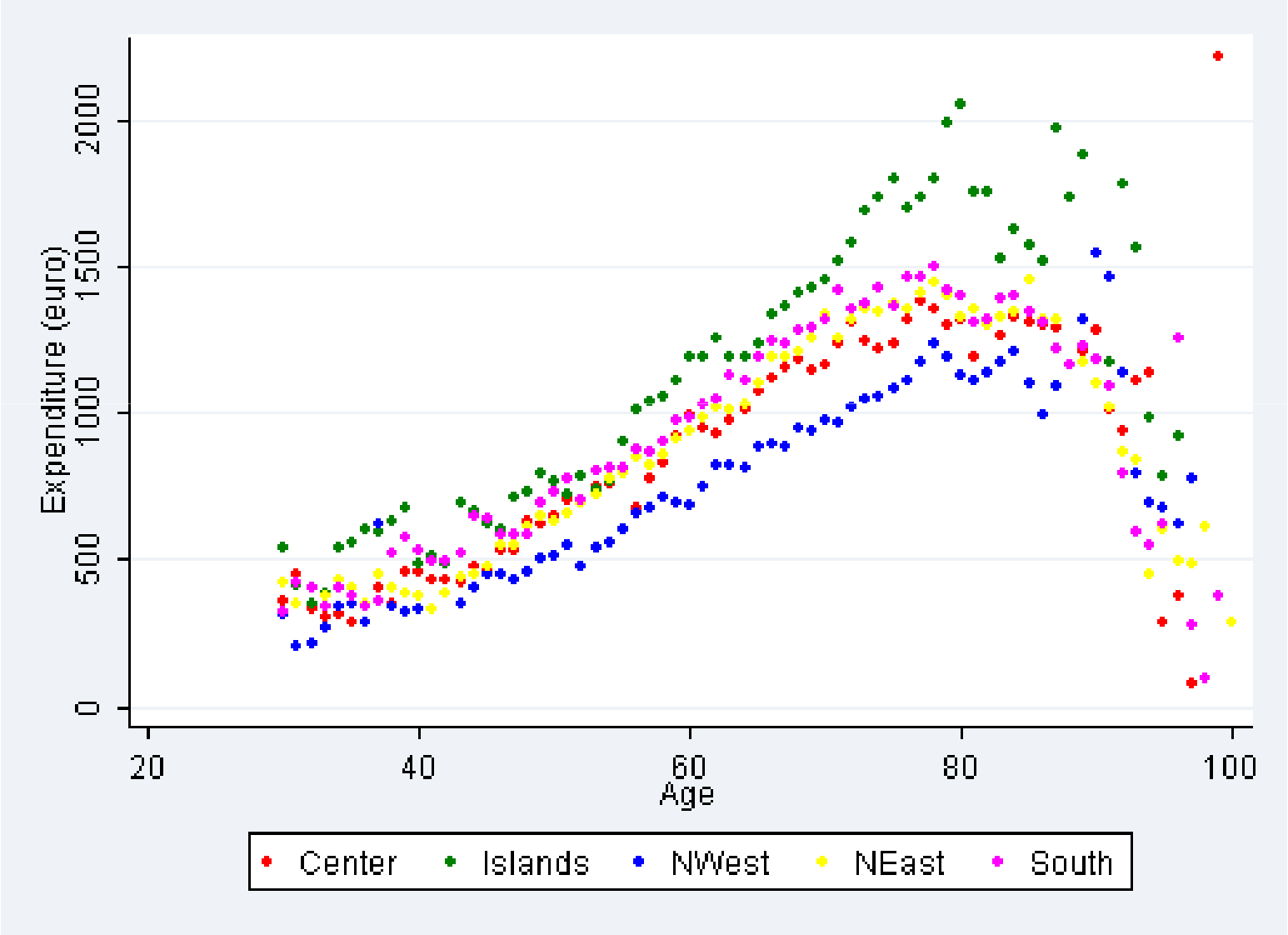
Costo annuale pro-capite per cura colesterolo (Colesterolo + comorbidità) per sesso



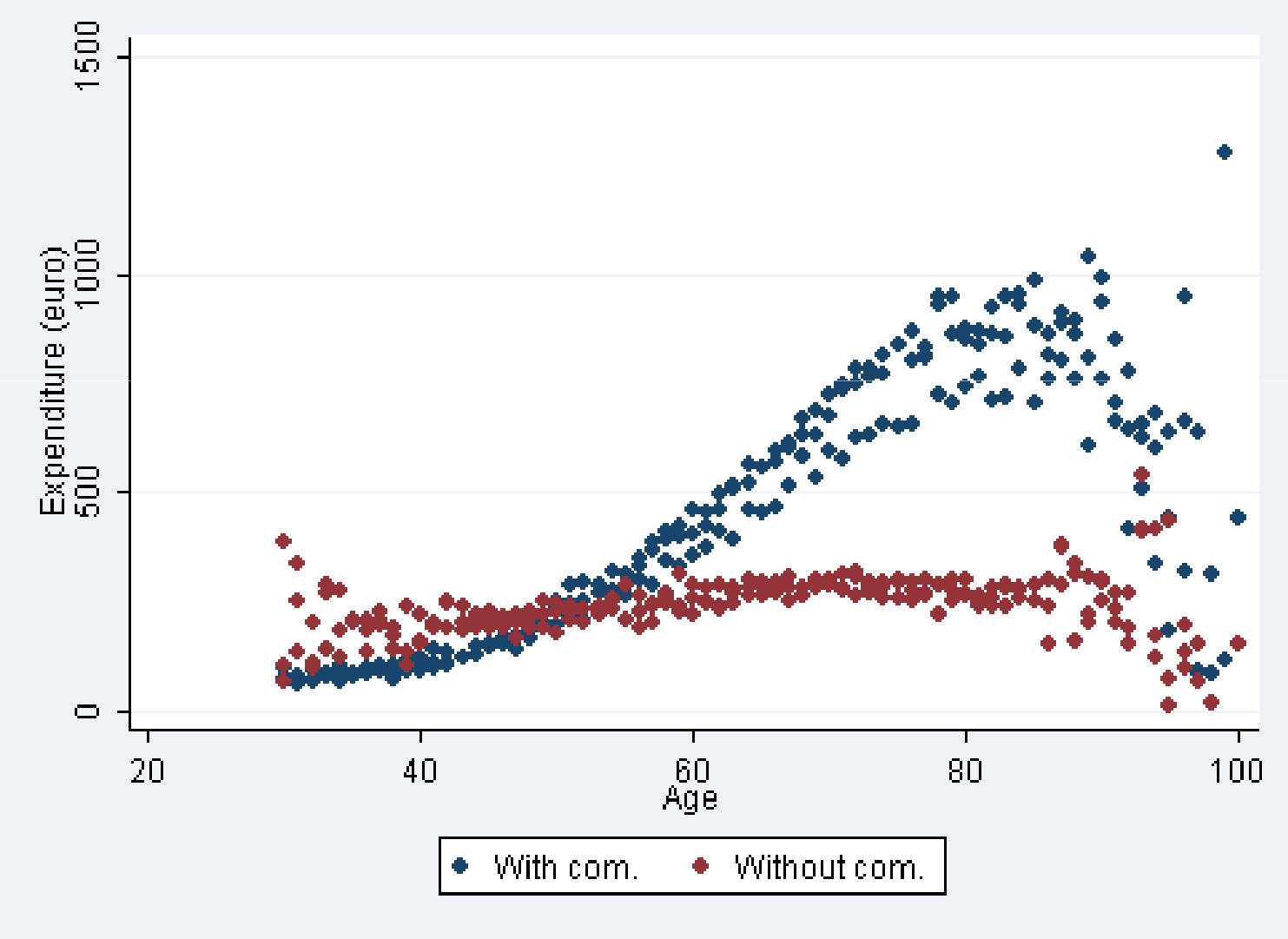
Costo annuale pro-capite per cura colesterolo (Colesterolo + comorbidità) per sesso e numerosità coorti



