

Donne e Aderenza alle Terapie con i farmaci equivalenti

Claudio Mencacci

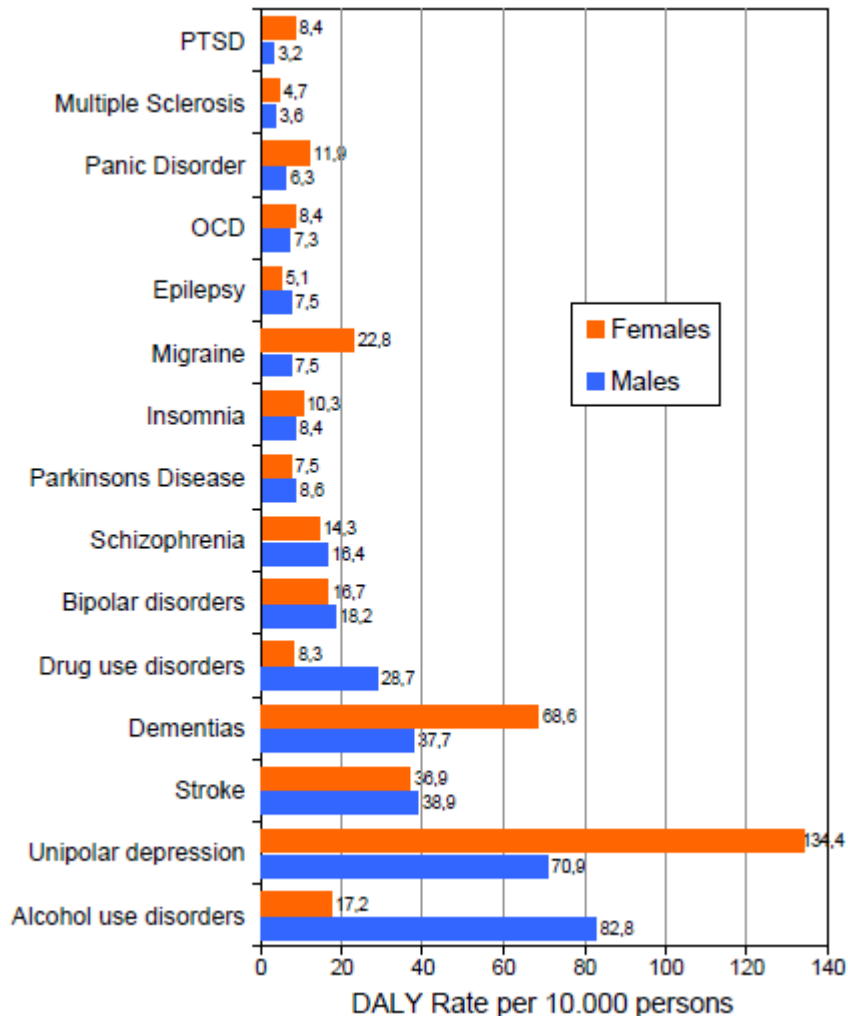
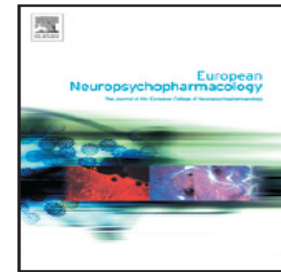
Direttore Dipartimento Neuroscienze

A. O. Fatebenefratelli, Milano



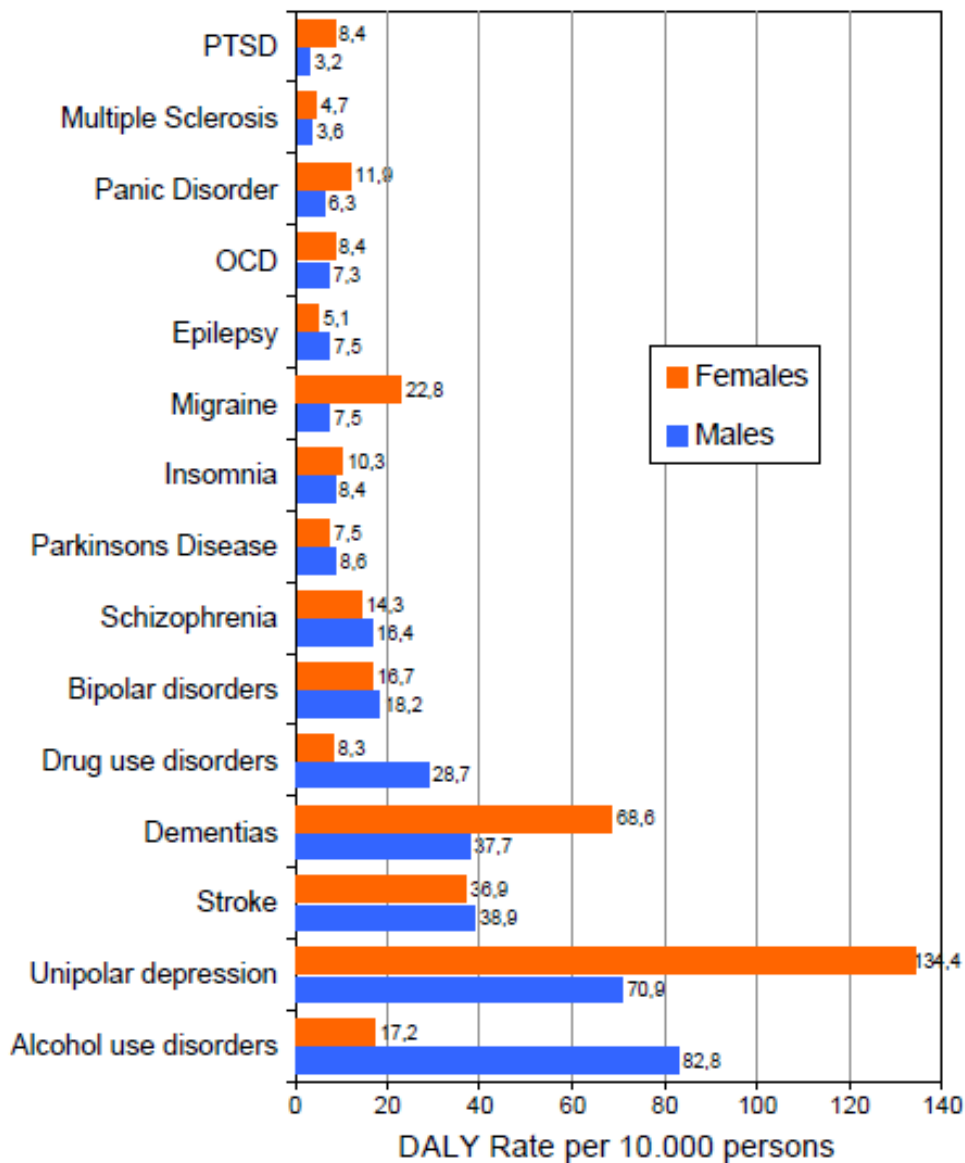
The size and burden of mental disorders and other disorders of the brain in Europe 2010

