

**Informazione e dis-
informazione sugli
psicofarmaci nella prospettiva
dei paesi a basso reddito**

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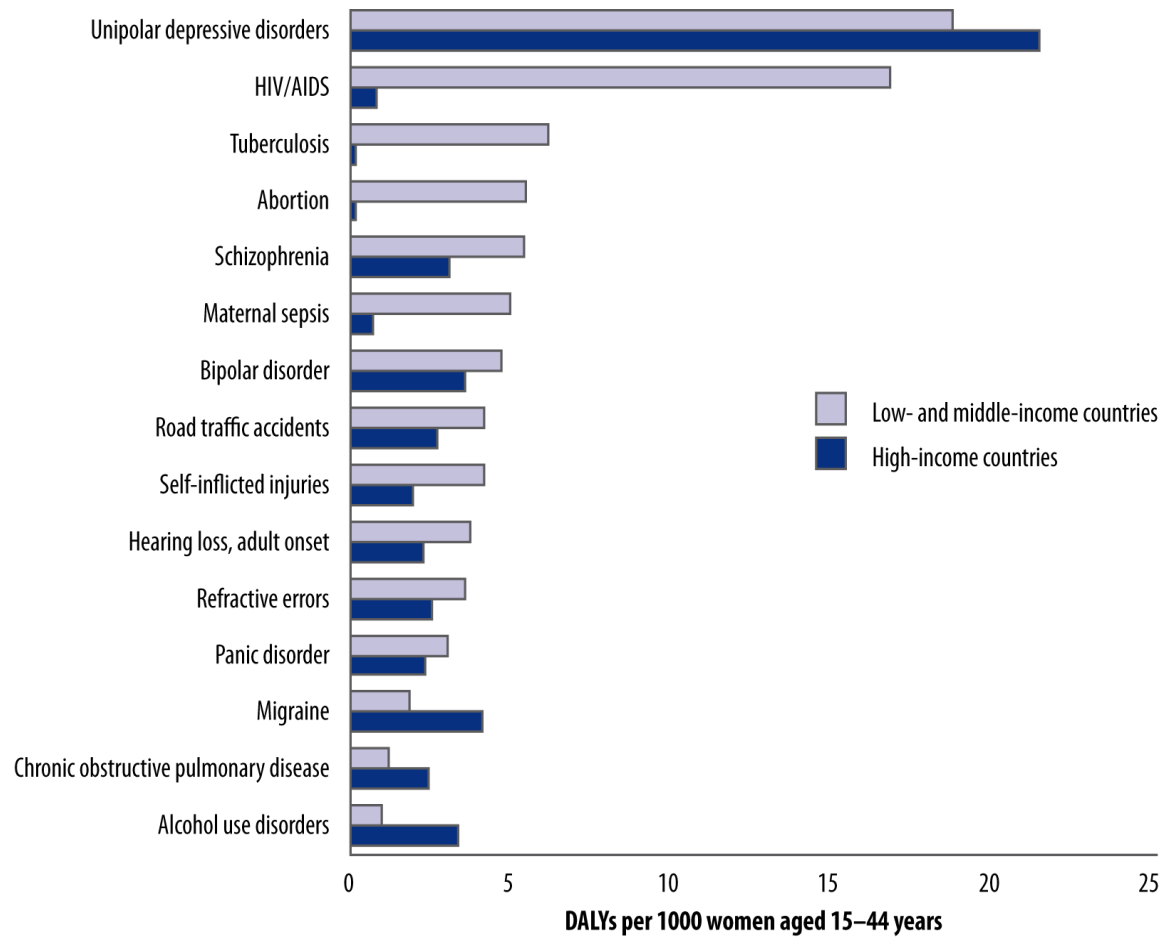
Paesi a basso e medio reddito e Assistenza Psichiatrica

- **I disturbi mentali sono gli stessi che nei paesi ad alto reddito?**
- **Il “burden” é lo stesso?**
- **Le risorse per il trattamento sono le stesse?**
- **Il gap fra trattati/non trattati è lo stesso?**

Un “burden” elevato e un drammatico gap fra trattati e non trattati

- High burden:
 - **14%** del 2004 **Global Burden of Disease** misurato in Disability-Adjusted Life Years (DALYs) è attribuibile ai disturbi mentali, da abuso di sostanze e neurologici
- Large treatment gap:
 - **76-85%** nei paesi a basso e medio reddito
 - **35.5-50.3** nei paesi a alto reddito