Costo annuale pro capite per cura colesterolo (patologia + comorbidità) per regione

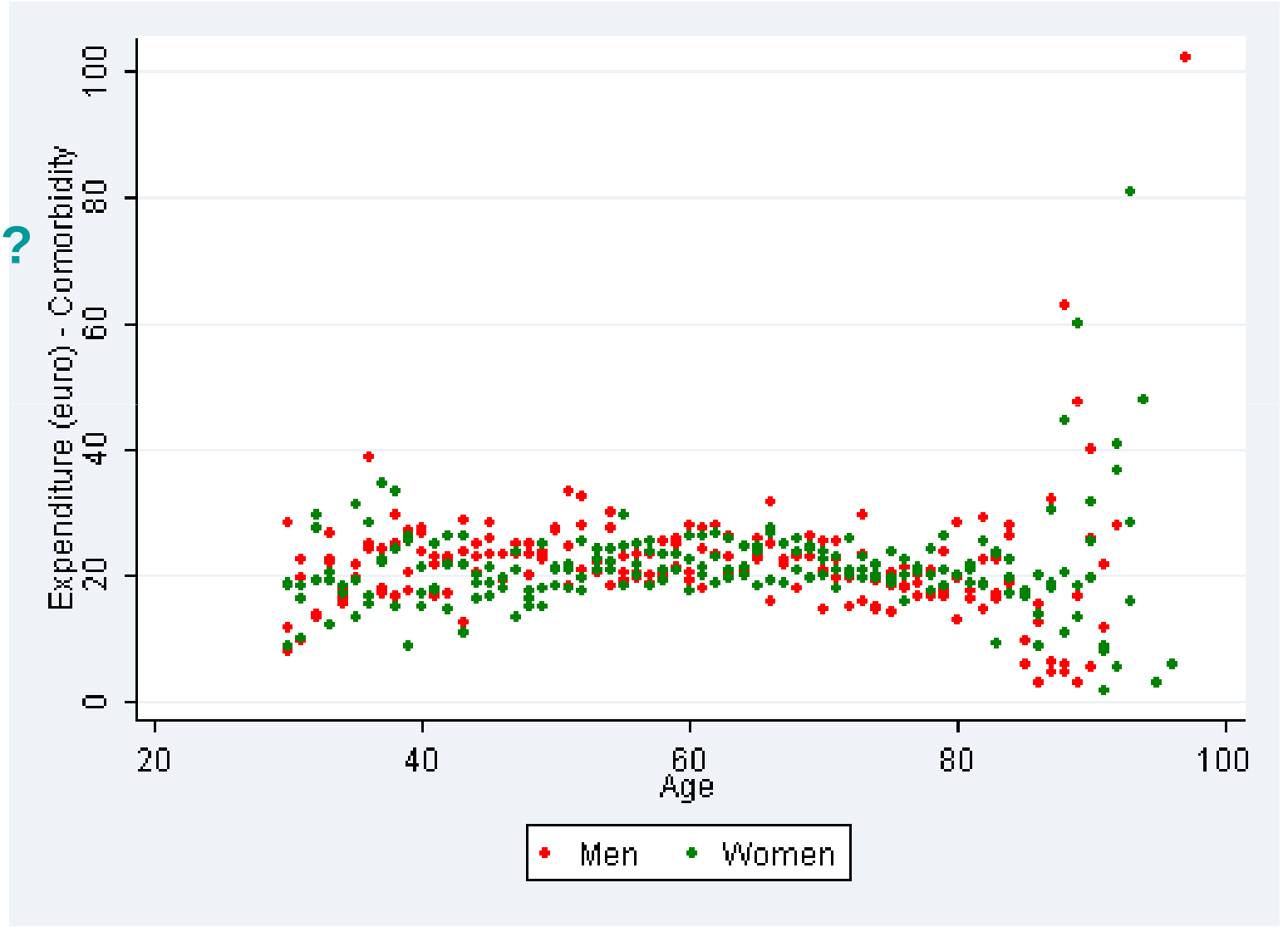


Costo annuale pro-capite per cura colesterolo (patologia e comorbidità)



