
ADA Consensus Statement

**For internal purposes only
Not to be shared with anyone outside Lilly.**

Lilly
Answers That Matter.

Agenda

The situation

Scope and membership of the panel

Lilly Medical perspective

Lilly's position

Potential Impact

What do you need to do?

Living the Lilly Brand

**For internal purposes only
Not to be shared with anyone outside Lilly.**

File name/location

Company Confidential
Copyright © 2000 Eli Lilly and Company

What is the situation?

Two papers have recently been published looking at diabetes and patients with severe mental illness

- Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes. *Diabetes Care* February 2004;27(2)
- A Special Report; Managing Metabolic Concerns In Patients With Severe Mental Illness, December 2003

**For internal purposes only
Not to be shared with anyone outside Lilly.**

File name/location

Company Confidential
Copyright © 2000 Eli Lilly and Company

What is a consensus statement?

This is an opinion generated by 8 panelists following a 1-day meeting in November, 2003.

This is not an ADA position paper nor is it a publication of new guidelines endorsed by ADA.

**For internal purposes only
Not to be shared with anyone outside Lilly.**

Scope of questions considered by the ADA consensus panel

1. What is the current use of antipsychotic drugs?
2. What is the prevalence of obesity, pre-diabetes, and type 2 diabetes in the populations in which atypical antipsychotics are used?
3. What is the relationship between the use of these drugs and the incidence of obesity or diabetes?
4. Given the above risks, how should patients be monitored for the development of significant weight gain, dyslipidemia, and diabetes, and how should they be treated if diabetes develops?
5. What research is needed to better understand the relationship between these drugs and significant weight gain, dyslipidemia, and diabetes?

**For internal purposes only
Not to be shared with anyone outside Lilly.**

Panel Members & Sponsorship

Panel Members:

- Eugene Barrett, MD, PhD, Chair
- Lawrence Blonde, MD
- Stephen Clement, MD
- John Davis, MD
- John Devlin, MD
- John Kane, MD
- Samuel Klein, MD
- William Torrey, MD

Support

provided by educational grants from Astra Zeneca, Bristol Myers Squibb,
Janssen, Pfizer, and Eli Lilly and Company

For internal purposes only

Not to be shared with anyone outside Lilly.

What is the Lilly Medical Perspective

WHAT DO WE AGREE WITH?

1. We believe that any attempt to provide guidance to improve patient care is the right thing to do in the best interest of patients.
2. We agree that the prevalence of diabetes among individuals with schizophrenia and affective disorders is 2X or more higher than the general population.
3. We agree that baseline screening of risk factors, and ongoing monitoring, should be conducted in all patients prescribed an atypical antipsychotic.
4. We agree that for people who develop worsening of glycemia or dyslipidemia, referral to a clinician with experience dealing with diabetes is recommended.
5. We agree that nutrition and physical activity counseling should be provided for all patients who are overweight or obese, particularly if they are starting treatment with an atypical antipsychotic that is associated with significant weight gain.

**For internal purposes only
Not to be shared with anyone outside Lilly.**

WHAT WERE THE LIMITATIONS OF THE ONE-DAY CONSENSUS PANEL?

1. The topic of differential efficacy and the overall adverse event profiles of antipsychotic drugs was not discussed in detail as the scope of this conference was narrowly focused on weight and potentially related issues
2. Although participants did have access to much of the published information available prior to the meeting, a thorough scientific review of all of the available data was not possible during the one day consensus panel. In any case, the panelists did not have access to the same range of non-public data included in the FDA review.

**For internal purposes only
Not to be shared with anyone outside Lilly.**

What Lilly's position?

- 1. We agree with the majority of the conclusions from this one day consensus conference, including the need for baseline screening and follow up monitoring for worsening of glucose control for all atypical antipsychotics. Lilly does not agree with a controversial conclusion of this opinion paper: the total body of evidence does not support differential rates of diabetes risk among atypical antipsychotics.**
- 2. We agree with the FDA which recently issued class labeling related to hyperglycemia, which calls for monitoring of all patients treated with atypical antipsychotics. The FDA based their labeling decision on an exhaustive, multi year review of all available data, including case reports, epidemiological studies and clinical data. This class labeling includes the following language:**

“Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment emergent hyperglycemia related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia related adverse events in patients treated with atypical antipsychotics are not available.”

- 3. We are concerned that the inconsistency between FDA labeling and this one day consensus opinion may confuse clinicians and their patients, leading to inappropriate discontinuation of atypical antipsychotics and lack of appropriate monitoring for all patients.**

**For internal purposes only
Not to be shared with anyone outside Lilly.**

What's the potential impact of the ADA consensus statement?

This publication can give the competition fuel for the story they are already telling: Choose the anti-psychotic based on risk of diabetes

Some assertions from the ADA consensus statement could lead to inappropriate discontinuations of Zyprexa and lack of appropriate monitoring of metabolic effects during treatment with other atypicals, which may have detrimental consequences for patients

IMPORTANT NOTE: The FDA has stated that they have not changed their decision regarding diabetes class labeling for atypicals

**For internal purposes only
Not to be shared with anyone outside Lilly.**

What is our strategy?

Strategy: To continue doing what we are doing now

- Proactively provide weight management tools and resources to customers to help them help their patients
- Have empathy towards the difficulty that patients have in managing their weight, and conviction in the resources we can provide to help them help their patients.
- Promote FDA class labeling awareness and understanding
- Recommend assessing patients for risk factors of diabetes and monitoring for symptoms of hyperglycemia

**For internal purposes only
Not to be shared with anyone outside Lilly.**

How should you communicate with customers?

“Lilly supports any initiative on behalf of patient care. In fact, Lilly was the sponsor that brought the topic forward for the ADA to discuss. The ADA consensus statement concludes that there is a differential risk of diabetes among the atypical anti-psychotics. This opinion differs significantly from Lilly, multiple opinion leaders and FDA. What is consistent with ADA, FDA and Lilly is the need for assessing patients for risk factors of diabetes and monitoring for symptoms of hyperglycemia on a patient-by-patient basis regardless of the atypical anti-psychotic prescribed.”

This communication is for use in responding to an unsolicited request by a healthcare professional; Please review the guidelines set forth in GPP-01-004, paragraph #2; on how to appropriately respond to unsolicited questions from customers.

**For internal purposes only
Not to be shared with anyone outside Lilly.**

Living the Lilly Brand

Innovation

Medical / Clinical Data

Active listening and responding

Reliable and Trustworthy

**For internal purposes only
Not to be shared with anyone outside Lilly.**

File name/location

Company Confidential
Copyright © 2000 Eli Lilly and Company