



# Treating challenging behaviors with Antiepileptic and Mood Stabilizer Drugs in IDD

An empirical study

**Maria Laura Galli**, Giuseppe Chiodelli, Luigi Croce  
Serafino Corti, Mauro Leoni, Francesco Fioriti, Lucio Cottini

Fondazione Sospiro - Cremona, Italy



# General Aim

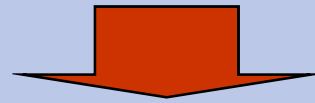
1. To change mental health condition, through the alignment of prescription patterns to Evidence Based Guidelines and integrated CBT approach
2. To explore use and effects of AEDs and psychotropic medications on Challenging Behaviors (CBs) and psychopathology, in 37 adults with IDD living in residential setting



# Premises

MAIN STUDY: The effectiveness of mood stabilizers management for and antiepileptic medication for the behaviour problems in adults with intellectual disability: a systematic review

S. Deb et al., *Journ. of Intell. Disab. and Res.*, 2008



- Most studies have methodological problems
- We need additional *methodologically sound trials* are needed, in order to suggest the effectiveness of these drugs in CBs



## Premises [cont]

- Studies on AED:
  - Antiepileptic drugs have behavioral effects in people treated for epilepsy or psychiatric problems  
*S. Nadkarni and O.Devinsky, Epilepsy Currents, 2005*
  - Negative effects on behaviour are shown in people with IDD  
*Gates J., Challenging behaviour of persons with Mental Health Disorders and Severe Developmental Disability, 1999*



## Premises [cont]

- A few Guidelines are available:
  - Treatment of Psychiatric and Behavioural Problems in Mental Retardation  
Expert Consensus Guideline Series, *American Association on Mental Retardation*, 2000
  - Using medication to manage behaviour problems among adults with a learning disability  
S.Deb & G.Unwin, 2006
- Standardized Rating Scales are available to analyse psychopathological and behavioral functioning



## Premises [cont]

- An integrated medical plus psychological Model is necessary:
  - There are strong evidences of non-pharmacological cognitive-behavioral efficacy on CBs (Emerson, 2002)
  - The Biopsychosocial Model is suggested as a strong reference (Ellis, 1980; Dosen, 2005)
  - The Behavioral Ecological Model is suggested as a strong reference (Hovell et al., 2002)



# Working Hypothesis

The use of Prescription Guideline plus an integrated approach...

1. ...can positively influence:

- A. the level of CBs
- B. the indicators of psychopathology
- C. the general level of health

2. ...can increase:

- A. the individual involvement in activities
- B. the nr of positive behavior interventions



# Methodology

- Study design: AB, longitudinal ongoing clinical research
- Duration: 3 years
- Independent variable: implementation of psychopharmacological GL; Use of integrated medical-psychoeducational approach
- Dependent variables: (1). Disadaptive behavior symptoms (CBs); 1b. Mental health (psychopathology indexes); 1c: general level of health and (2) QOL objective levels; 2°: individual involvement in activities; 2b. Nr of positive behavior interventions
- Statistical analysis: SPSS analysis on quantitative data



# Subjects

- Nr of subjects: 37
- Age: M 47,79 (SD 13,05)
- Male/Female = 35/2
- Years of residential setting: M 20,17
- IDD severity features: severe-moderate (IQ) plus high incidence of CBs
- Absence of any epilepsy diagnosis
- Absence of a DSM-IV psychiatric diagnoses
- Prevalence of CBs/mental disorders: all subjects have severe impact
- High level of healths' problems (CIRS comorbidity: 2,70)
- Prevalence of Psychotropic Medications (AEDs NOT used for Epilepsy) Prescription: 100% (all subjects)



# Assessment

1. **DASH-II** (Diagnostic Assessment of the Severely Handicapped-II) (Matson, 1991): total score and 13 subscales
2. **ABC** (Aberrant Behavior Checklist–Community) (Aman et al. 1995): 5 subscales
3. **CGI** (Clinical Global Impressions) (W. Guy, Modified From: Rush J, et al: Psychiatric Measures, APA, Washington DC, 2000)



# Intervention (1)

## 1. Use of integrated medical-psychoeducational approach

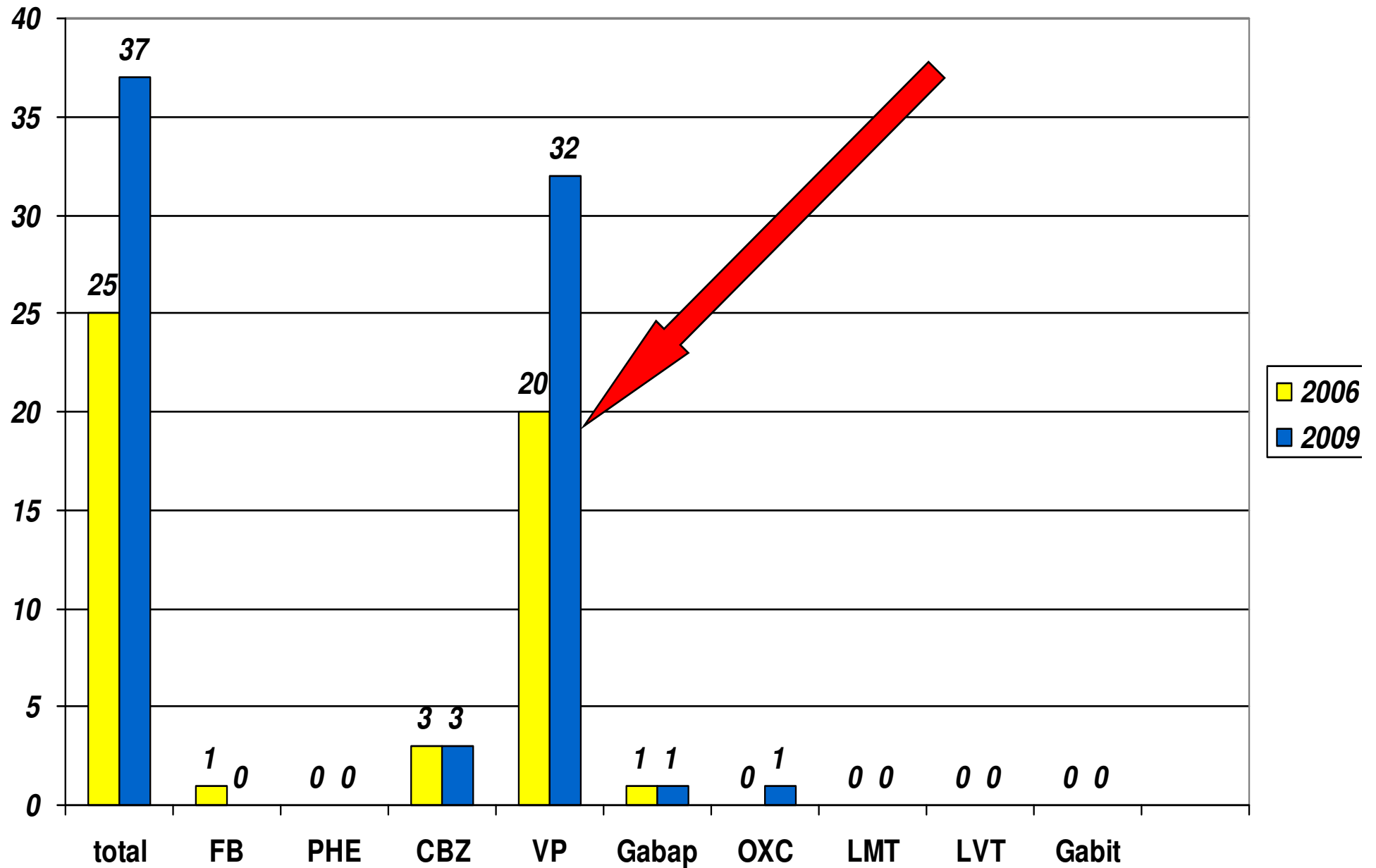
- Integrated approach between pharmacological and psychoeducational interventions (Wieseler, 1999):
  - Level of individual treatments (persons with IDD)
  - Level of clinical consensus (staff evaluation and multiprofessional intervention)
  - Level of services organisation
- Psychoeducational Approach (Blom, 1967):
  - CBT framework of references for practice and treatments
  - Intervention on individual development, on CBs, and on the environment



