

Weight Gain Management

European Planners Meeting

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Weight Gain Management

- ◆ **Be prepared for the issue and related concerns**
 - No "Flinch Factor"

Weight Gain Management

◆ Probe to determine reason for concern

- Is the MD seeing substantial weight gain in his/her own patients?
- Is the concern brought up by the competition?
- Has the MD read about weight gain with atypical antipsychotics in the literature?

◆ Acknowledgement of the class side effect

- This is a class phenomenon - see it with clozapine, risperidone, quetiapine, ziprasidone
- In clinical trials, 41% of olanzapine-treated patients gained $\geq 7\%$ over their baseline body weight.
 - » Average mean gain was 3.53 kg
- Weight gain at 1 year (HGAI) suggests a slower rate of gain relative to the first 6 weeks of treatment

◆ Acknowledgement of the class side effect

- In HGAJ, at 1 year (N=349)
 - » a minority of patients gained >10kg (28%)
---> most gain between 10-15 kg
 - » 16% of patients **LOST** weight
 - » **Over 56% of patients gained \leq 10 kg!**
- Ziprasidone not necessarily the solution, as 10% weight gain in general population (likely to be more in pts who gained weight with Zyprexa)

Weight Gain Management

- ◆ **Is there any way to predetermine which patients will experience weight gain?**
 - Initial work has been done on predictors of weight gain: increased appetite, clinical response, low baseline BMI

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- ◆ **Clarify the impact on treatment plan**
 - Weight gain leading to discontinuation / patient loss occurred in a very limited number of cases in clinical trials
 - » Only 7 of 2500 (0.3%) Zyprexa-treated patients discontinued due to weight gain
 - Trade-off with efficacy/safety/tolerability benefits received with Zyprexa

Weight Gain Management

- ◆ **How should the MD manage this "class" side effect?**
 - "What are your suggestions, Doctor?"

Weight Gain Management

◆ How should the MD manage this "class" side effect?

- There have been no clinical trials conducted to examine weight gain to date, but anecdotally:
 - » Tried changes in diet/exercise?
 - ◆ Weight gain is class phenomenon - with atypical compounds patient is able to function again and lead a healthier more active lifestyle
 - » Change in dose?
 - » Co-prescribe a treatment to control weight?
 - » Last option should be alternative therapy

◆ **Don't introduce the issue!!!**

- Maintain focus on main message. Primary objective is to **effectively control** all symptoms of psychoses and **reintegrate** the patient.

Weight Gain Management

- ◆ ADDENDUM - Use of Medical Letter
 - Current Medical Letter is being updated
 - Check with local Medical Information personnel for contact

- ◆ Pilot study looking at mechanism of action of weight gain with antipsychotic
- ◆ Two studies looking at fluoxetine add-on to manage olanzapine caused weight gain
- ◆ One pilot study looking at adjunctive therapy with Meridia (weight loss compound)
- ◆ Initial evaluation of results of pilot studies will result in a larger Lilly conducted trial planned for 1999.