European Neuropsychopharmacology (2011) 21, 655–679

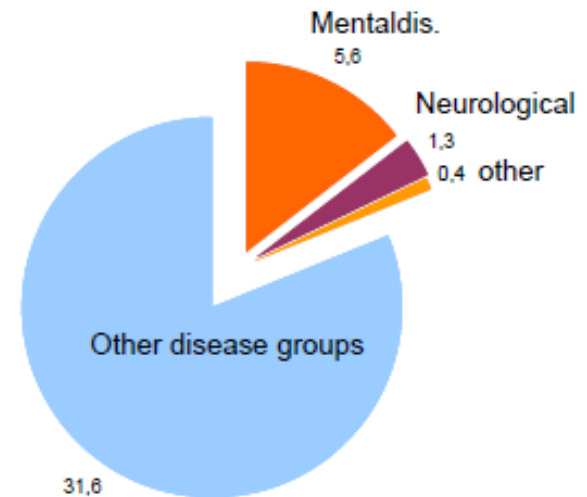


In the EU, **mental and other disorders of the brain** are responsible for a huge proportion of overall burden of disease: almost **1 in 3** of all years of life lost due to premature mortality in women, and almost 1 in 4 in men are due to disorders of the brain.

The three most important contributors to burden of disease are **DEPRESSION** (7.2% of the overall burden of disease in Europe), **ALZHEIMER'S DISEASE/DEMENTIA** (3.7%) and **ALCOHOL USE DISORDERS** (3.4%).



Males: Total neuropsychiatric: 23.4%



Females: Total neuropsychiatric: 30.1%

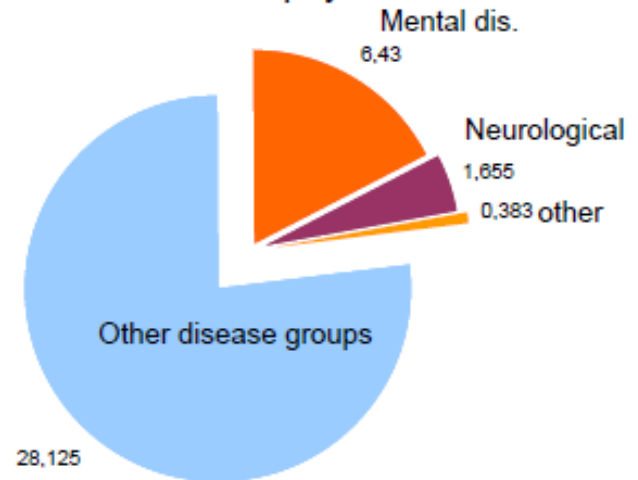


Fig. 2 Summary of DALY estimates.

Impact of depression

Affects 350 million people worldwide

- **As low as 10% receive adequate treatment***
- 90% of people who die by suicide have a diagnosable and treatable psychiatric disorder at the time of their death

Increasing prevalence data:

- Barriers for adequate treatment
- Earlier onset in life
- 40% not detected
- 50-60% of GPs stigmatised



ECNP/EBC REPORT 2011

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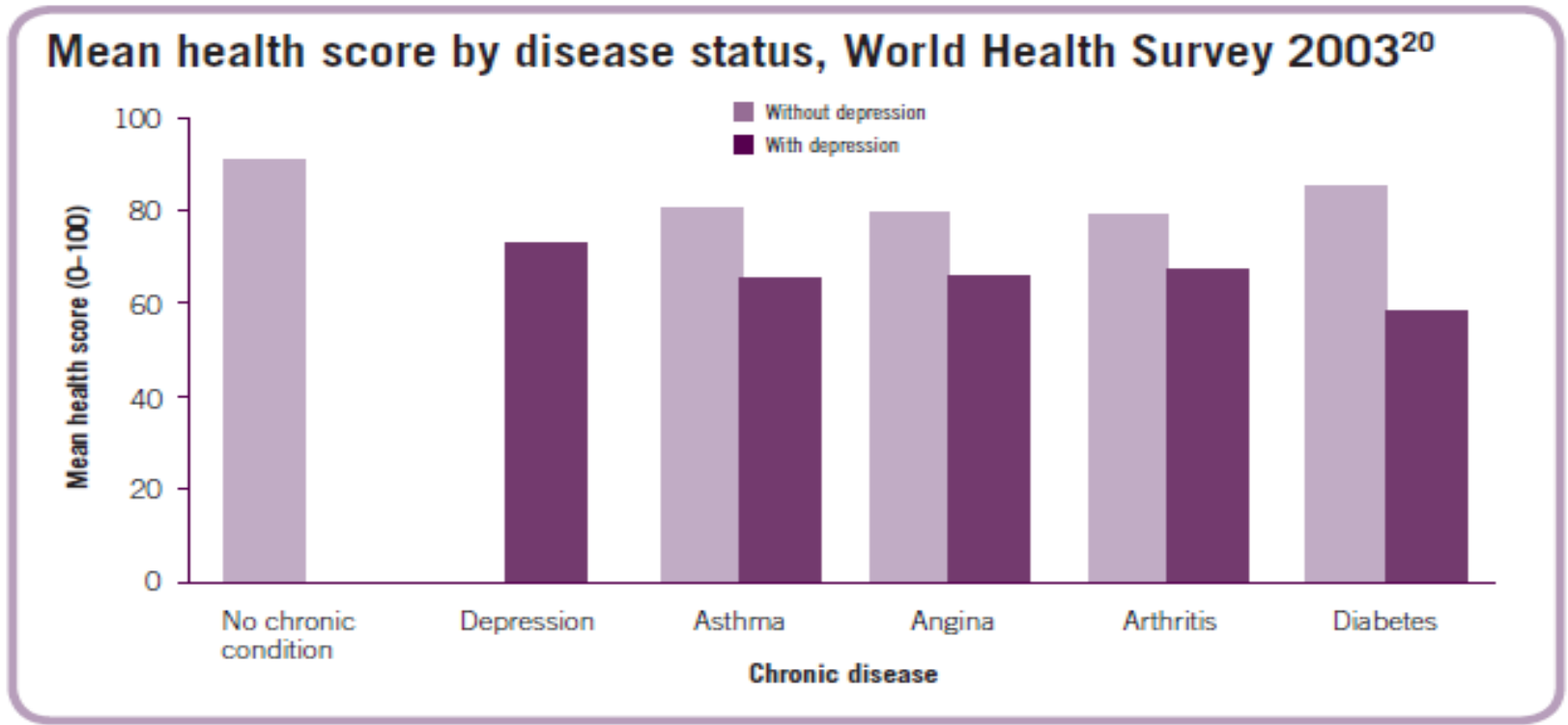