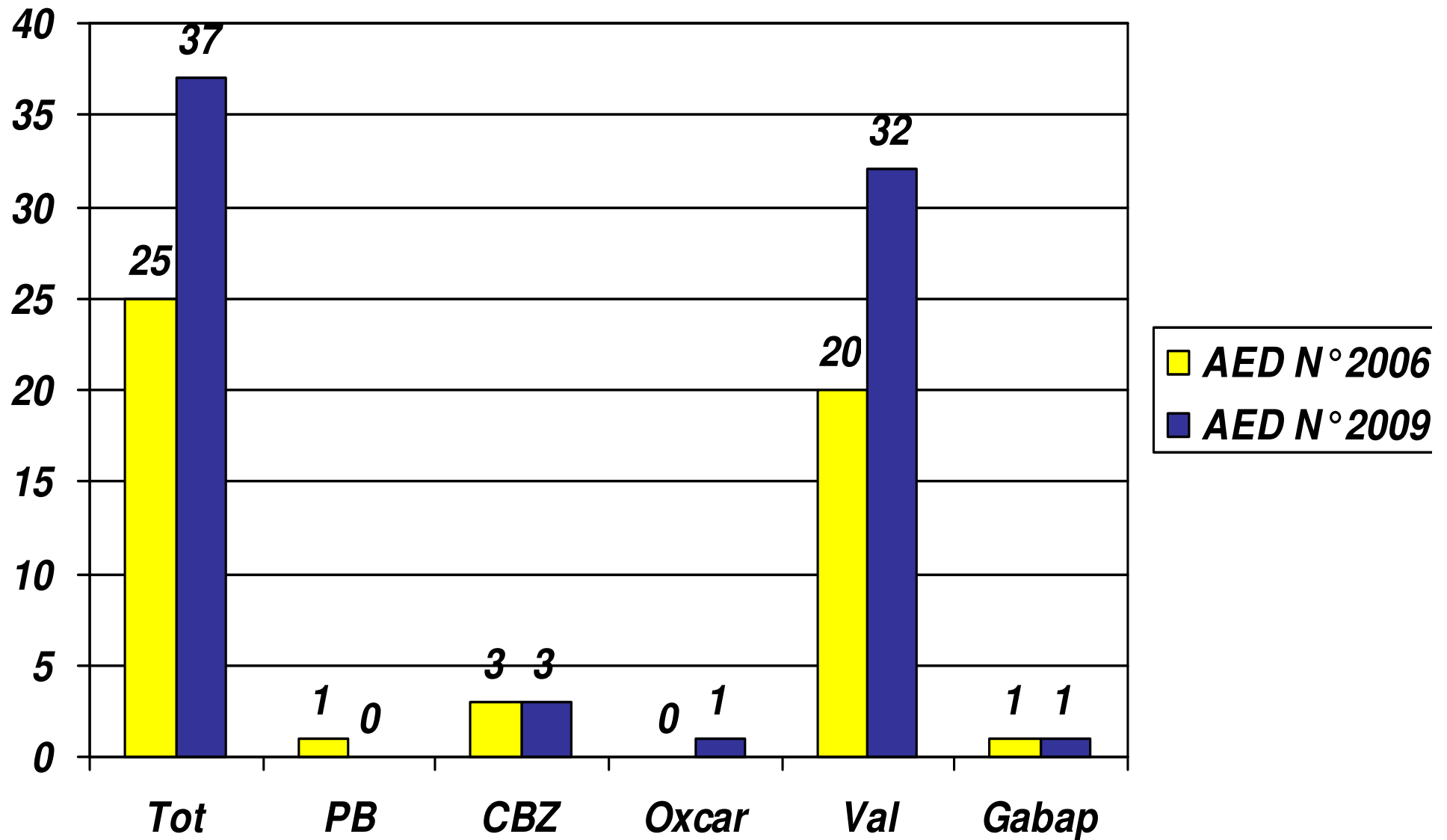
## Intervention (2)

2. Use of Guide Lines for psychotropic prescriptions (AEDs), with a specific selection of the sample:
  - Subjects in psychoactive medications treatment, with severe CBs
  - Part of the sample (25 sbjs) already in treatment with AED
  - AED treatment introduced for remaining part of sample