Leading causes of disease burden for women aged 15–44 years, high-income countries, and low- and middle-income countries, 2004



LEADING CAUSES OF YEARS OF LIFE LIVED WITH DISABILITY

By income categories

Low and middle income countries		
1	Unipolar depressive disorders	10.4%
2	Refractory errors	4.7%
3	Hearing loss, adult onset	4.4%
4	Alcohol use disorders	3.5%
5	Cataracts	3.3%
6	Schizophrenia	2.8%
7	Birth asphyxia and birth trauma	2.4%
8	Bipolar disorder	2.4%
9	Osteoarthritis	2.4%
10	Iron-deficiency anaemia	2.4%

High income countries		
1	Unipolar depressive disorders	14.6%
2	Hearing loss, adult onset	6.2%
3	Alcohol use disorders	5.7%
4	Alzheimer and other dementias	5.4%
5	Osteoarthritis	4.1%
6	Refractory errors	4.0%
7	COPD	3.5%
8	Diabetes mellitus	3.4%
9	Asthma	2.6%
10	Drug use disorders	2.4%

Number of deaths and burden of suicide (2004 update)

Region	Numbers of death	DALYs (%)
Africa	50,000	0.3
America	69,000	1.1
E Mediter.	36,000	0.8
Europe	151,000	2.0
SE Asia	252,000	1.6
W Pacific	286,000	2.0
<i>World</i>	<i>844,000</i>	<i>1.3</i>

Percentage of total global mortality and DALYs attributable to psychoactive substances

Risk factor	High mortality developing countries		Low mortality developing countries		Developed countries		Worldwide
	Males	Females	Males	Females	Males	Females	
<u>Mortality</u>							
Tobacco	7.5	1.5	12.2	2.9	26.3	9.3	8.8
Alcohol	2.6	0.6	8.5	1.6	8.0	-0.3	3.2
Illicit drugs	0.5	0.1	0.6	0.1	0.6	0.3	0.4
<u>DALYs</u>							
Tobacco	3.4	0.6	6.2	1.3	17.1	6.2	4.1
Alcohol	2.6	0.5	9.8	2.0	14.0	3.3	4.0
Illicit drugs	0.8	0.2	1.2	0.3	2.3	1.2	0.8