BURDEN OF DEPRESSION

- Chronic and recurrent disease
- Comorbidities
- Sleep disorders associated
- Impairment of Quality of Life
- Caregiver's burden
- Functional impairment
- Significant economic impact



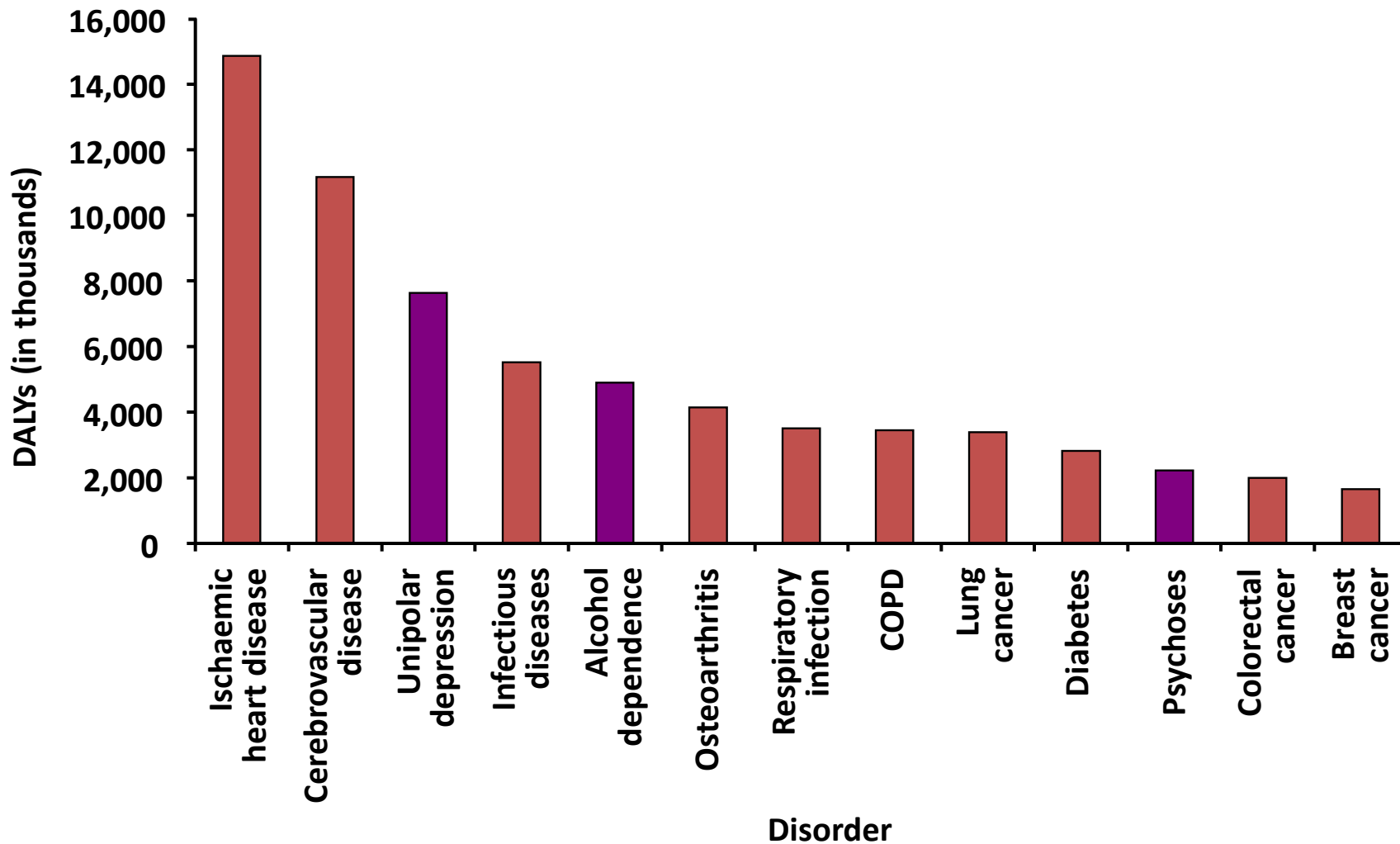
Mental illness: depression worsens the health of people with chronic illness



“Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”

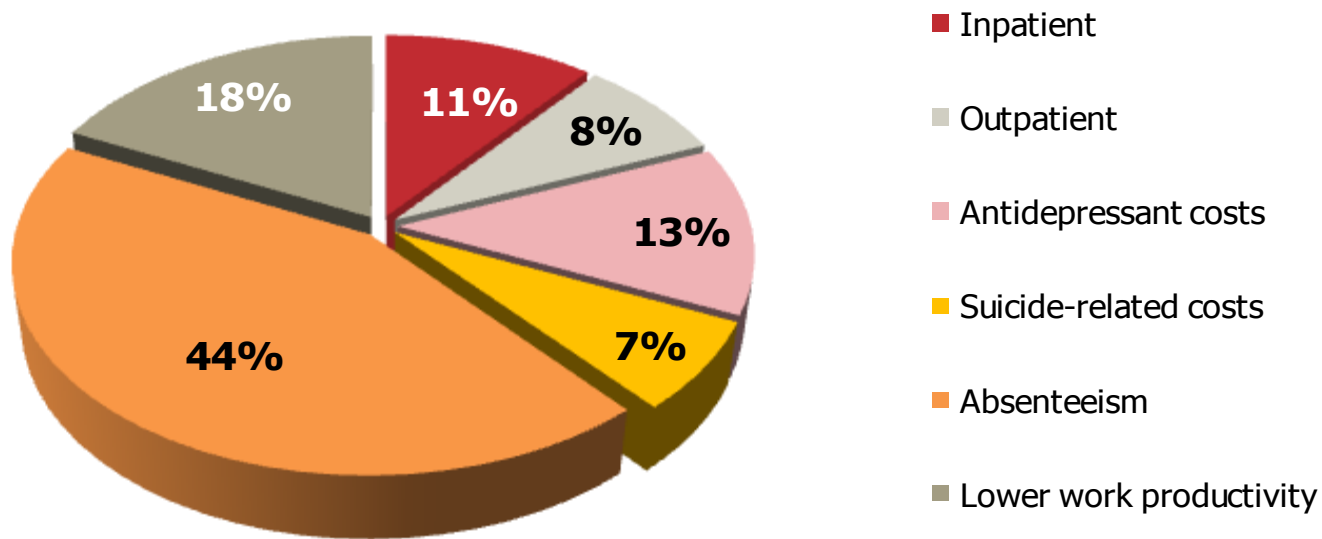
Preamble to the Constitution of the World Health Organization, as adopted by the International Health Conference, New York, 19–22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the WHO, no. 2, p. 100) and entered into force on 7 April 1948