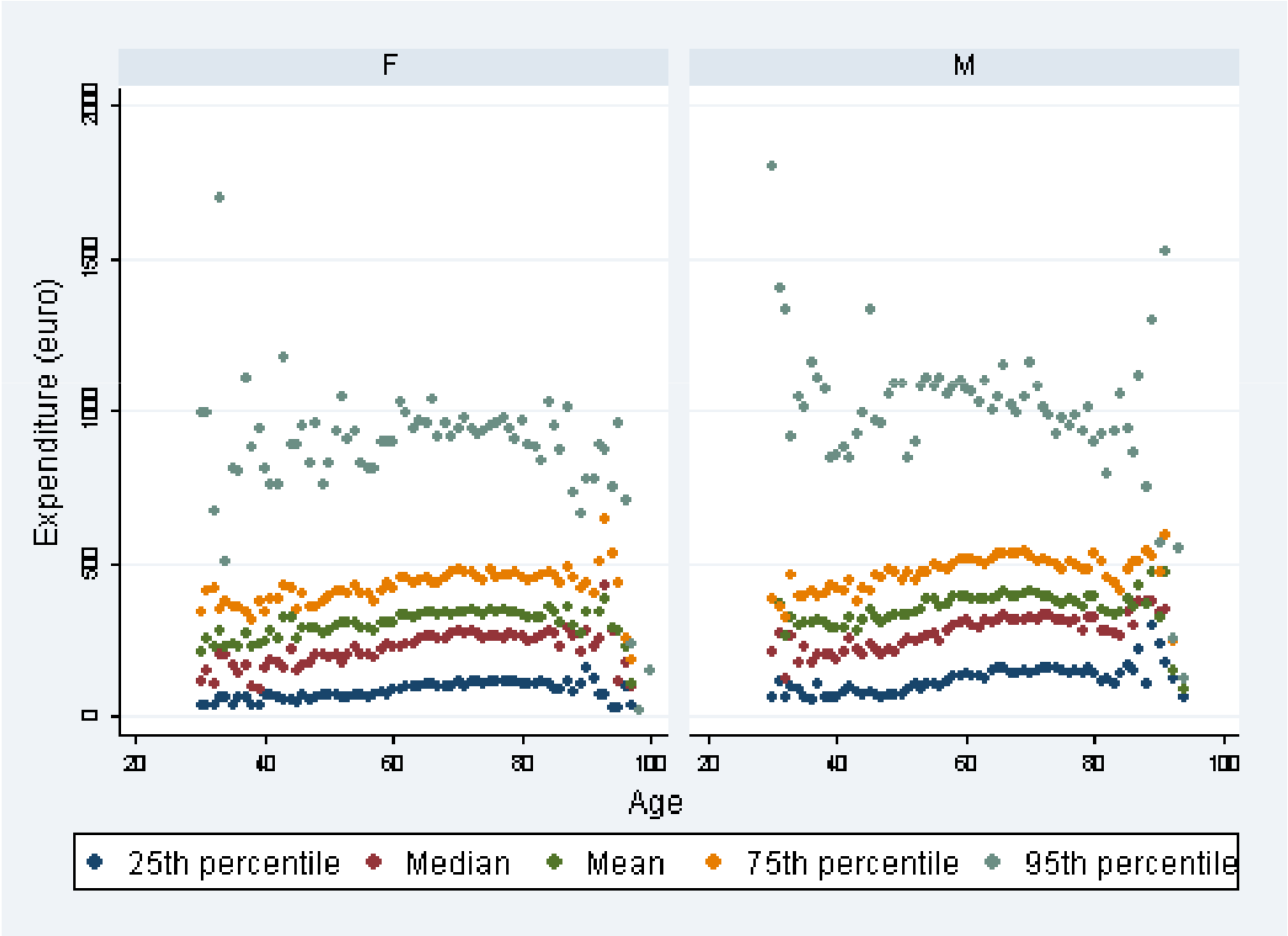
Costo annuale pro-capite per accertamenti legati al colesterolo (Colesterolo)

?