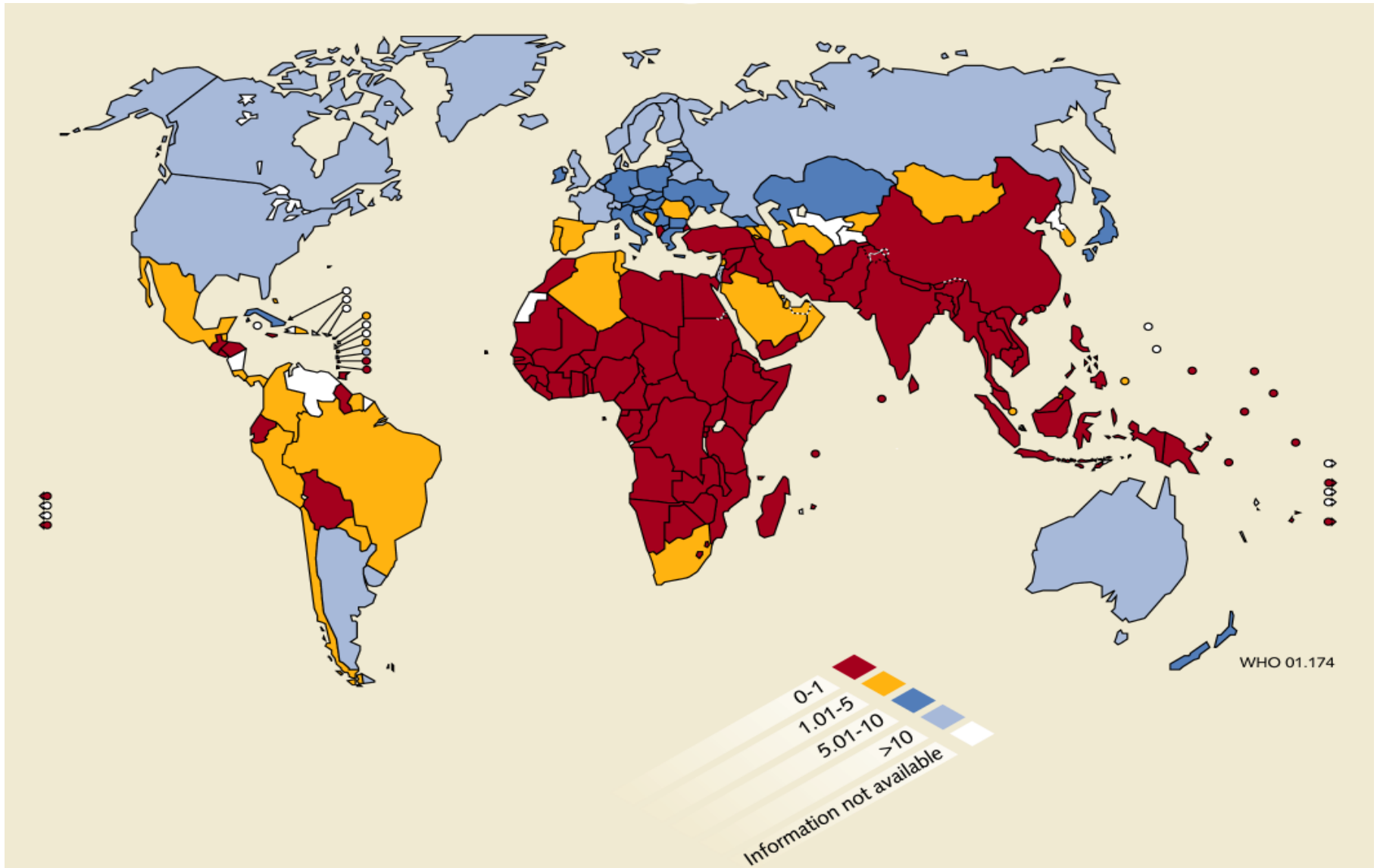
2030 rankings: The future leading causes of DALYs lost

World	1	HIV/AIDS
	2	Unipolar depressive disorder
	3	Ischaemic heart dis.
High-income countries	1	Unipolar depressive disorder
	2	Ischaemic heart disease
	3	Alzheimer
Middle-income countries	1	HIV/AIDS
	2	Unipolar depressive disorder
	3	Cerebrovascular
Low-income countries	1	HIV/AIDS
	2	Perinatal
	3	Unipolar depressive disorder