Health burden – DALYs (disability adjusted life years)



“Burden” economico della depressione (2000)

Distribuzione dei costi



Ricadute in farmaco-economia dell'aderenza

Il miglioramento dell'aderenza comporta una riduzione dei costi



The importance of “adherence”

“Current methods of improving medication adherence for chronic health problems are mostly complex, labor-intensive, and not predictably effective. The full benefits of medications cannot be realized at currently achievable levels of adherence; therefore, more studies of innovative approaches to assist patients to follow prescriptions for medications are needed.”

Side effects remain a barrier to treatment adherence

- Of treatment initiators, only 25% to 50% of patients adhere to their antidepressant regimen as recommended

Non-compliance (missed doses)

- Forget to take the medication as prescribed
- Gained a lot of weight
- Lost my sex drive or orgasm
- I started feeling better

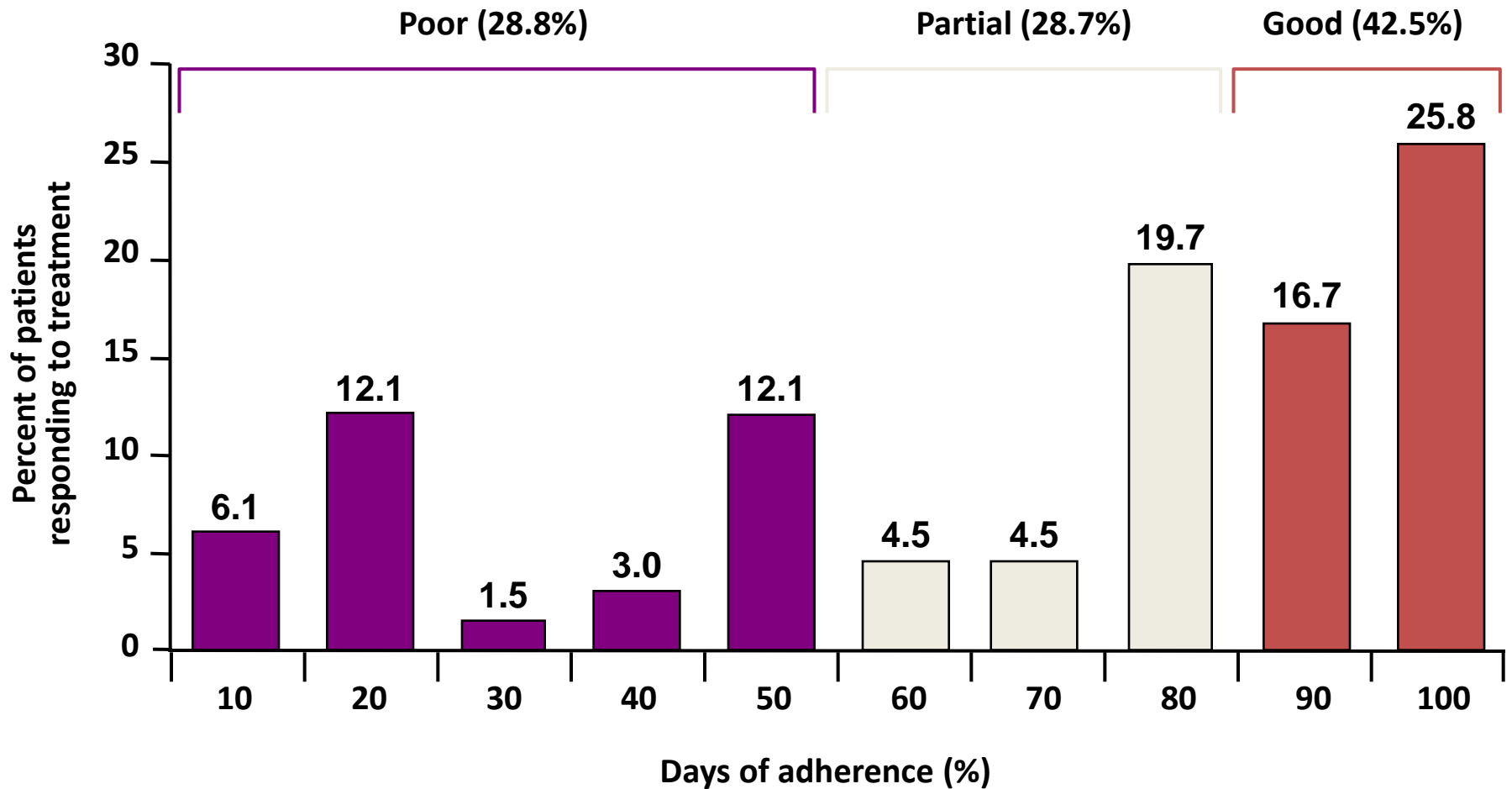
Discontinuation (stopped doses)

- Wasn't working
- Didn't like the way it made me feel
- Lost my sex drive
- Tired during the day
- Gained a lot of weight

Adherence to treatment

- Non-adherence is estimated to range from 10–60% (median 40%) – **AIFA (2015) data Base ASL adherent 39.1%**
- The full benefits of medication cannot be realised at currently achievable levels of adherence
- Four components have been identified:
 - Perceived doctor–patient relationship
 - Preserved autonomy
 - Positive beliefs on antidepressants
 - Partner agreement (!)