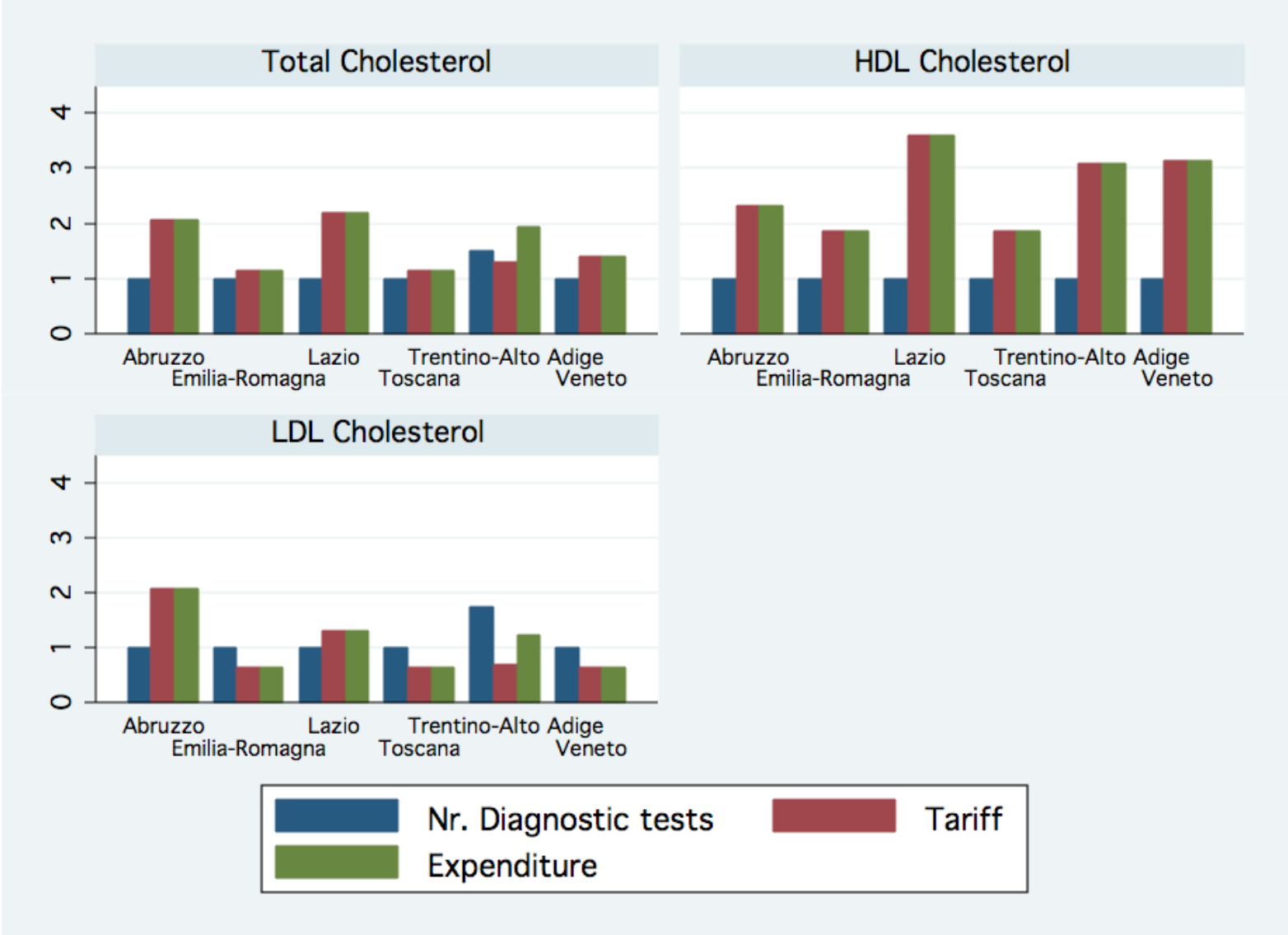


Distribuzione dei costi di cura Colesterolo

(Valori pro-capite annuali)



Test diagnostici, tariffe e spesa per regione e tipo di accertamento



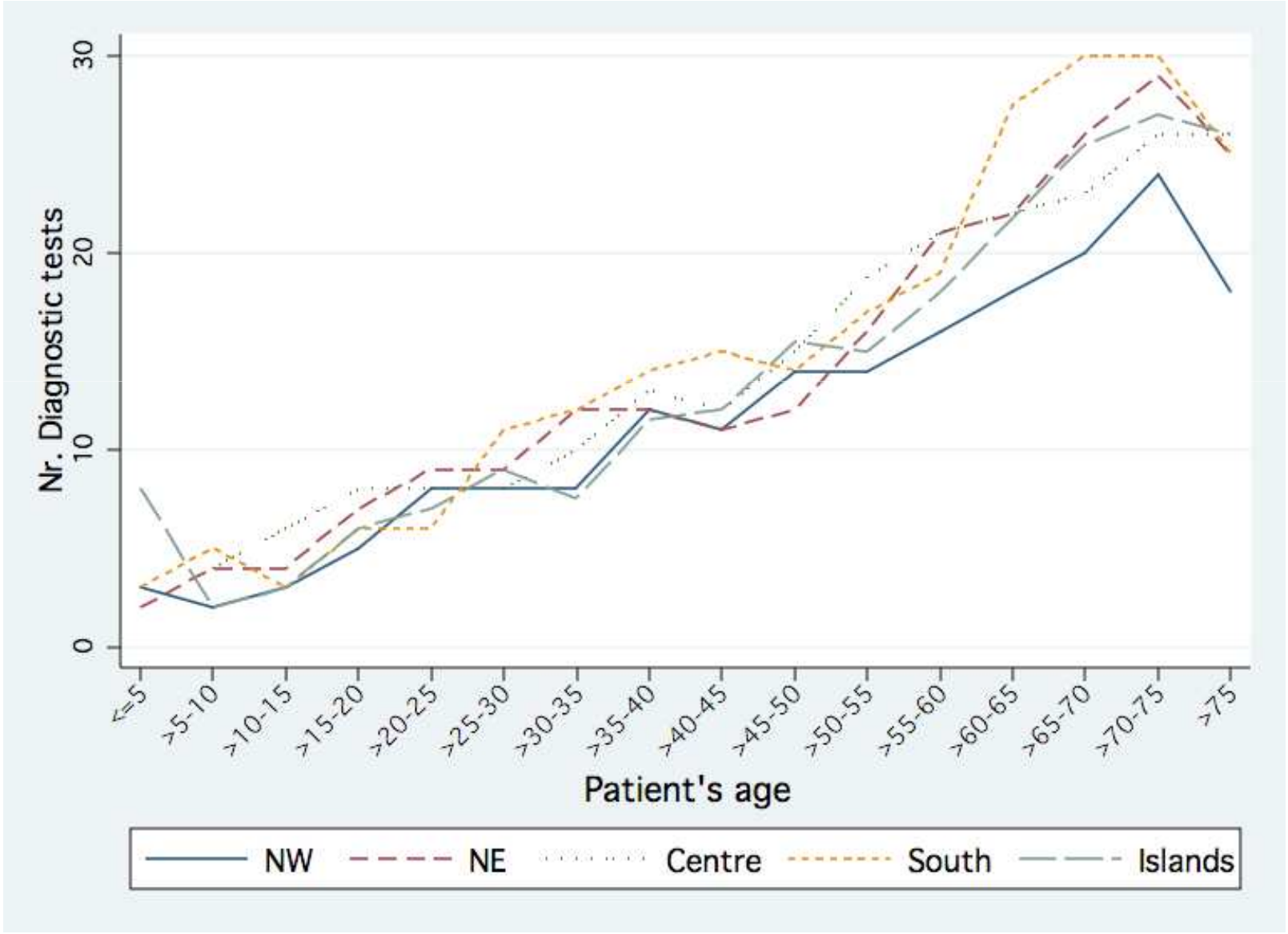
Esempi di costi standard per cura colesterolo

Treatment costs for CHOLESTEROL by region, sex, age, pathology – Diagnostic tests and specialistic visits