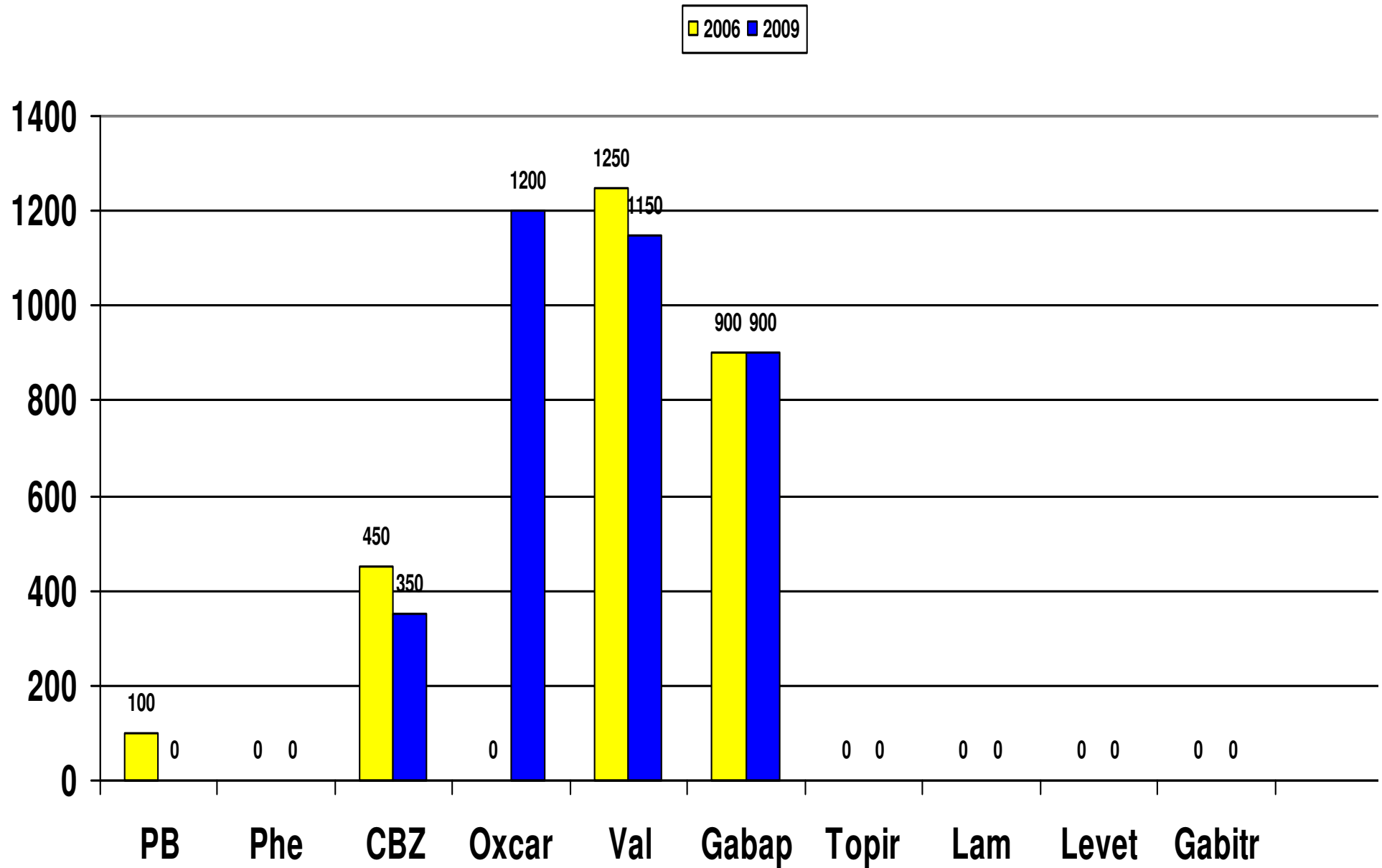
# Total number of subjects receiving AEDs and ALL types of drugs