Level of patient adherence with treatment regimen – frequency distribution



AIFA 2014

- Indipendentemente dall'antidepressivo utilizzato le Linee guida raccomandano un trattamento di almeno 6 mesi nei pazienti affetti da depressione, in virtù dell'alto rischio di recidiva a cui si attribuisce gran parte dei costi economici e sociali della depressione. Precedenti studi osservazionali hanno dimostrato che quasi il 50% dei pazienti in trattamento sospende trattamento nei primi 3 mesi ed il 70% nei primi 6 mesi

- Employees non-adherent to acute antidepressant treatment were **38.7% more likely to have disability absences** than adherent employees



Burton et al. Am J Manag Care 2007; 13: 105–112

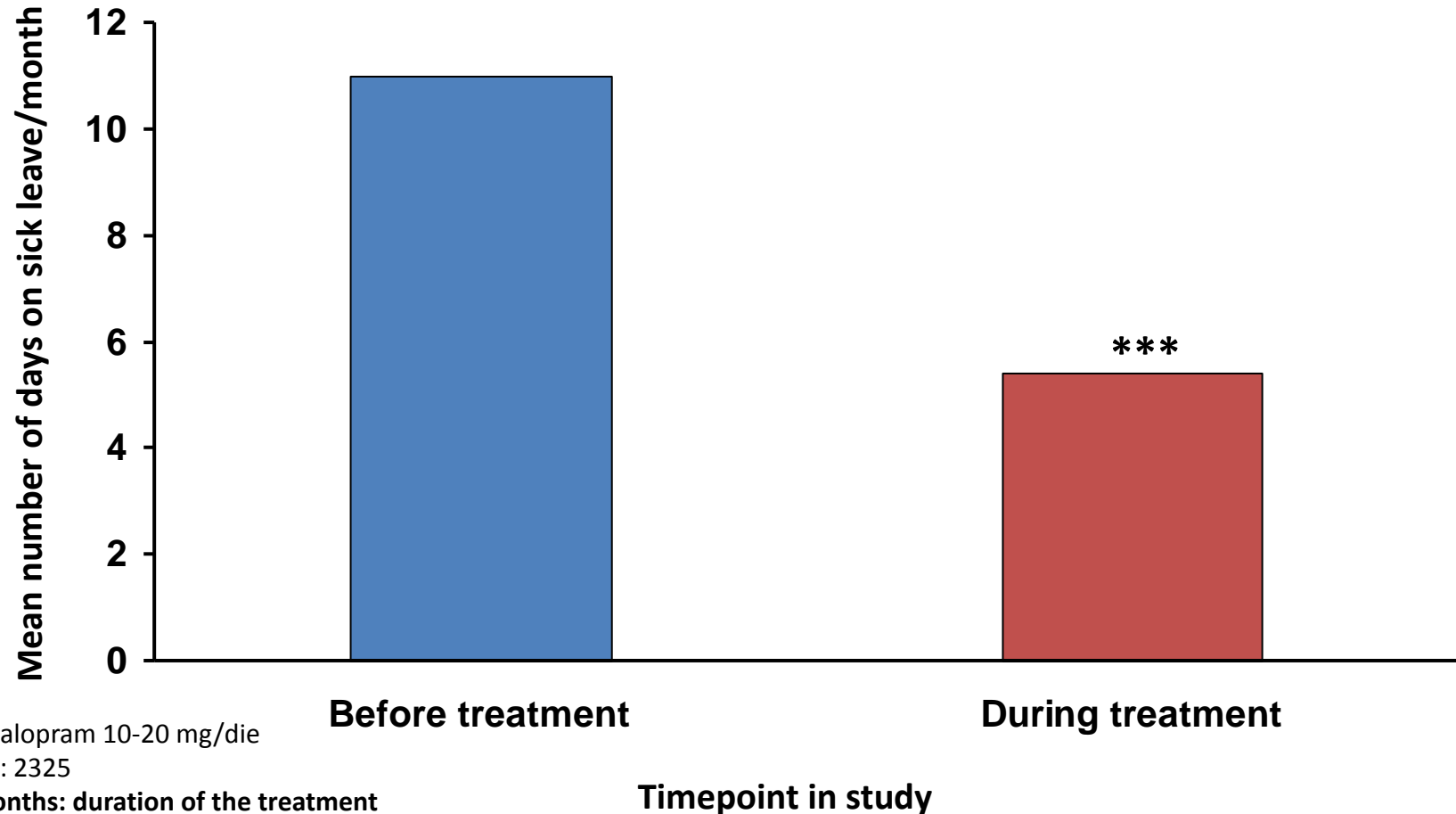
- Those non-adherent to continuation treatment were **46.1% more likely to**

Impact of depression on sick leave duration

Labour force activity in a community survey

	MDD treated	MDD not treated
Employed	33%	39%
Looking for work	5%	13%
Not in labour force	62%	47%
Worked as carefully as usual in past 4 weeks	56%	66%
Accomplished as much as usual in past 4 weeks	45%	56%

Antidepressant Effective treatment reduces sick leave duration



Escitalopram 10-20 mg/die
Ntot: 2325
3 months: duration of the treatment

*** $p < 0.001$;

Questo strumento è stato disegnato per 6 aree terapeutiche dal seguente Board Scientifico: Lo studio utilizza i dati estratti dagli archivi sanitari automatizzati di 5 ASL della Regione Lombardia:

DIABETE

Prof. Trevisan (Bergamo)

IPERTENSIONE

Prof. Agabiti Rosei (Brescia)

DISLIPIDEMIA

Prof. Catapano (Milano)

PSICHIATRIA Sertralina

Prof. Mencacci (Milano)

CARDIOLOGIA

Prof. Margonato (Milano)

REUMATOLOGIA

Prof. Montecucco (Pavia)