	Women						Men					
	Comorbidity			Pathology			Comorbidity			Pathology		
Regions	Age 55	Age 65	Age 75	Age 55	Age 65	Age 75	Age 55	Age 65	Age 75	Age 55	Age 65	Age 75
Abruzzo	357.1	415.8	414.3	43.9	64.4	30.9	104.0	292.0	463.7	63.6	48.7	27.8
Basilicata	226.7	108.9	237.0	66.7	71.9	19.2	62.8	182.7	273.7		32.1	8.7
Calabria	268.5	319.3	214.9	33.2	76.9	25.1	202.4	381.6	300.4	51.0	13.8	31.4
Campania	376.9	425.5	394.2	44.9	76.2	43.5	280.0	486.7	376.8	41.4	33.6	24.3
Emilia-Romagna	343.1	356.7	298.8	88.9	51.5	38.2	187.2	369.0	357.8	83.9	70.6	54.5
Friuli-Ven. Giulia	305.7	316.4	252.0	49.2	50.8	58.1	271.4	311.7	307.9	35.3	52.0	39.2
Lazio	310.4	422.7	305.6	67.7	76.9	27.4	493.6	332.9	297.6	44.7	50.0	67.9
Liguria	242.0	300.6	328.7	52.7	32.9	33.3	346.9	322.5	362.6	67.9	68.8	28.9
Lombardia	206.4	194.4	169.2	51.5	20.7	19.3	111.0	125.9	88.1	51.4	18.3	22.8
Marche	323.9	442.6	311.9	34.2	22.8	33.2	228.9	306.1	480.1	29.5	41.6	72.5
Piemonte	318.1	245.9	275.0	26.5	45.9	28.4	215.7	299.0	471.4	26.4	52.3	48.9
Puglia	353.5	427.4	332.9	62.6	48.0	36.5	325.7	352.0	314.3	16.7	50.9	30.1
Sardegna	336.6	365.1	299.3	98.3	22.4	11.7	143.3	309.6	404.5	31.0	47.4	20.6
Sicilia	337.5	387.0	499.8	54.2	55.9	65.5	268.7	288.1	418.6	27.4	31.7	57.4
Toscana	389.5	269.4	321.4	53.5	24.6	29.4	157.1	241.1	416.1	57.9	57.0	90.7
Trentino-Alto Adige	195.6	179.9	149.9	51.9	67.5	19.0	152.7	216.2	195.9	13.7	50.2	16.7
Umbria	346.6	422.4	284.0	31.3	69.3	41.4	275.2	352.6	510.2	14.2	66.0	28.1
Veneto	268.8	362.2	410.8	36.5	35.3	37.8	313.0	273.4	471.8	59.6	39.1	50.2

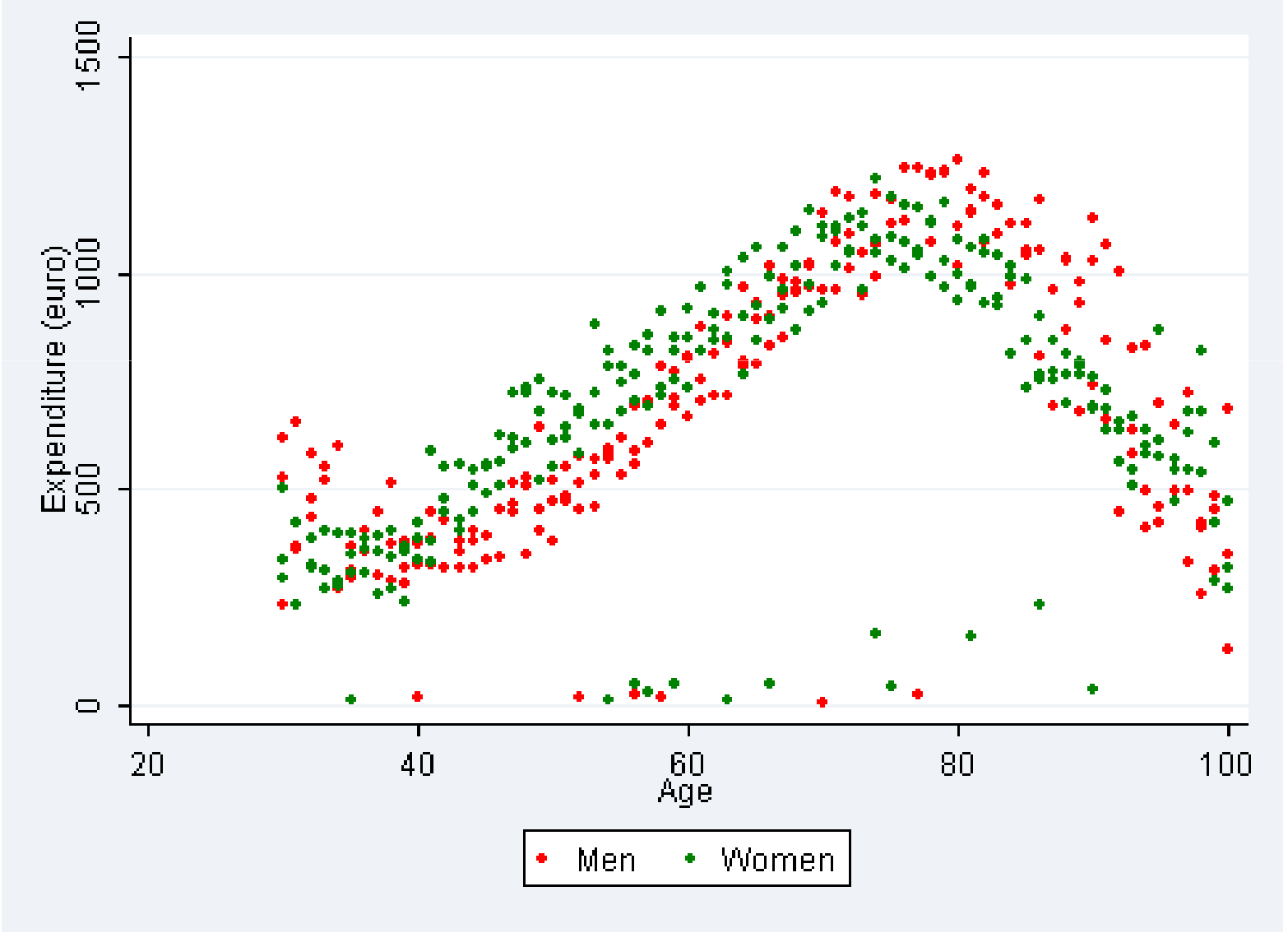
INDICATORI SU ATTIVITA’ MEDICI

Prescrizione di accertamenti diagnostici da parte dei MMG per area geografica e età paziente