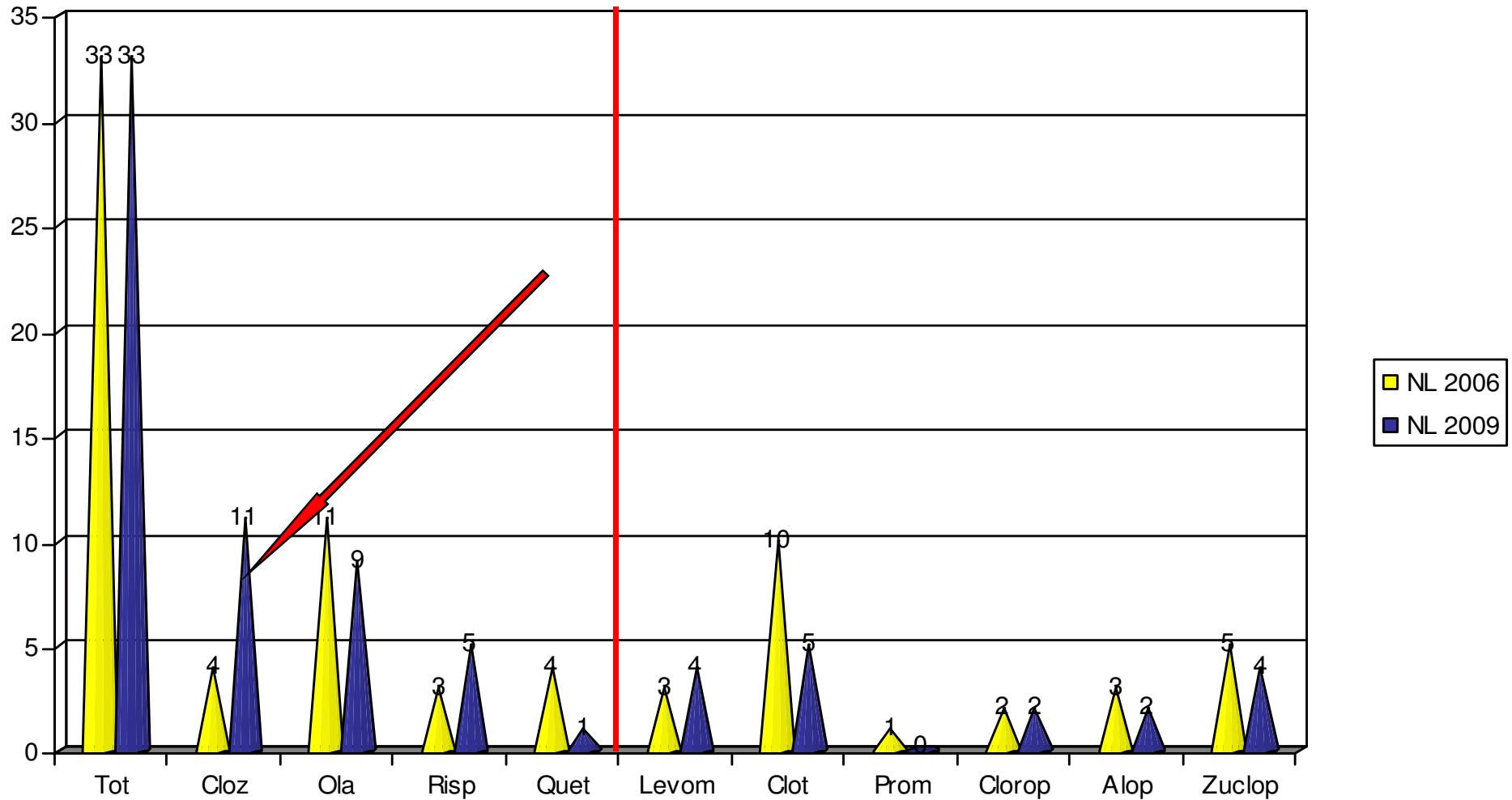
# AEDs N° Prescription



# Average dosage for each AED medication

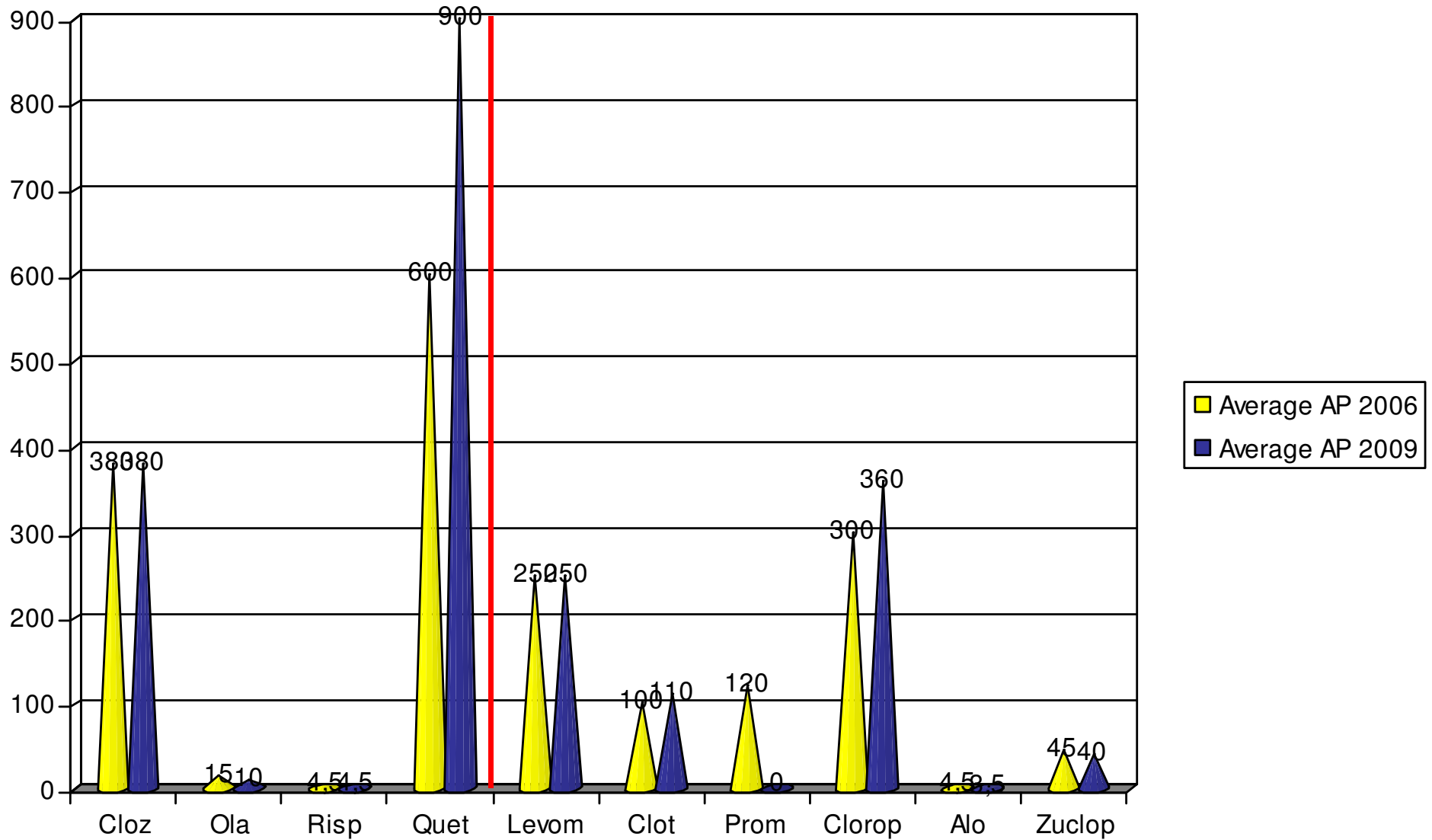


# Total AP prescriptions and different type of medication

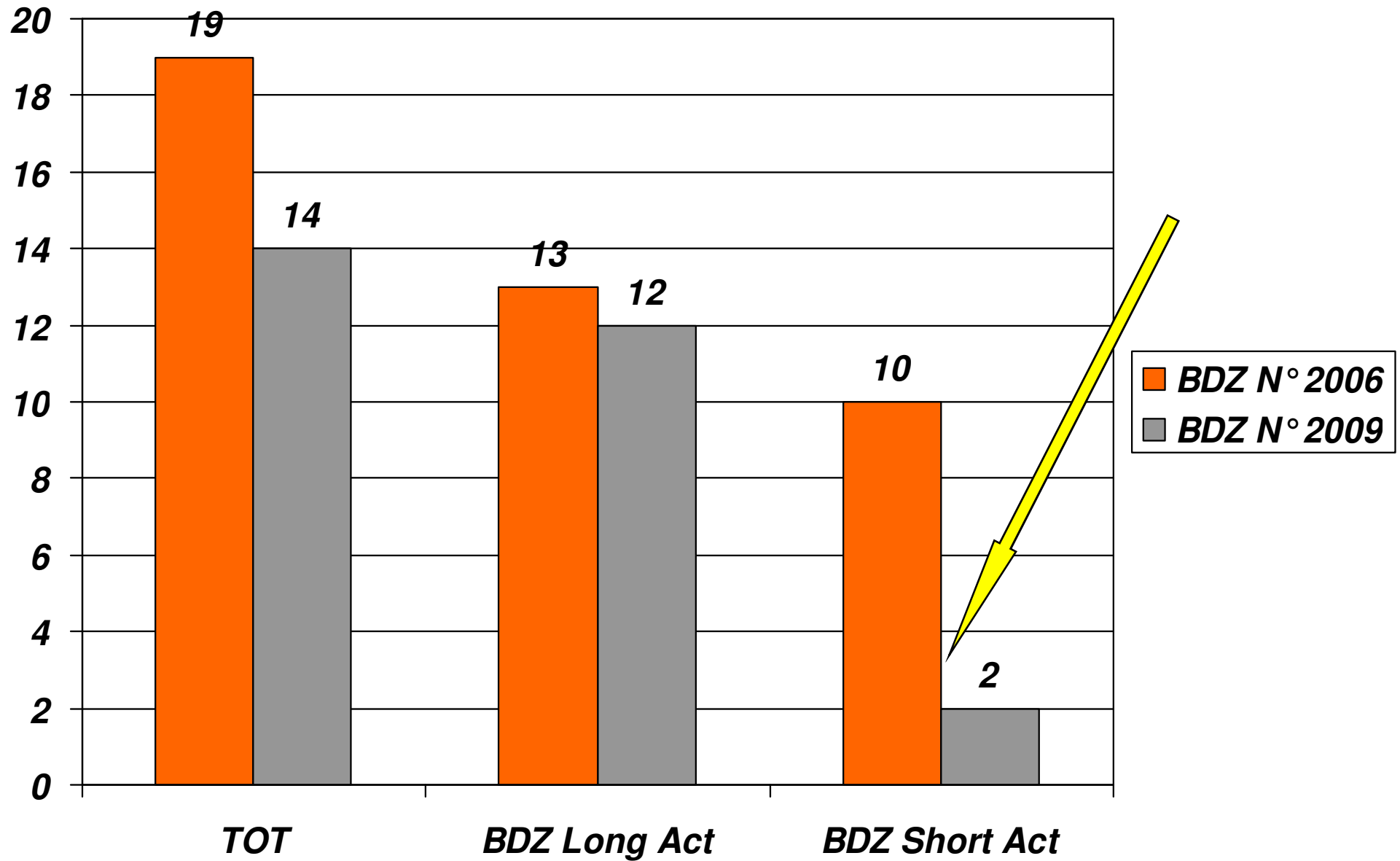


**Prescriptions means: total number of subjects assuming that drug**

# Average Dosage of AP



## Total number of BDZ prescriptions

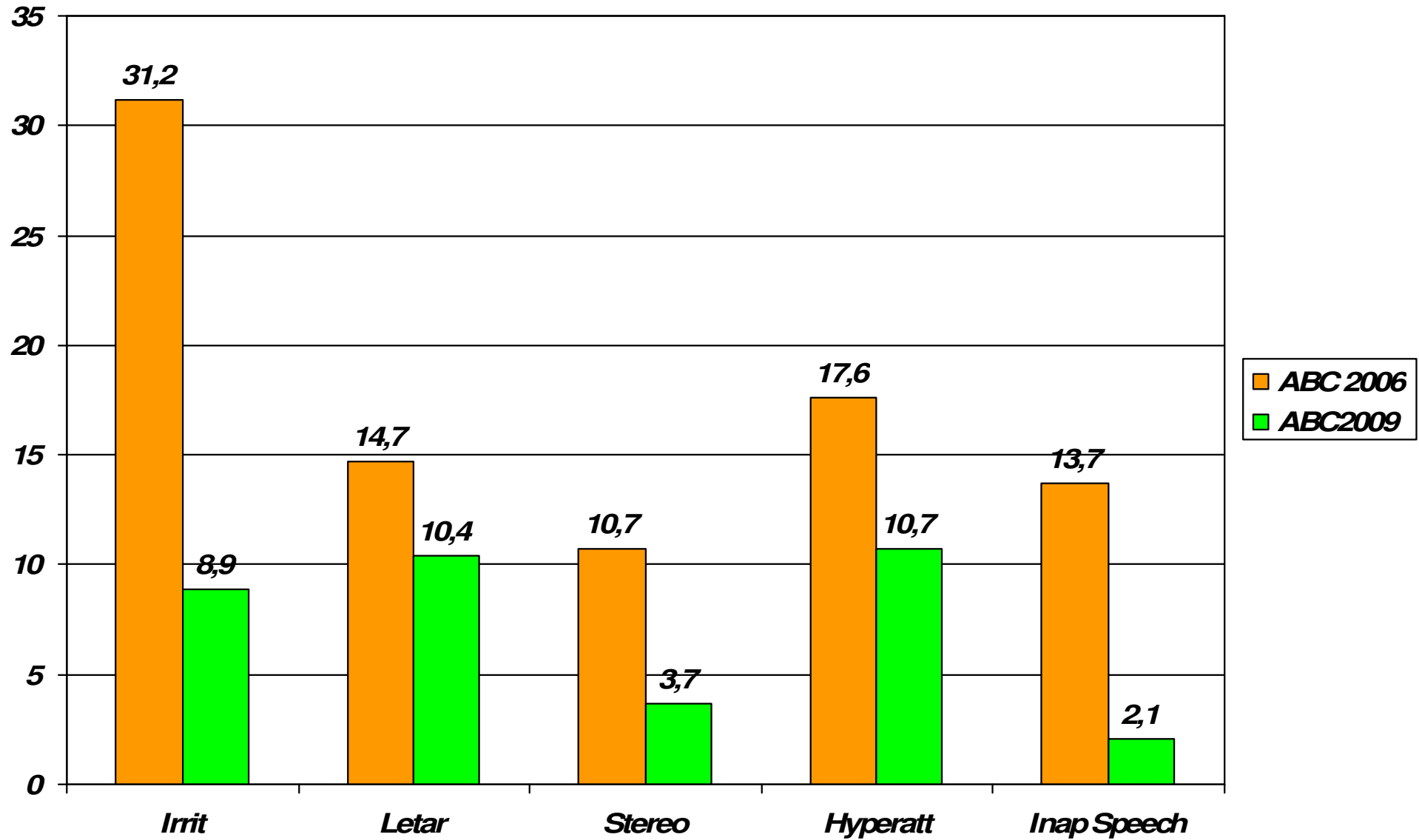




# Results (1A)

Reduction in total scores ABC

# Total score for the 5 ABC subscales





ABC Scales Measures	ABC IRRIT	ABC LETARG	ABC STEREOT.	ABC HYPERATT.	ABC INAPPR. SPEECH
2006	$\bar{X} = 31.270$ $s = 8,428$ $\bar{x}$	$\bar{X} = 14.756$ $s = 10,001$	$\bar{X} = 10,729$ $s = 5,635$	$\bar{X} = 17,594$ $s = 12,557$	$\bar{X} = 13,756$ $s = 9,325$
2009	$\bar{X} = 8.972$ $s = 7,525$	$\bar{X} = 10.486$ $s = 7,823$	$\bar{X} = 3,756$ $s = 3,569$	$\bar{X} = 10,757$ $s = 9,818$	$\bar{X} = 2,135$ $s = 2,162$
1 way ANOVA Repeated measures	F(1,36)=212; $p < .000000001$	F(1,36)=18.36; $p < .0001$	F(1,36)=70,47; $p < .0000001$	F(1,36)=28,87; $p < .00001$	F(1,36)=60,9; $p < .0000001$
Student T	$t = 14.560$ $p < .00000001$	$t = 4,584$ $p < .0005$	$t = 8,394$ $p < .000001$	$t = 5,373$ $p < .0001$	$t = 7,808$ $p < .000001$