FARMACOECONOMIA

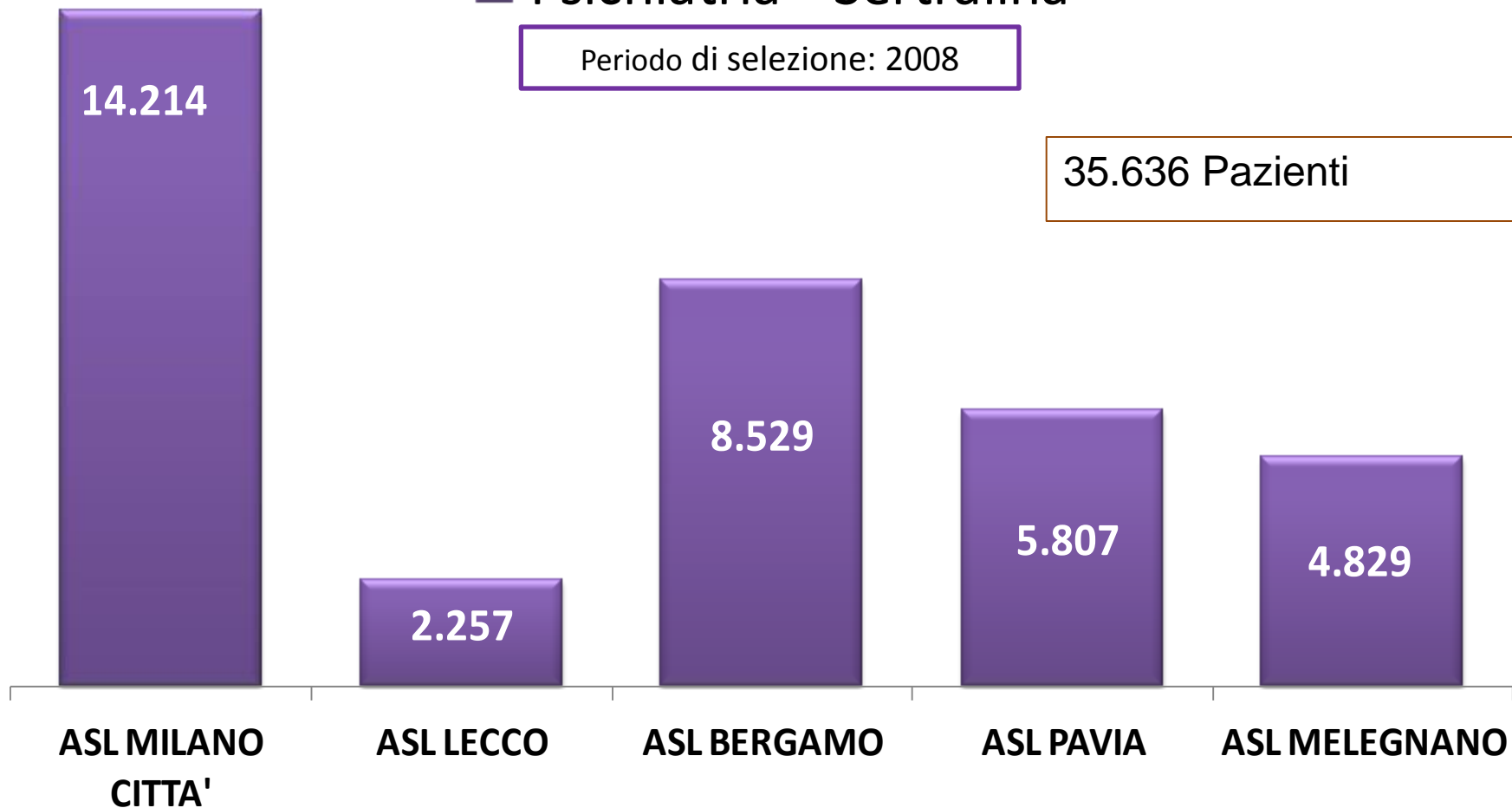
Prof. Colombo (Pavia)

Numerosità delle Coorti

■ Psichiatria - Sertralina

Periodo di selezione: 2008

35.636 Pazienti



Prevalenza delle Coorti (x100)