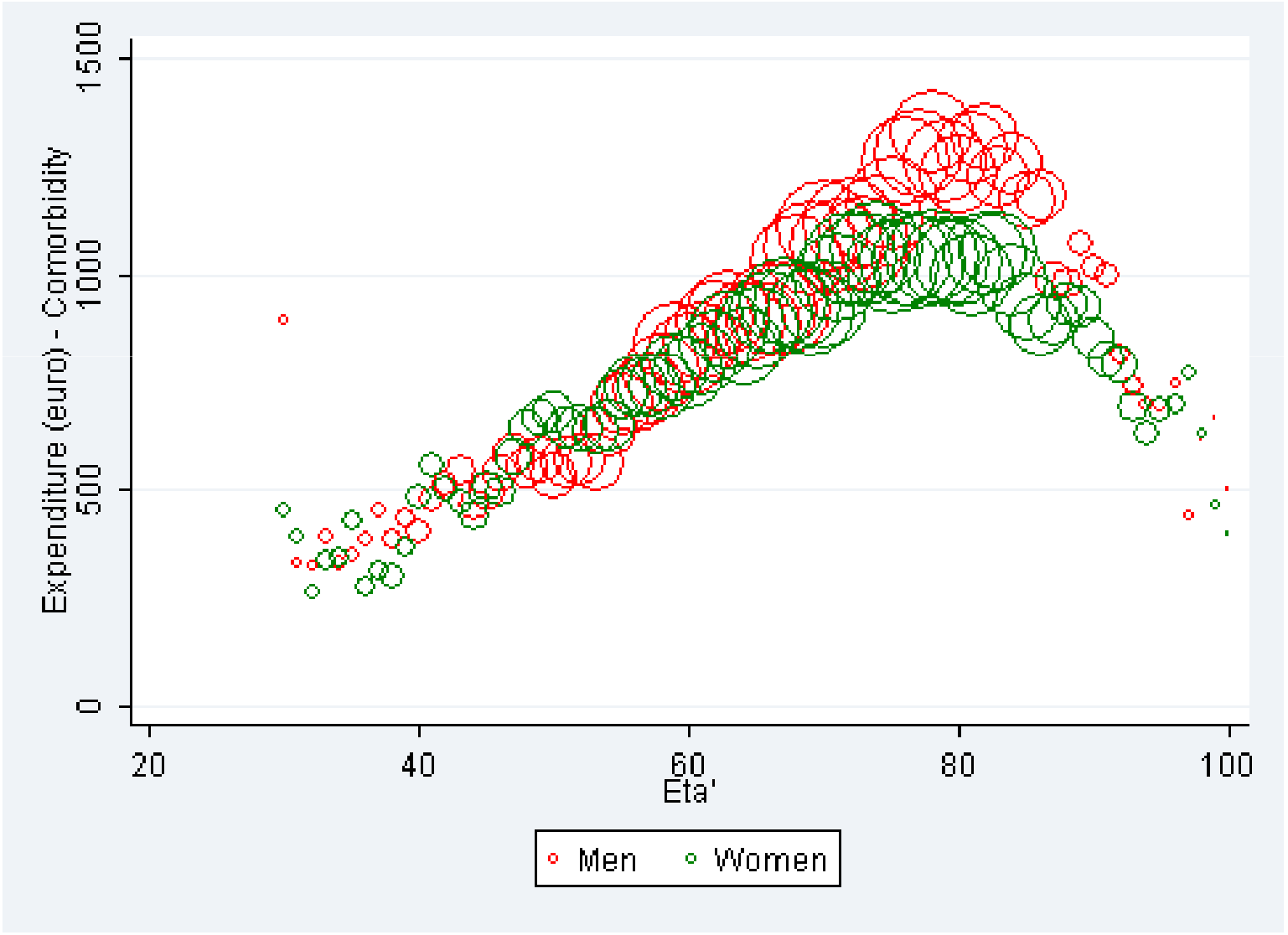


INDICATORI DI COSTO

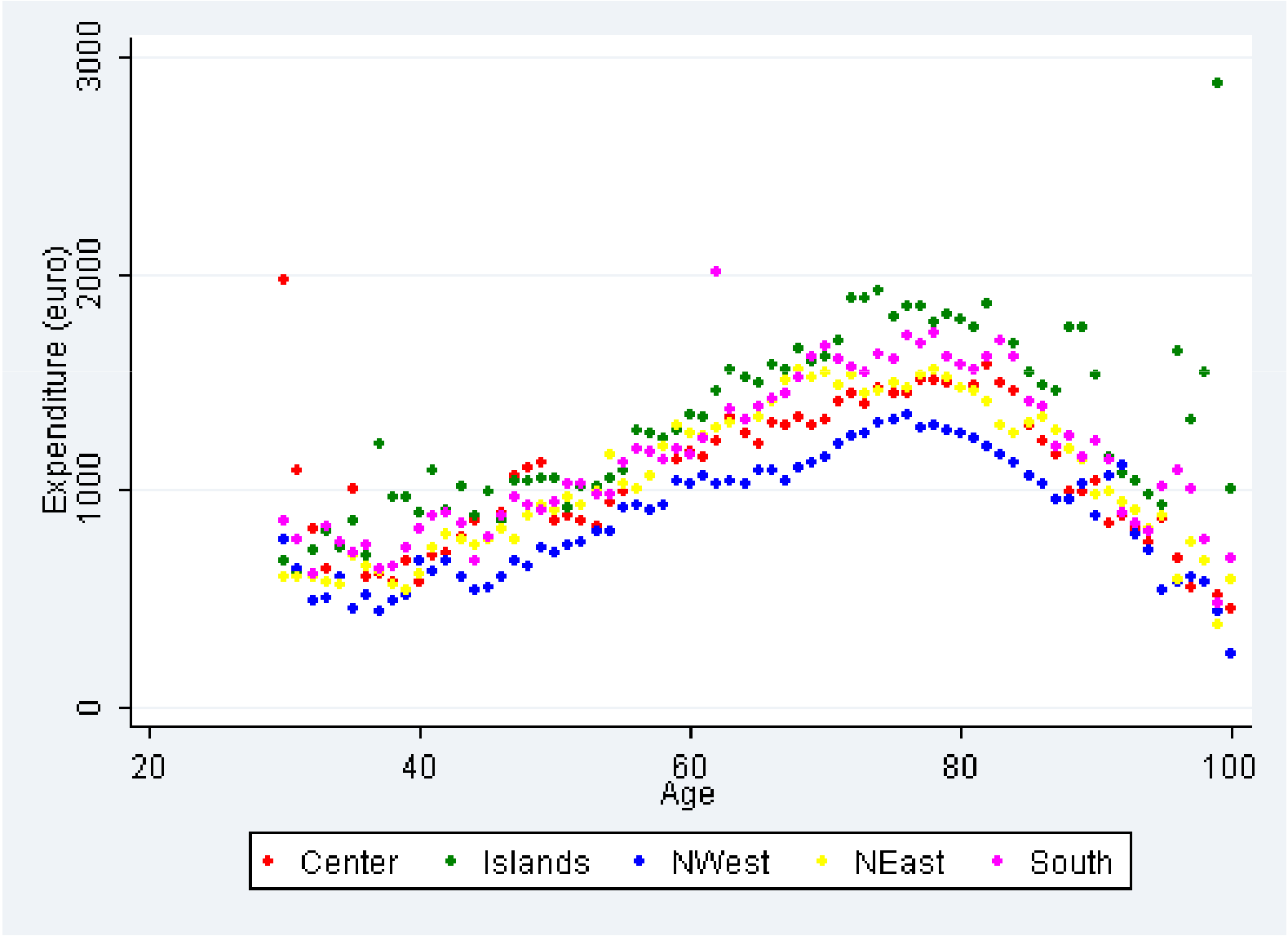
Costo annuale pro-capite per cura diabete (Diabete + comorbidità) per sesso