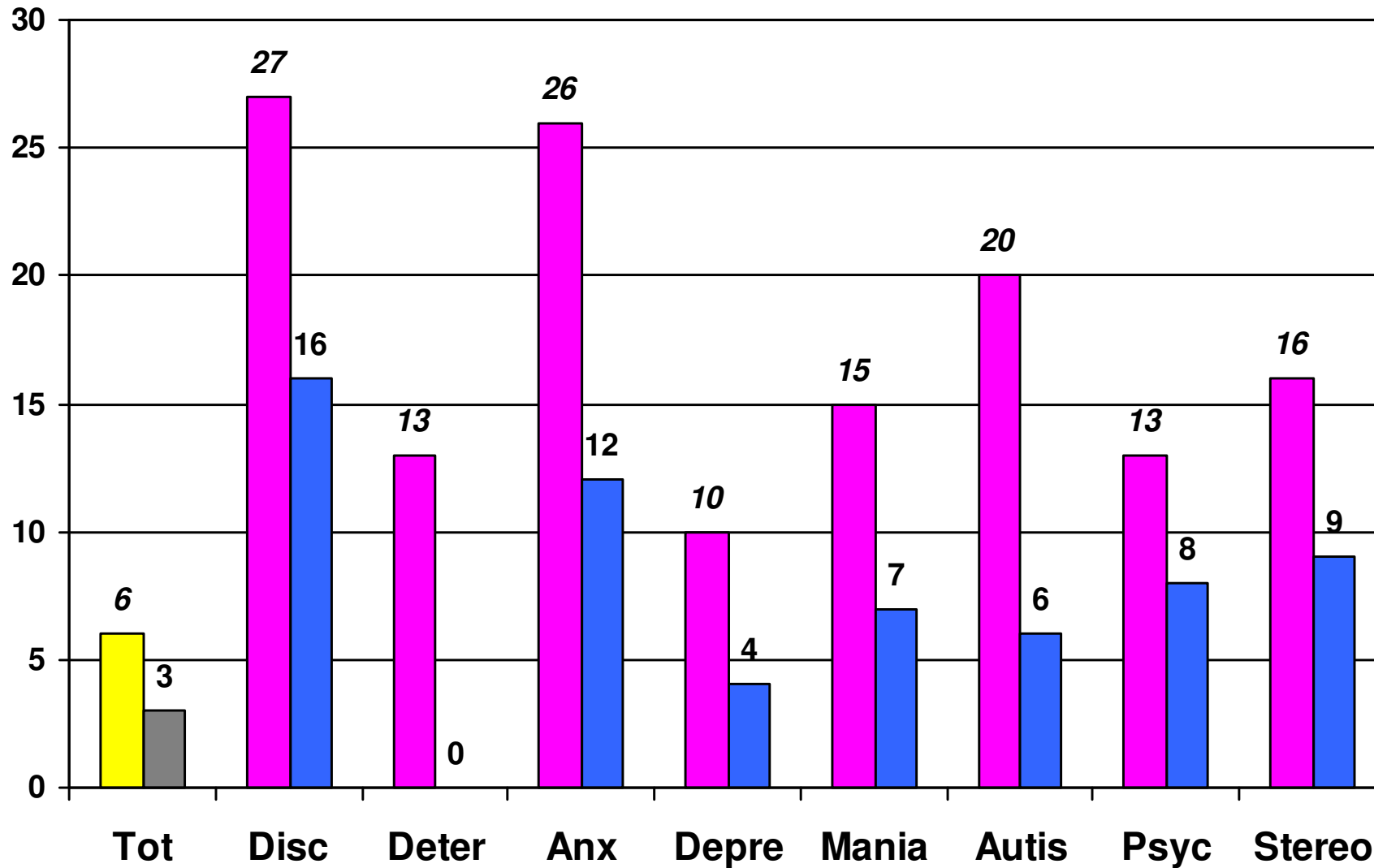


# Results (1B)

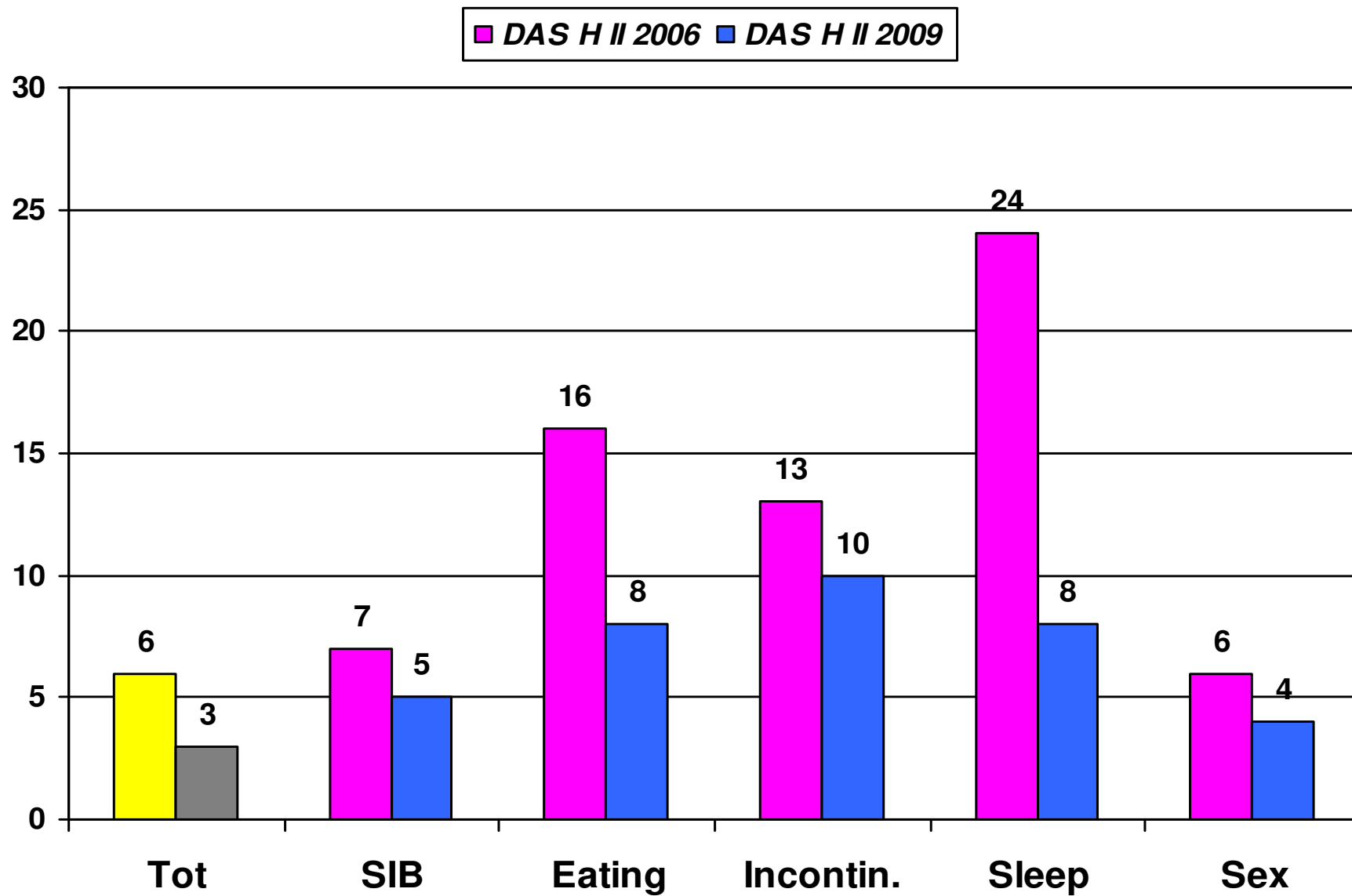
Decrease in DAS-H II total score  
and scales