EMERGENZE, DISASTRI E CONFLITTI

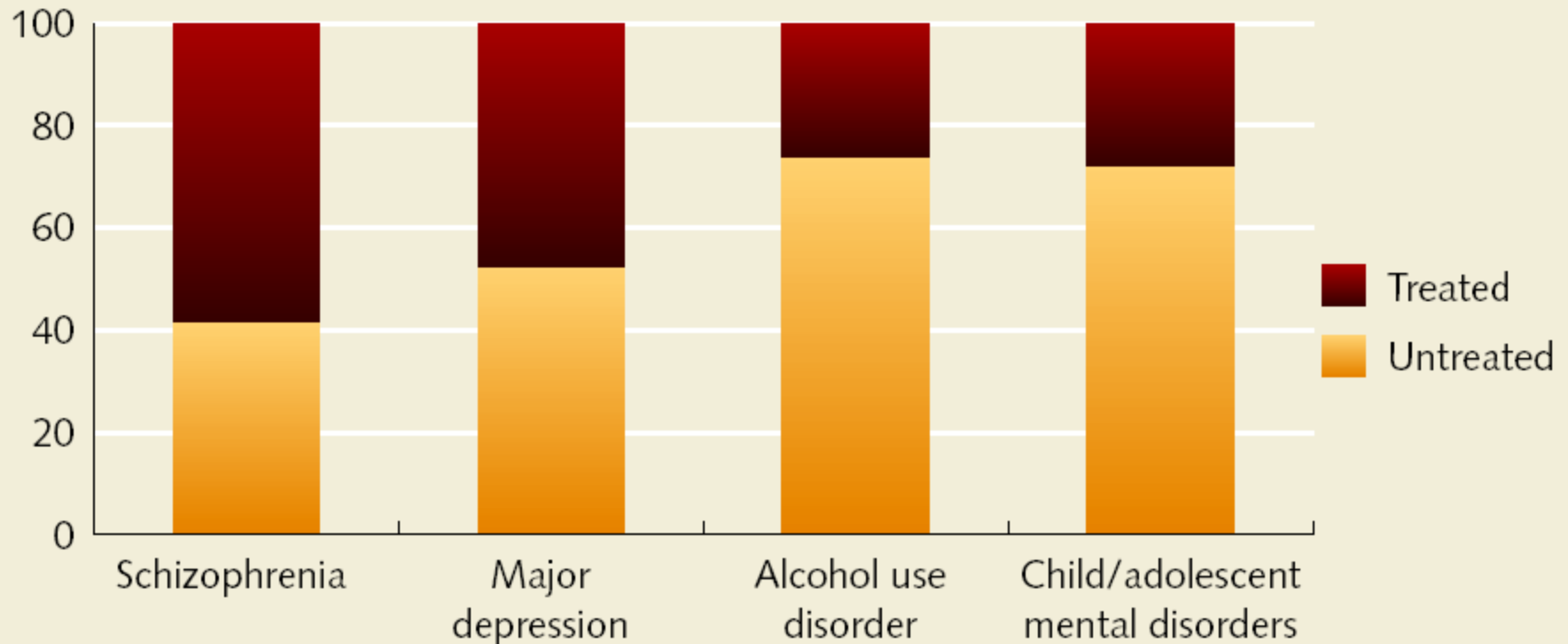


Number of psychiatrists per 100,000 population