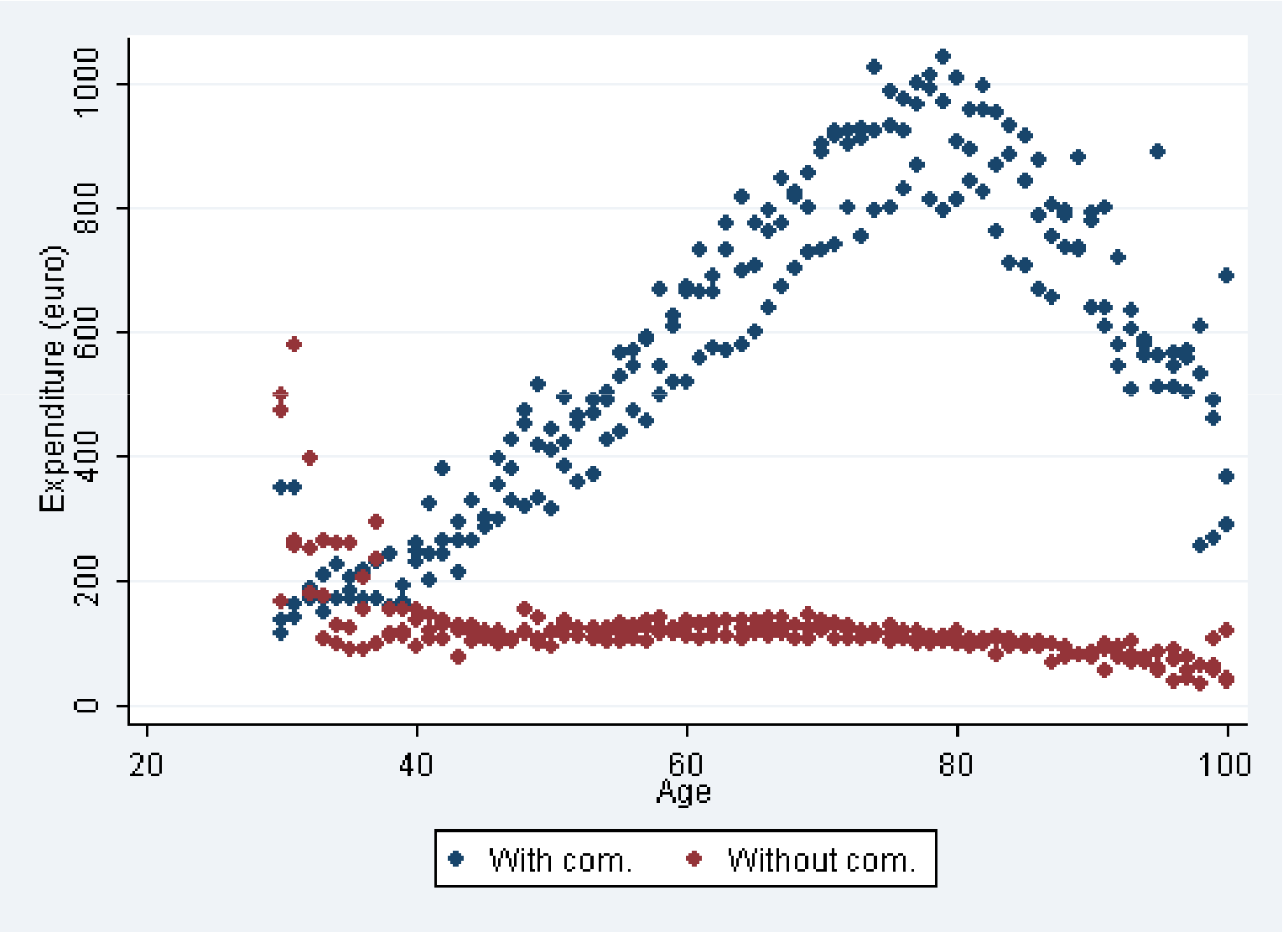
Costo annuale pro-capite per cura diabete (diabete + comorbidità) per sesso e numerosità coorti



Costo annuale pro capite per cura diabete (patologia + comorbidità) per regione



Costo annuale pro-capite per cura diabete (patologia e comorbidità)