# Average for psychopathologic DAS-H II subscales

■ *DAS H II 2006* ■ *DAS H II 2009*



# Average for behavioural DAS-H II subscales



	Absent DISC	Present DISC
2006	10	27
2009	21	16
<b>c<sup>2</sup> = 6,72 p &lt; 0,01</b>		

	Absent DET	Present DET
2006	24	13
2009	37	0
<b>c<sup>2</sup> = 15,77 p &lt; 0,0001</b>		

	Absent ANX	Present ANX
2006	24	13
2009	25	12
<b>c<sup>2</sup> = 0,06 n.s.</b>		

	Absent DEP	Present DEP
2006	27	10
2009	33	4
<b>c<sup>2</sup> = 3,17 n.s.</b>		

	Absent MAN	Present MAN
2006	22	15
2009	32	7
<b>c<sup>2</sup> = 4,05 p &lt; 0,05</b>		

	Absent AUT	Present AUT
2006	17	20
2009	31	6
<b>c<sup>2</sup> = 11,62 p &lt; 0,001</b>		

	Absent SCHIZ	Present SCHIZ
2006	24	13
2009	29	8
$c^2 = 1,66$ n.s.		

	Absent SIB	Present SIB
2006	30	7
2009	32	5
$c^2 = 0,40$ n.s.		

	Absent SPHYNT.	Present SPHYNT.
2006	24	13
2009	27	10
$c^2 = 0,57$ n.s.		

	Absent STEREO	Present STEREO
2006	23	16
2009	28	9
$c^2 = 2,96$ $p < n.s.$		

	Absent EAT.	Present EAT.
2006	21	16
2009	29	8
$c^2 = 3,95$ $p < 0,05$		

	Absent SLEEP	Present SLEEP
2006	13	24
2009	29	8
$c^2 = 14,10$ $p < 0,0005$		

	Absent SEX	Present SEX
2006	21	6
2009	23	4
$c^2 = 0,49$ $p < n.s.$		



# Results (1C)

Improvement in CGI



<b>CLINICAL GLOBAL IMPRESSION (CGI) - 2009</b>	<b>Efficacy Index nr subjects</b>
<b>Extremely improved</b>	<b>29</b>
<b>Improved</b>	<b>8</b>
<b>Worsened</b>	<b>0</b>



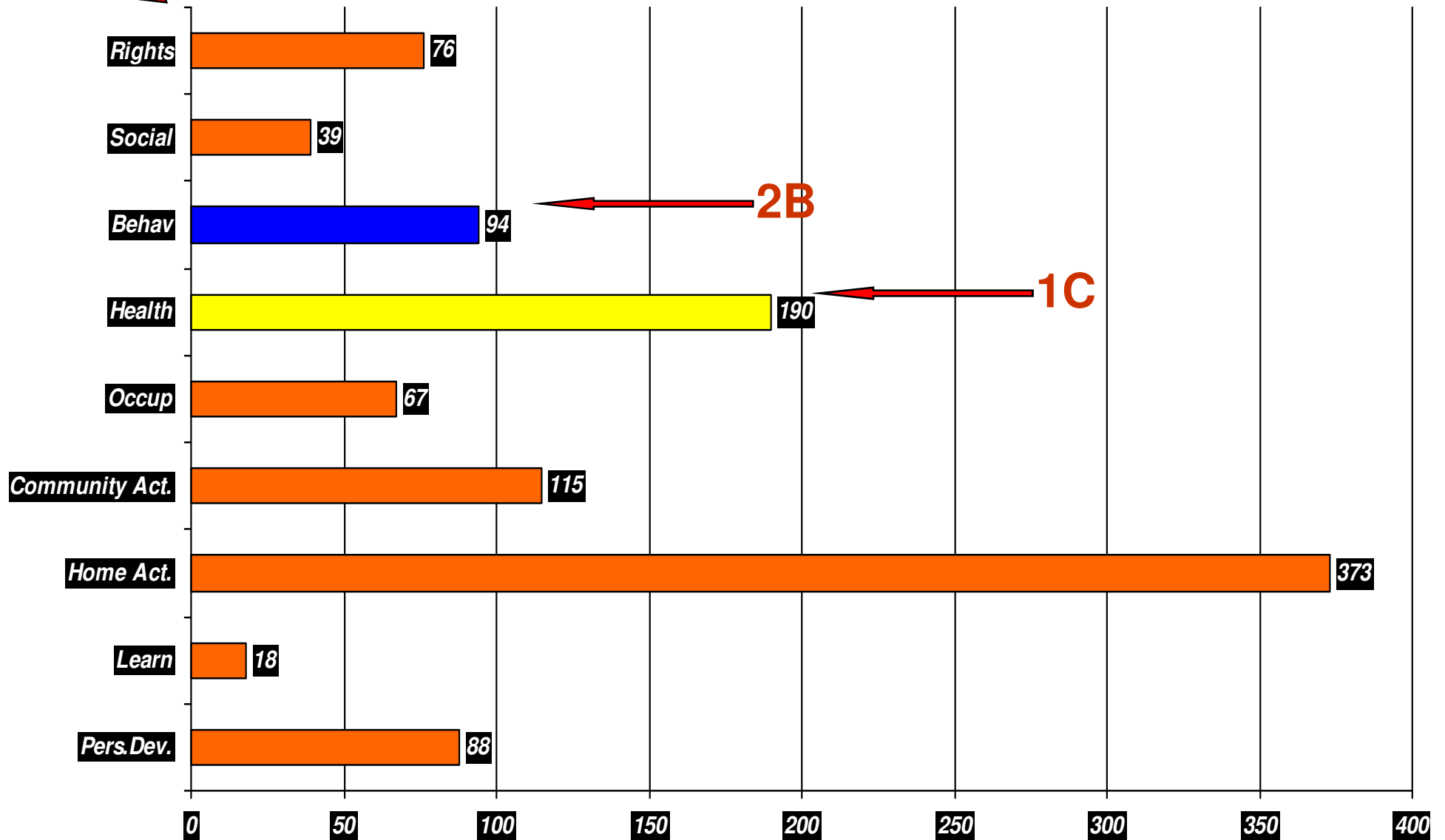
## Results (2)