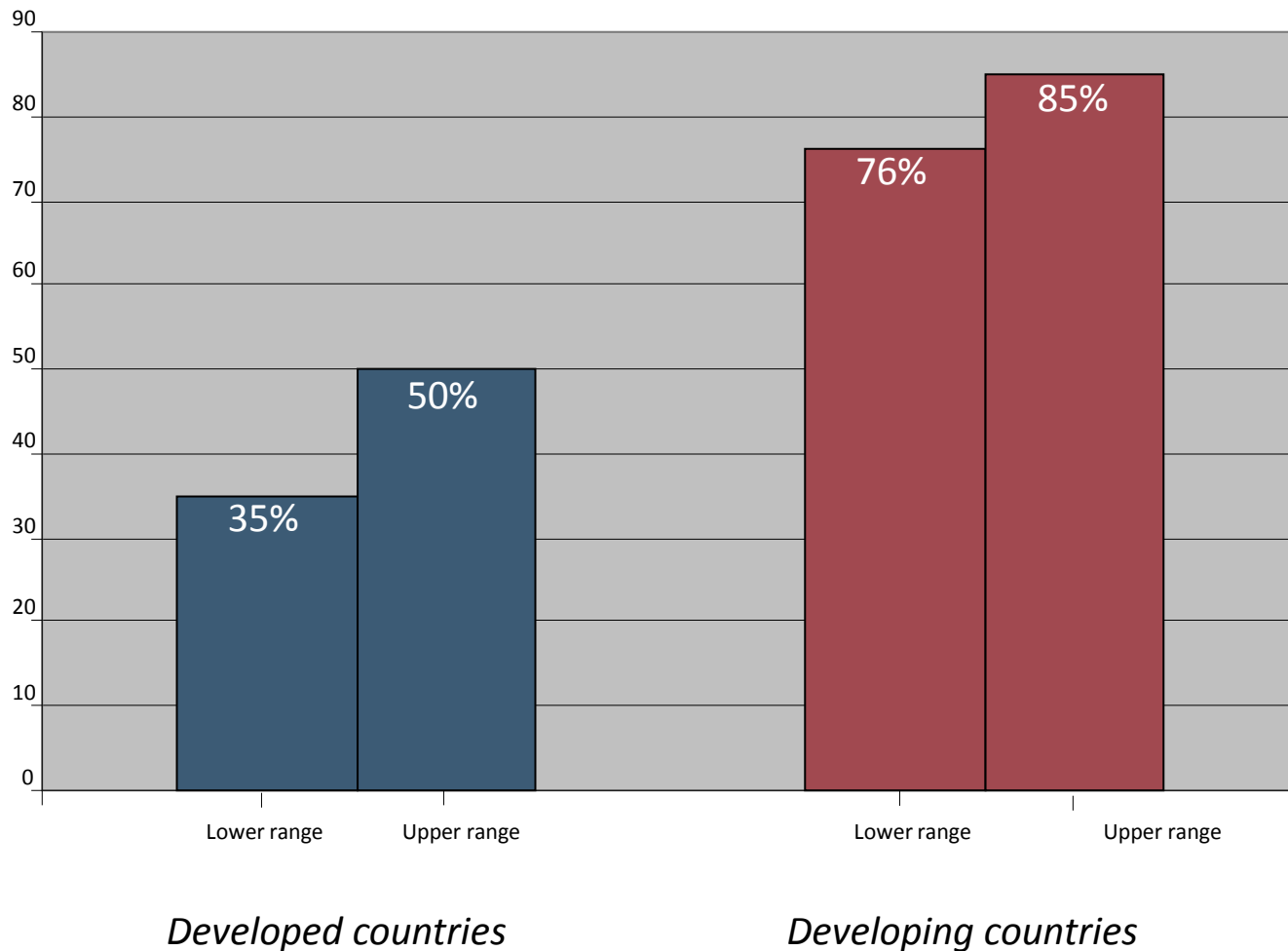


The treatment gap

Treatment gap rates (%) by disorder (world)



