

Issues Management Planning

Diabetes

The Lilly logo is written in a black, cursive script font.

Answers That Matter.

Diabetes

Issue

- Diabetes is a significant liability for Zyprexa due to its impact on physicians' prescribing habits, patient's overall health, and potential additional label changes.

Our Position

- When choosing a medication, side effects should be considered within the context of overall efficacy, tolerability and the seriousness of the illness. There are no studies that demonstrate a causal relationship between Zyprexa and the development of diabetes. Epidemiological studies suggest that diabetes may occur in patients taking antipsychotic medications at comparable rates. Therefore the potential for a patient to develop diabetes should not be a differentiating factor when choosing antipsychotic medications.

Evidence for Position

- High incidences of diabetes and hyperglycemia – in the case of diabetes, as much as 2 to 4 times that of the general population – have been reported in patients with severe mental illness for more than 50 years, even before the introduction of antipsychotics.
- Lilly Advanced PCS study, Lilly IMS Study, Janssen Health Plans Study, Janssen Quebec Medicare Study

Diabetes

Rational for Position

- Diabetes is common in the general population.
- Diabetes is more prevalent in people with severe mental illness (2-4 times greater than the general population).
- Diabetes can occur in patients taking antipsychotic medications – at comparable rates.
- Therefore antipsychotic therapy should be based on the efficacy of the medication in controlling the psychiatric disorder and not focus concern on diabetes.

Marketplace Feedback

- Diabetes is associated most closely with Clozaril and Zyprexa among the atypical antipsychotics.
- The issue has mainly been driven by competitive marketing efforts through misinterpreted scientific evidence
 - As a result, MDs tend to look for diabetes with Zyprexa patients more than with others
- Diabetes has been elevated to the #1 concern when choosing an antipsychotic.
- Psychiatrists do not want to treat diabetes – they will refer
- Many psychiatrists are willing to help patients manage weight gain
- The competition has been relentless in their attempts to equate Zyprexa use with the development of diabetes.

Customers Needs

- Diabetes education
- Ready access to consultation of endocrinologists and diabetes educators – for training (CME, etc.)
- Simple solutions to deal with the weight gain

Diabetes

What We Know

- Latest US MR shows that diabetes is the #1 reason physicians are concerned about potential weight gain with Zyprexa.
- Same MR shows that physicians who feel hyperglycemia is a side effect of a specific agent, 99% believe it is specific to Zyprexa.
- Physicians in the US do make conscious decisions not to prescribe Zyprexa (23%) due to concerns about diabetes and may also discontinue the use of medication (18%) due to diabetes.
- Olanzapine causes modest elevations of mean random glucose.
- There is an epidemic increase in the prevalence of DM in the US.
- 1/3 of DM is undiagnosed.
- Comparable increase in the incidence and risk of DM during treatment with antipsychotics (conventional and atypical) vs. general patient population.
- The TED analysis shows consistencies with well established risk factors of DM. Patients that develop DM on olanzapine and other antipsychotics have other common, often pre-treatment, characteristics (risk factors) with patients that develop diabetes and are not on antipsychotics.
- Glucose elevation correlates with weight gain.

What We Don't Know

- The impact of olanzapine on patients already at risk of developing diabetes.
- The long term impact of Zyprexa induced weight gain on the development of diabetes.
- How to best, practically, support MD's in assessing DM risk and appropriate patient follow up.

Diabetes

Key Messages

- Diabetes is increasingly common in the general population
- Diabetes occurs at a higher rate (2-4 times that of the general population) in schizophrenic and bipolar patients.
- Epidemiological studies indicate comparable rates of diabetes among patients treated with antipsychotics.
- A number of factors affect risks for the development of diabetes such as: family history, aging, ethnicity, previous history of glucose intolerance, obesity, dyslipidemia, lack of exercise, hypertension, high-fat diet, excessive alcohol use, hyperprolactinemia and significant mental illness. Therefore, one should assess patients for risk factors and consider recommending preventative therapy.
- Because there is no antipsychotic which is riskier than another in causing diabetes, this should not be a differentiating factor in the selection of an antipsychotic medication.
- The primary considerations for choosing an antipsychotic should be its overall risk/benefit profile – that is - its efficacy in treating the psychiatric illness and its overall tolerability.

Diabetes

Key Messages

- Diabetes is increasingly common in the general population and occurs at a higher rate (2-4 times that of the general population) in schizophrenic and bipolar patients.
- Because diabetes is common in the population you treat, and epidemiological studies indicate comparable rates of diabetes among patients treated with antipsychotics, you are likely to detect diabetes in some of your patients, regardless of the antipsychotic medication you choose.
- PROBE: Does this information match your perceptions?
 - If Yes – Transition to efficacy message
 - If no – ask why?
 - If due to more weight gain – offer weight management suggestions/solutions – transition to efficacy message
 - If due to belief Zyprexa causes diabetes – show epidemiological data and probe again
 - If doctor does not believe epidemiological data ask what would they need to see to believe and what they have seen that makes them believe differently.

Diabetes

• Desired Evolution

Action Steps	Desired Outcome	Responsibility	Timing
<ul style="list-style-type: none"> • Drive in the minds of our customers that the short term risk of developing diabetes is comparable with other agents. 	<ul style="list-style-type: none"> • Comparable rates 	<ul style="list-style-type: none"> • Affiliate level 	<ul style="list-style-type: none"> • ASAP
<ul style="list-style-type: none"> • Educate psychiatrists on DM (see SCC) 	<ul style="list-style-type: none"> • Comparable rates 	<ul style="list-style-type: none"> • Product & Affiliate Team level 	
<ul style="list-style-type: none"> • More research <ul style="list-style-type: none"> • Physician perceptions • Customer needs 	<ul style="list-style-type: none"> • Better understanding 	<ul style="list-style-type: none"> • Product Team 	
<ul style="list-style-type: none"> • Focus on delivering Zyprexa's brand promise 	<ul style="list-style-type: none"> • Higher sales through acknowledging customer concerns about diabetes while focusing on Zyprexa's benefits to health care professionals and patients. 	<ul style="list-style-type: none"> • Affiliate level 	<ul style="list-style-type: none"> • ASAP

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