- A. nr of activities and participation (increased)
- B. nr of positive behavior intervention on CBs (increased)

# Total number of objectives in QOL Domains

2A

■ Pers.Dev. ■ Learn ■ Home Act. ■ Community Act. ■ Occup ■ Health ■ Behav ■ Social ■ Rights

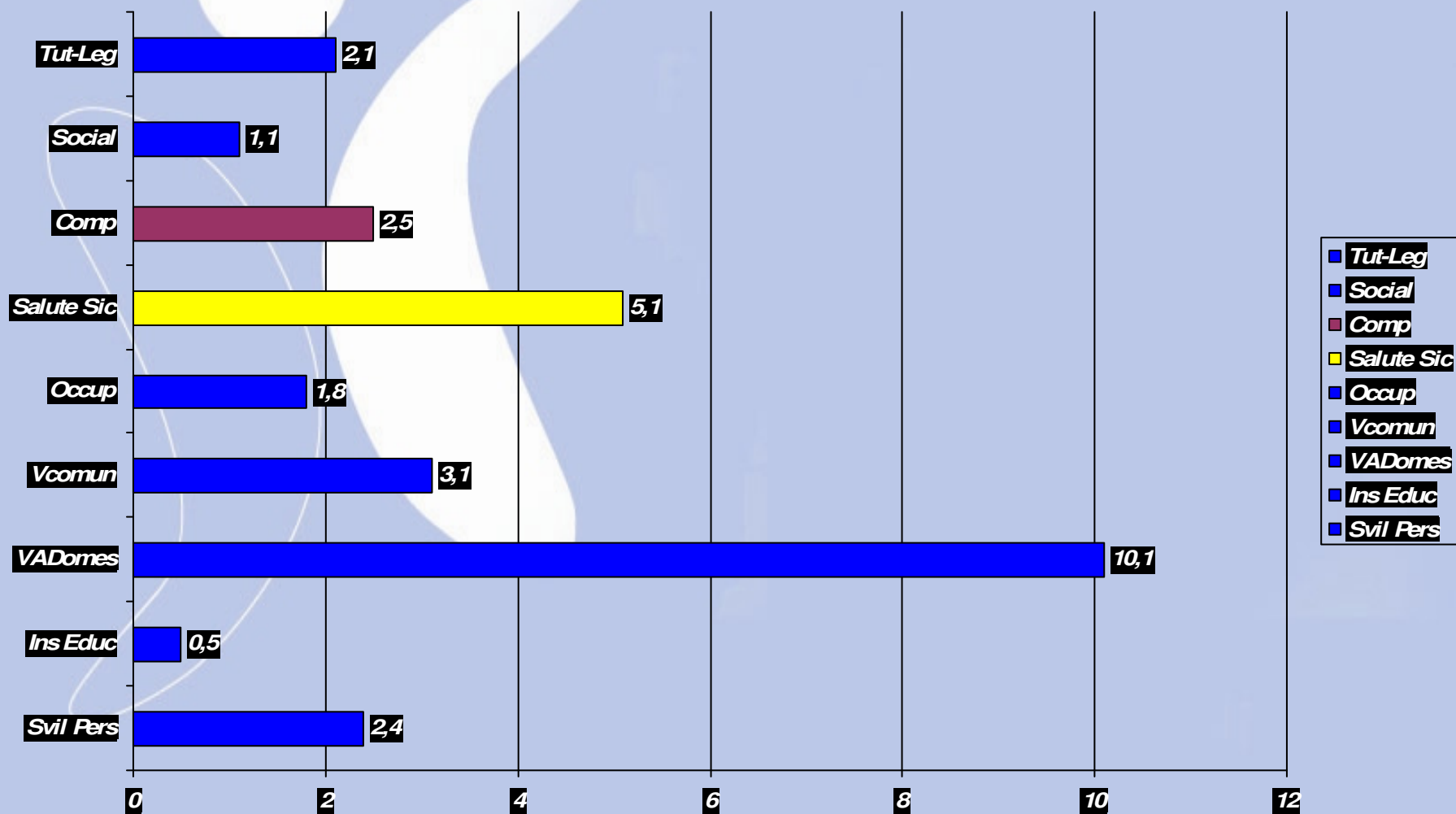


2B

1C



## Average numbers of objectives in the QOL Domains





# Conclusion

The use of an integrated approach and guidelines for psychotropics - AEDs prescription in IDD with Mental disorder can have effectiveness through:



# Concusion

1. Reduction of the level of psychopatology and CBs without increasing sedation
2. Re-assessment and re-modelling the prescription pattern of other psychoactive medications (AP and BDZ)



# Discussion

3. When prescriptions are based on individual functioning and Quality of Life indicators (not purely clinical symptoms) side effects are better controlled



# Discussion

3. When improving the level of mental health, we notice a significant improvement in general level of health
4. Enhancing the individuals development through supports activities and implementing participation into life's environment...



# Limitations and Strengths

- Small sample size
- Low level of control in the study design, because of the high number of factors to monitor
- Deficit in random and blindness selection
- Residential setting:
  1. low representativeness of the group
  2. A setting which consent a strict clinical control of a new drug introduced and its side effects
  3. A coherent way of prescription



# Contacts

- **Maria Laura Galli**

[maria\\_laura.galli@fondazionesospiro.it](mailto:maria_laura.galli@fondazionesospiro.it)

- **Giuseppe Chiodelli**

[giuseppe.chiodelli@fondazionesospiro.it](mailto:giuseppe.chiodelli@fondazionesospiro.it)