Gap in treatment: Serious cases receiving no treatment during the last 12 months

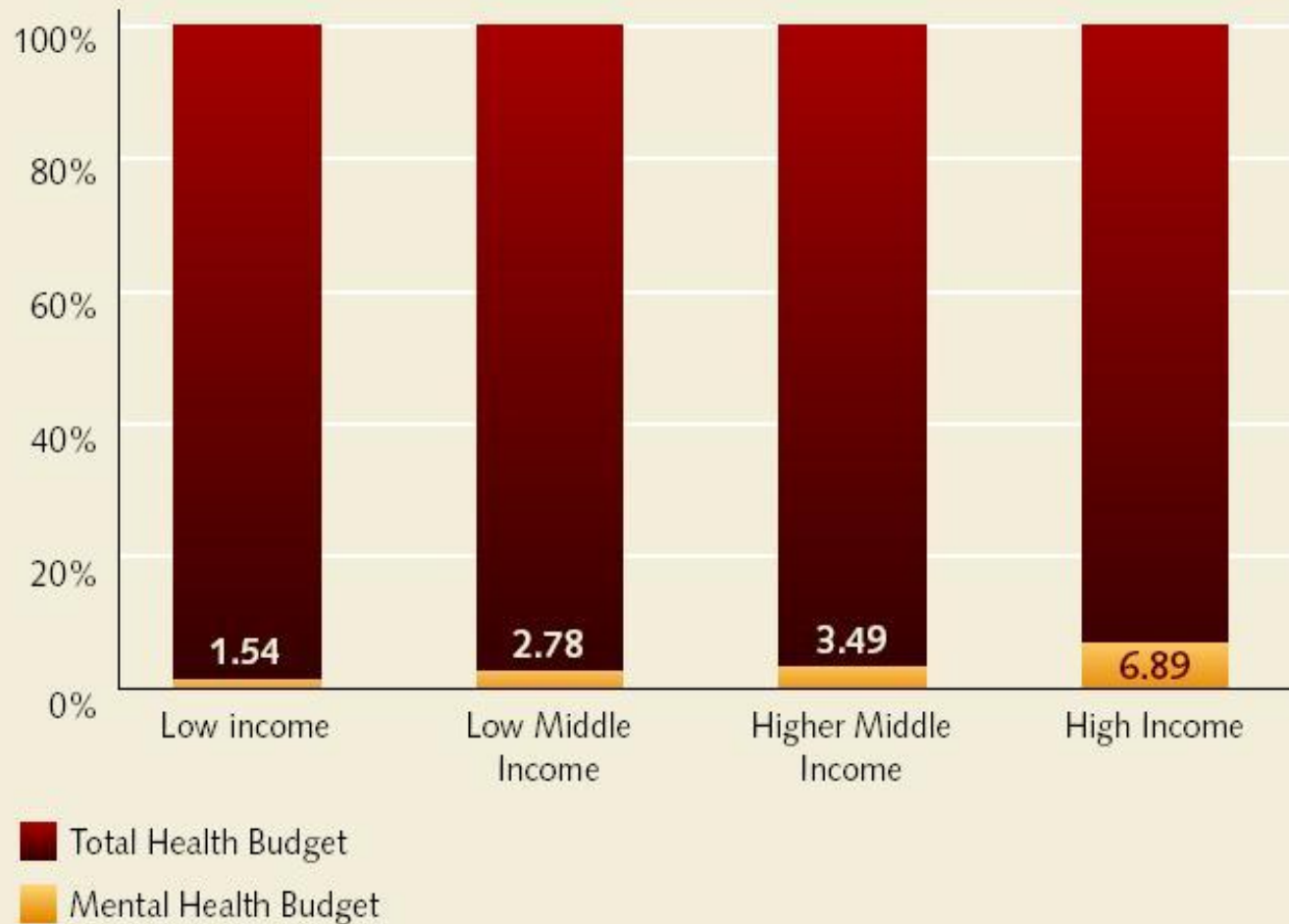


(WHO World Mental Health Consortium, JAMA, June 2nd 2004)

Gap in budget:

The gap between the burden and the budget

Share of mental health budget in total health budget of countries by income level (%) (World Bank classification)



8 PRIORITÁ per i Paesi a Basso e Medio Reddito

- **Depressione**
- **Schizofrenia**
- **Suicidio**
- **Epilessia**
- **Demenze**
- **Alcol**
- **Sostanze**
- **Ritardo Mentale**

Il Mondo Reale di BigPharma

Farmaci Top per spesa di marketing diretto

1° *Nexium*

Esomeprazolo

Proton Pump Inhibit.

Astra Zeneca

2° *Lunesta*

Eszopiclone

Ipnótico-Sed.

Sepracor

11° *Wellbutrin*

Bupropione

Dopamine RI

Glaxo SK

14° *Ambien*

Zolpidem

Ipnótico-Sed.

Sanofi

Il Mondo Reale di BigPharma

- **La spesa reale di U.S.marketing di BigPharma è cresciuta da 11.4 bilioni di dollari nel 1996 a 29.9 bilioni di dollari nel 2005**
- **La spesa nella pubblicità diretta al consumatore (ove consentita) è cresciuta del 330% dal 1996 al 2005**

Il Mondo Reale di BigPharma

- 84% della informazione di marketing minimizza o omette informazioni sugli effetti collaterali o esagera la efficacia
- **Lilly** condannata per Strattera (atomoxetina) per “false or misleading advertisement”
- **Pfizer** condannata per Zoloft (sertralina) per omissione dell’informazione sui rischi di suicidalità

SSRI

- “We found a bias toward the publication of positive results. Not only were positive results more likely to be published, but studies that were not positive, were often published in a way that conveyed a positive outcome”.
- “Selective reporting deprives researchers of the accurate data they need to estimate effect size realistically.
- “By altering the apparent risk-benefit ratio of drugs, selective publications can lead doctors to make inappropriate prescribing decisions that may be in the best interest of their patients and, thus, the public health””

(Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy. Turner and coll. New England J. Med. 2008)

SSRI

- “Meta-analyses of antidepressant medications have reported only modest benefits over placebo treatment...”
- “Drug-placebo differences in antidepressant efficacy increase as a function of baseline severity, but are relatively small even for severely depressed patients. The relationship between initial severity and antidepressant efficacy is attributable to decreased responsiveness to placebo among very severely depressed patients, rather than to increased responsiveness to medication”

(Initial Severity and Antidepressant Benefits: A Meta Analysis. Kirsh and coll. PLoS Medicine 2008)

ATIPICI

- “As a group they are no more efficacious, do not improve specific symptoms, have no clearly different side-effect profiles than the first generation antipsychotics, and are less cost-effective”

(The spurious advance of antipsychotic drug therapy. Tyrer and Kendall, Lancet 2009)

ATIPICI

- “There is no clear evidence that atypical antipsychotics are more effective or are better tolerated than conventional antipsychotics. Conventional antipsychotics should usually be used in the initial treatment of an episode of schizophrenia unless the patient has previously not responded to these drugs or has unacceptable extrapyramidal side effects”

