Weight Gain Management

European Planners Meeting
Barcelona
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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?
Weight Gain Management

- 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 ≥7% over their baseline body weight.
    » Average mean gain was 3.53 kg
  - Weight gain at 1 year (HGAJ) suggests a slower rate of gain relative to the first 6 weeks of treatment
Weight Gain Management

◆ 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 ≤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
Weight Gain Management

- 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
Clinical Management of Weight Gain

- 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.