■ Psichiatria - Sertralina

Periodo di selezione: 2008



Assistibili 2008 ASL Milano Città: 1.368.544

Assistibili 2008 ASL Lecco: 335.867

Assistibili 2008 ASL Bergamo: 1.070.386

Assistibili 2008 ASL Pavia: 511.300

Assistibili 2008 ASL Melegnano: 560.907

DISTRIBUZIONE PER SESSO

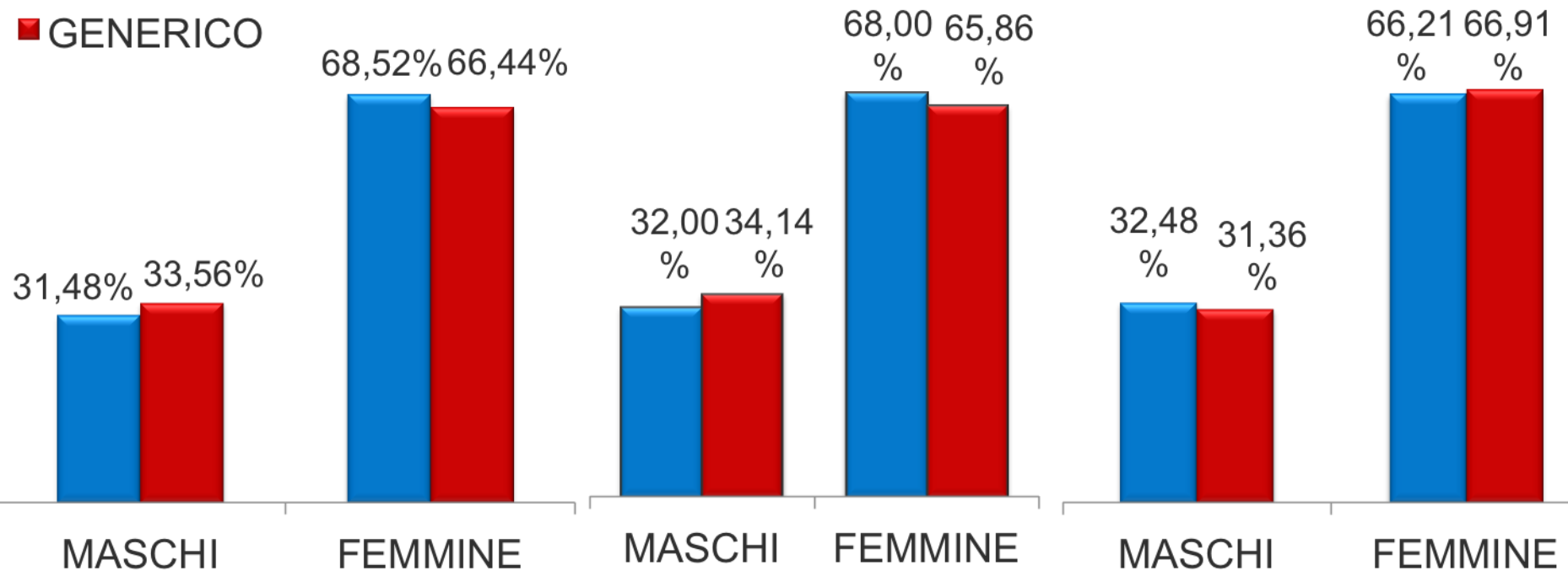
ASL LECCO

ASL PAVIA

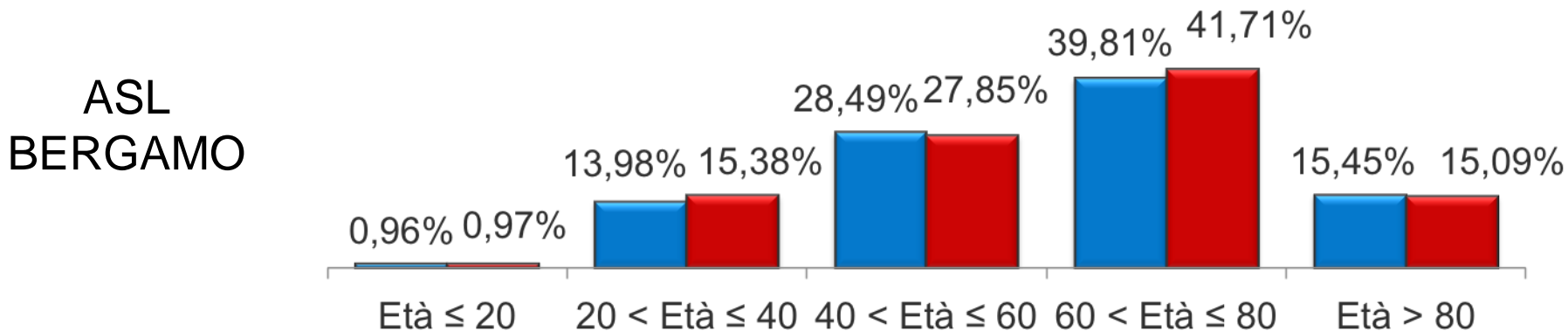
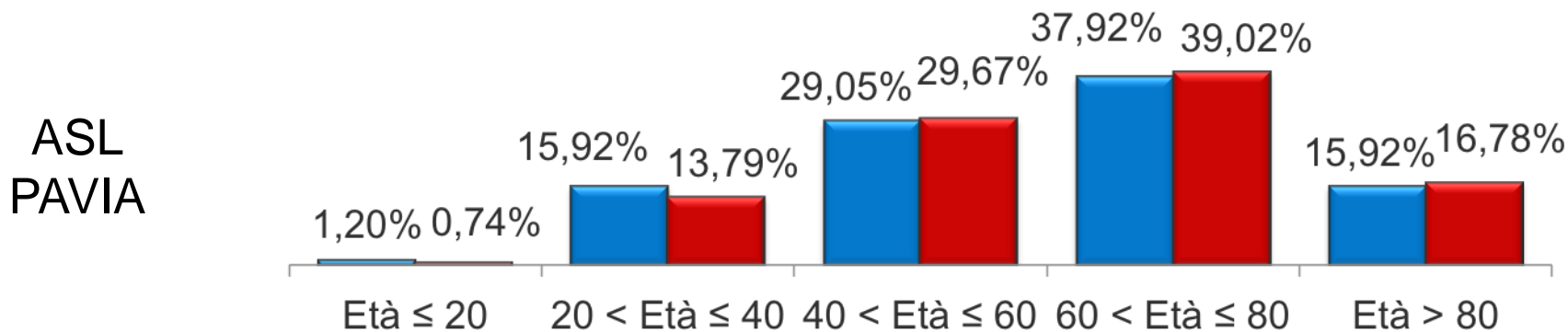
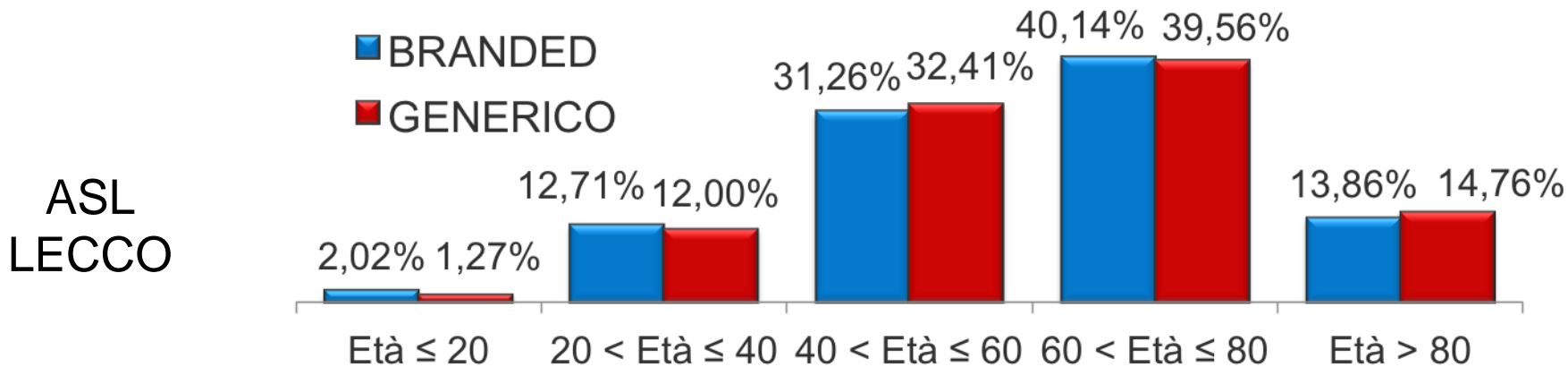
ASL BERGAMO

■ BRANDED

■ GENERICO



DISTRIBUZIONI PER CLASSI DI ETA'