Esempi di costi standard per cura diabete

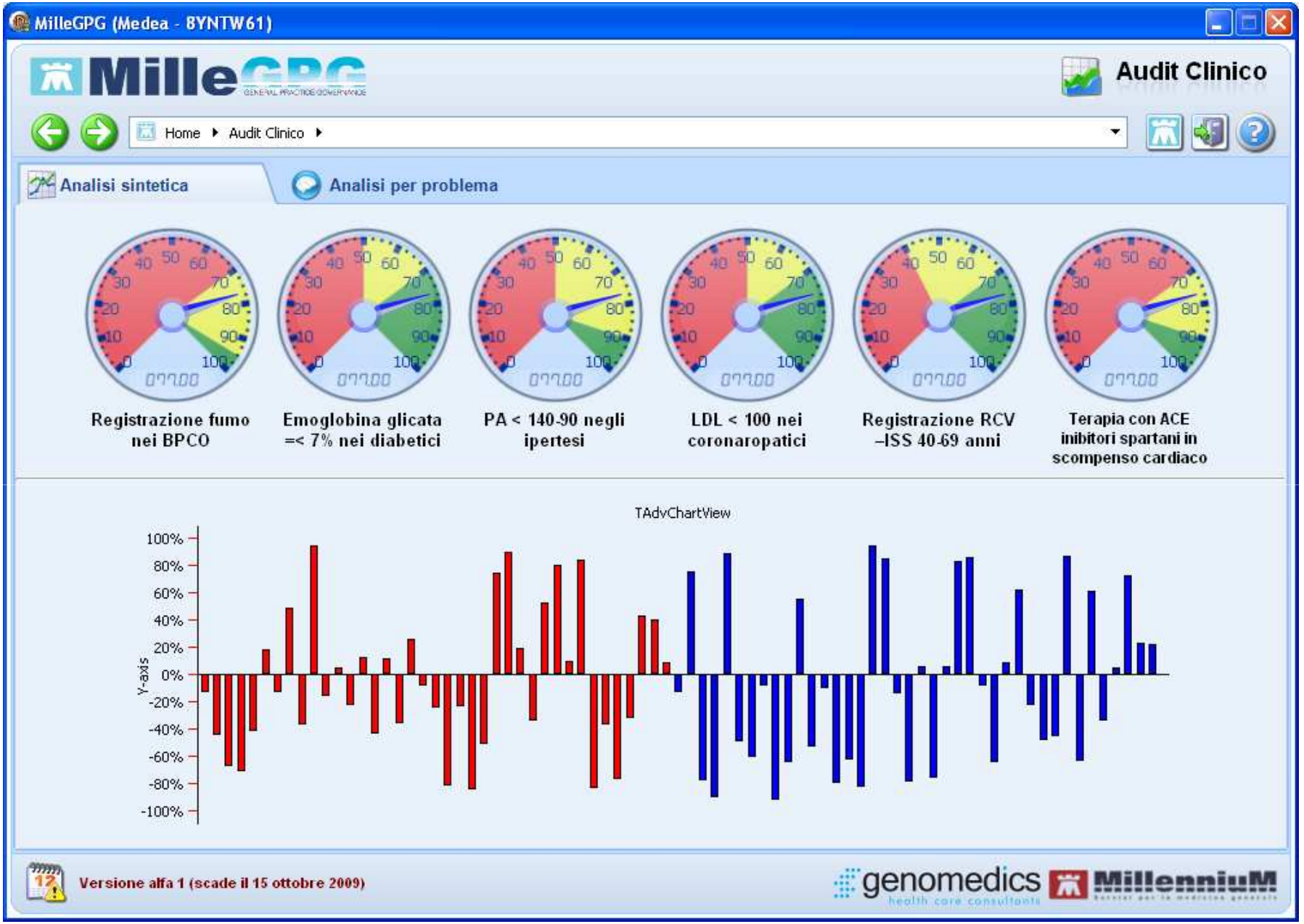
Treatment costs for DIABETES by region, sex, age, pathology – Diagnostic tests and specialistic visits

	Women						Men					
	Comorbidity			Pathology			Comorbidity			Pathology		
Regions	Age 55	Age 65	Age 75	Age 55	Age 65	Age 75	Age 55	Age 65	Age 75	Age 55	Age 65	Age 75
Abruzzo	306.5	352.4	311.2	114.6	186.7	156.9	194.1	257.8	403.4	117.6	100.6	103.1
Basilicata	54.4	370.3	191.4	78.7	90.1	42.6	154.9	330.7	295.9	68.1	95.8	37.3
Calabria	218.9	247	376.3	90.2	103.3	125.8	213.8	286.7	355.6	102	147.4	97.9
Campania	296.7	411.2	353.1	155.4	157.7	146.3	289.9	397.7	361	110.7	133.6	118
Emilia-Romagna	263.4	336.1	256.2	133.2	119.1	127.1	201.8	359.6	335.5	136.5	149.3	125.9
Friuli-Ven. Giulia	254.3	244.5	289.3	86.3	100.4	91.5	213.5	326.1	282.9	105.4	105.8	76.9
Lazio	209.9	324.2	301.4	95.5	108.4	160	300.8	505.1	346.7	118.9	150	94.8
Liguria	287.1	225.9	240.9	102.3	120.7	99.1	115.4	229.2	211.8	136	119.1	109.7
Lombardia	104.9	188.6	126.5	23.1	61.6	83.8	87	161	130.8	47.3	66.6	68.6
Marche	145.6	268.6	395.4	125.5	206.3	51.2	495.8	248.6	328.7	121.9	127.4	120
Piemonte	272.3	272	344.9	67.1	117.8	101.6	226	265.5	359.2	114.1	102.6	123
Puglia	180.3	356	267.9	93.2	104.6	89.9	355.9	305.1	239.1	129.1	113.4	85.4
Sardegna	80.6	266.6	322.7	31	42.4	88.5	212.3	198.1	277.9	98.7	129.2	86.3
Sicilia	375.8	323.2	421.3	111.1	154.5	124.7	281.8	278.4	287.2	121.4	111.6	105.1
Toscana	194.6	219.6	281.9	108.8	71.1	101.6	211	273.5	272.4	108.2	89.4	77.1
Trentino-Alto Adige	290.7	313.5	170.6		52.4	67.1	275.1	151.7	127	46.2	77.5	86.8
Umbria	236.7	390.6	297.2	120.5	115	105.8	184.7	313.4	387.4	133.9	73.7	203.2
Veneto	185.3	290	497.7	83.4	149.7	152.7	281.7	329.6	336.7	122.4	136.3	107.2

Conclusioni

1. HS represents an important source of information for output and productivity analysis as it is based on

2. More important, the and of the information collected could be easily improved if needed.
3. We plan to have a of our model - with several of the above mentioned measures implemented - by the


MilleGPG (Medea - BYNTW61)
MilleGPG
Audit Clinico
Home ▸ Audit Clinico ▸
Analisi sintetica
Analisi per problema
Registrazione fumo nei BPCO
Emoglobina glicata =< 7% nei diabetici
PA < 140-90 negli ipertesi
LDL < 100 nei coronaropatici
Registrazione RCV –ISS 40-69 anni
Terapia con ACE inibitori spartani in scompenso cardiaco
TAdvChartView
100%
80%
60%
40%
20%
0%
-20%
-40%
-60%
-80%
-100%
Y-axis
Versione alfa 1 (scade il 15 ottobre 2009)
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