(Atypical antipsychotics in the treatment of schizophrenia: systematic overview and meta regression analysis. Geddes and coll. BMJ, 2000)

ALTRI

- “Merck systematically underreported mortality from its drug, rofecoxib, which it claimed slows progression in Alzheimer disease.”
- “ Merck ghost authored and guest authored clinical papers written by company employees but published under the names of academics”

(Psychiatry and Human rights. L. Eisenberg, 2009)

Il Mondo Reale di BigPharma

- “Drug companies don’t have education budgets; they have marketing budgets from which their ostensibly educational activities are funded.”
- “Continuing Medical Education funded by Drug companies is a case of the fox not only guarding the chicken coop, but living inside it”

(continua)

Il Mondo Reale di BigPharma

(continua)

- “It’s easy to fault drug companies....Still, apologists might argue that, despite its legal transgressions, the pharmaceutical industry is merely trying to do its primary job-furthering the interests of its investors...”
- “Doctors, medical schools, and professional organizations have no such excuse”

(Big Pharma, Bad Medicine. Angell Marcia, past editor in chief of the New England Journal of Medicine, 2000)

Psicofarmaci e Paesi a Basso e Medio Reddito

DUE SFIDE

1. Farmaci ancora con Brevetto o comunque costosi che cercano di entrare nel mercato (SSRI e Atipici)
2. Cultura Psicofarmacologica Assente

**Farmaci ancora con Brevetto o comunque
costosi che cercano di entrare nel mercato
(*SSRI e Atipici*)**

**Autorità sanitaria
in conflitto con psichiatri**

- Profilo Rischi/Benefici: fonti di informazione
- Utilizzazione “reale”
- Strategie di monitoraggio delle prescrizioni e feed back “critici”

Spesa Farmaceutica come % della Spesa Sanitaria

- Europa 13%
- Thailandia 35%
- Indonesia 39%
- Mali 65%

Cultura Psicofarmacologica Assente

- Limitazione linguistica (es: America Latina, Paesi Slavofoni)
- Accesso a letteratura internazionale indipendente (costi, distribuzione)

Cultura Psicofarmacologica Assente

- Scarsa capacità di “leggere” la letteratura (Angell M.):
 - a) “Protocols designed to yield favorable results for sponsors”
 - b) “Drug compared with another drug administered at a dose so low that the sponsor’s drug looks more powerful”
 - c) “D that is likely to be used by older people will be tested in young people, so that side effects are less likely to emerge”
 - d) “Comparing a new drug with a placebo, when the relevant question is how it compares with an existing drug”
 - e) Too small sample of patients
 - f) Too short period of experimental observation
 - g) Use of Surrogate End Points

Meaningful or surrogate end-points



Cultura Psicofarmacologica Assente

- Informazione esclusivamente dalla Industria
 - Finanziamento da parte dell'Industria di TUTTE le attività di Formazione
 - “We note with alarm the enormous largesse drug companies distribute to psychiatrists in under resourced countries like Pakistan, to promote drugs that are prohibitively expensive for the vast majority of Pakistani patients”
- (Murky waters: the pharmaceutical industry and psychiatrists in developing countries. Khan M., 2006.*
- Curricula Universitari “poveri”

Hamburg, WPA World Congress

Estimado Benedetto,

Te escribo para pedirte un favor. Aquí me han dado unos cupones para almorzar y cenar más me han dado una invitación para un gran banquete la noche del Jueves (todo esto es un "regalo" de la Farmaceutica XXXX).

Podrias ayudarme de manera que yo pueda devolver los cupones y en lugar de ellos tener un descuento para comprarme el Goodman and Gillman. Me gustaria tanto tenerlo pero no me lo puedo permitir (tu conoces nuestros sueldos modestos que cuando viajamos al primer mundo ni valen la orina del perro!)

Tu amigo

Roberto

Dobbiamo volere fortemente essere un esempio di rigore scientifico e morale

“ THE PROVISION OF MEDICAL CARE IS NOT
PRIMARILY A LEGAL OR FISCAL EVENT; IT IS A
MORAL TRANSACTION”

(Leon Eisenberg, 2008)