PERSISTENZA

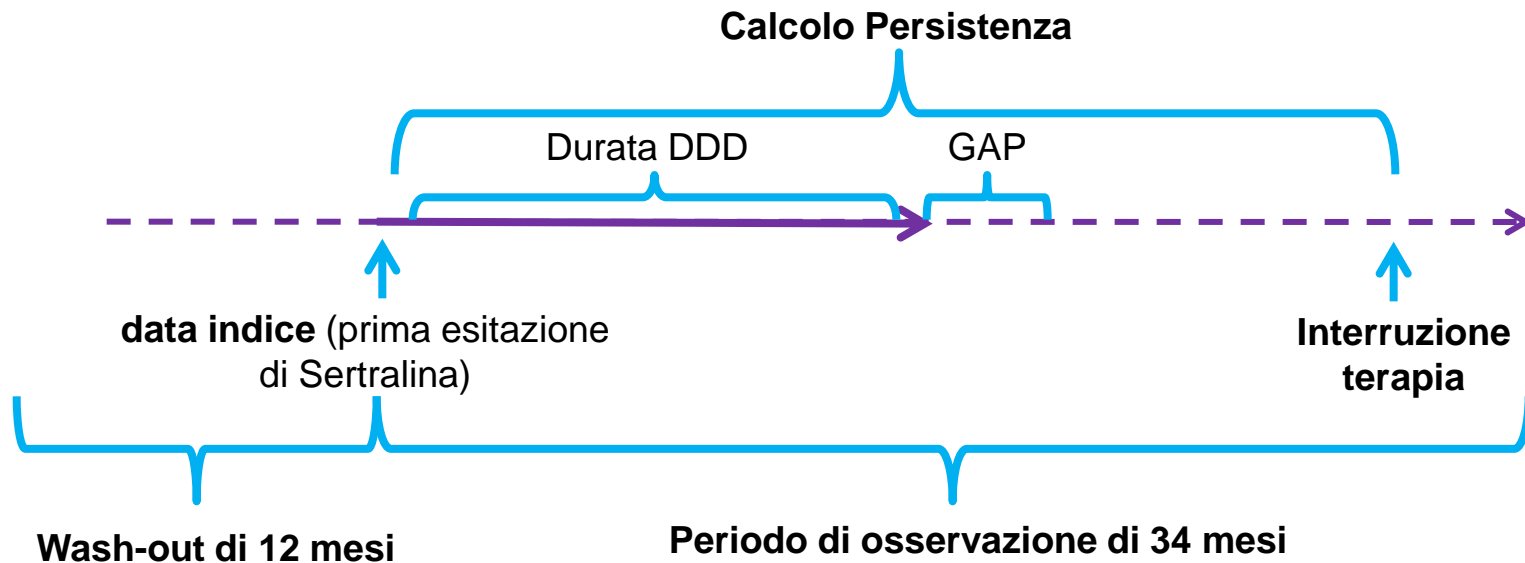
➤ **Analisi della Persistenza**

Definizione di Persistenza: continuazione della terapia per il periodo di tempo consigliato.

Tecniche di analisi:

•utilizzo dei **DDD** (Defined Daily Dose) per il calcolo della durata di terapia teorica.

GAP: 30 giorni



PSICHIATRIA - Sertralina

Persistenza

	Tipologia	N	Mean	Median	SD	p-value (Wilcoxon)
LECCO	Branded	264	180.2	89.5	227.5	N.S.
	Generico	141	119.2	85.0	104.6	
PAVIA	Branded	574	165.5	81.5	222.6	0.0081
	Generico	517	187.0	101.0	224.4	
BERGAMO	Branded	864	170.9	90.0	213.5	N.S.
	Generico	769	193.6	90.0	239.5	

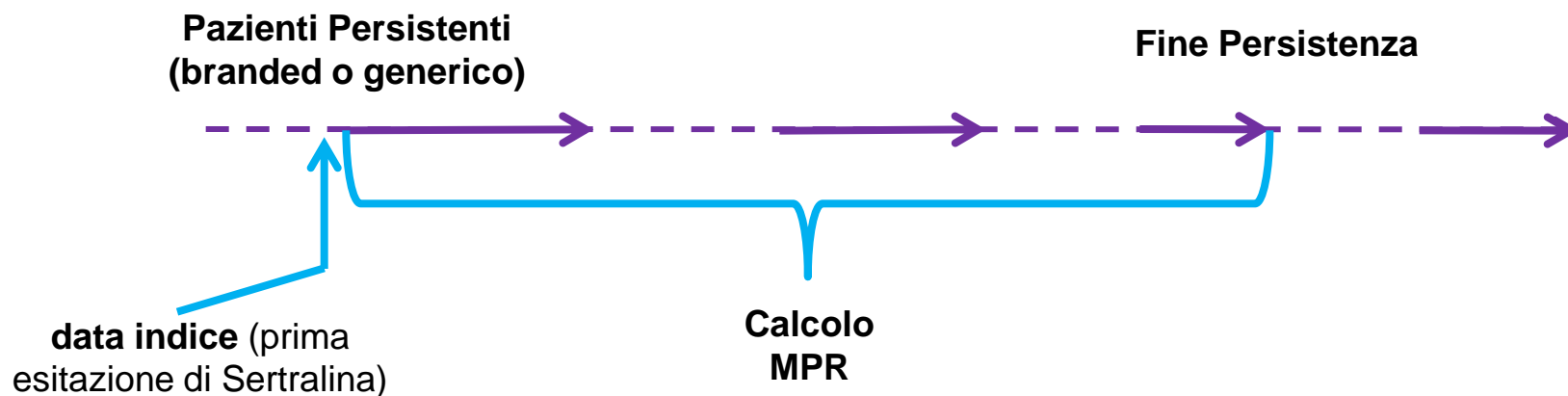
✓ Differenze non significative per Lecco e Bergamo.

✓ Maggiore persistenza per il generico su Pavia.

COMPLIANCE

➤ Analisi della Compliance

Metodo 2 : Calcolo Compliance **soltanto sui pazienti persistenti nel periodo di persistenza.**



$$\text{Compliance} = \frac{(\text{numero confezioni nel periodo di persistenza}) \times (\text{numero di DDD a confezione})}{\text{totale giorni di persistenza}}$$

PSICHIATRIA

COMPLIANCE

	Tipologia	N	Mean	Median	SD	P-value (Wilcoxon)
ASL LECCO	Branded	264	0.98	1.0	0.04	N.S.
	Generico	141	0.99	1.0	0.04	
ASL PAVIA	Branded	574	0.98	1.0	0.05	N.S.
	Generico	517	0.98	1.0	0.04	
ASL BERGAMO	Branded	864	0.98	1.0	0.07	0.0320
	Generico	769	0.99	1.0	0.05	

Differenze non significative per Lecco e Pavia.

Maggiore Compliance per il generico su Bergamo.

NON SOSTITUIBILE

- E' il medico responsabile, anche legalmente delle cure e degli esiti.
- Importante, quindi ,ridurre i fattori che possono influire sulla aderenza alle cure e anche quei fattori biologici che possono interferire con il buon esito clinico raggiunto.
- Si consiglia di mantenere sempre lo stesso “brand di Generico “con il quale si è iniziata la cura e raggiunto gli esiti positivi

NON SOSTITUIBILE

- Lo specialista e non il farmacista è garante e contemporaneamente responsabile degli esiti della cura
- **La dizione non sostituibilità**, esercitata anche su una molecola a brevetto scaduto, rappresenta una garanzia per il paziente e il medico, sia sulla continuità sia su efficacia terapeutica.

La riduzione degli effetti nocivi delle cause patogene e dei fattori di rischio (**Stress**), ha avuto un impatto tale che l'OMS definisce il concetto di **SALUTE** non più e soltanto "l'assenza di malattia", ma:

