Zyprexa
Side Effect Tracking Study
MR Download

Tom Reck

Revised 10/28/02
Overview

- Study Design
- Key Findings
- Recommendations
- Next Steps
Tracking Study - Objectives

Track changes in physicians’ perceptions of the relationship between taking psychotropic medications and the occurrence of weight gain, hyperglycemia, and diabetes.

Specifically:

- Which agents are most commonly associated with weight gain, hyperglycemia, and diabetes?
- How do these associations influence prescribing behavior?
- What types of patients are not considered good candidates for specific psychotropic agents?
- What are physicians’ attitudes toward weight management with patients taking psychotropic medications?
Methodology

- Internet based survey
- Study fielding:
  - Wave 1: Feb. 2001
  - Wave 2: Jul. 2001
  - Wave 3: Jan. 2002
  - Wave 4: Aug. 2002
- Participants
  - 100 PCPs for Waves 1-4
  - 225 - 240 Psychs for Waves 1-4
    - 75 - 80 each from private practice, CMHC and institution
  - 150 LTC physicians for Wave 4
    - 75 Psychs & 75 PCPs
Overview

• Study Design
• Key Findings
• Recommendations
• Next Steps
Key Findings

- Only part of the Zyprexa Diabetes’ Story is resonating with customers
- Market impact of key events in Q2 2002 (Japan label change, APA, etc.) not perceived – yet...
- Risperdal’s launch in PCP starting to show effects
- MDs seeing diabetes more often w/ other meds
- LTC Psychs (1st time measured) are more concerned about weight gain AND diabetes in nursing home patients than LTC PCPs
  - Higher avoidance & discontinuation for NH Pt than expected
Four Elements of the “Diabetes Story”
How are we doing?

Zyprexa’s Diabetes Story

1. The rates of diabetes are comparable across atypical APs.
2. Weight Gain does not equal diabetes.
3. The prevalence of diabetes is 2-4 higher among the mentally ill.
4. There are many other diabetes risk factors besides weight gain.

Market Agreement

Low
Low
High
High*

* Not directly measured in this study
Q300 Do you think hyperglycemia and/or diabetes is more prevalent in patients receiving treatment for mental illness as compared to the general population?
Psychs: Why is there a higher prevalence of diabetes in SPMI? Believe diabetes is a Zyprexa problem AND it’s related to illness.

Q305 To what do you attribute this higher level of hyperglycemia and/or diabetes?

* Zyprexa Side Effect Tracking Study (Wave 4) – Aug 2002
PCPs: Why is there a higher prevalence of diabetes in SPMI? Starting to believe it’s a Zyprexa problem – Impact of Risperdal’s Launch

Q305 To what do you attribute this higher level of hyperglycemia and/or diabetes?

* Zyprexa Side Effect Tracking Study (Wave 4) – Aug 2002
Psychs: nearly 100% association w/ Zyprexa
Sample too small to measure w/ PCPs

Element #1

Zyprexa
Depakote
Risperdal
Seroquel
Geodon

0% 20% 40% 60% 80% 100%

Wave 4 (n=158)
Wave 3 (n=136)
Wave 2 (n=122)
Wave 1 (n=117)

Note: The sample size for the PCPs was insufficient for reporting.

Q310 Which specific psychotropic agent(s) do you associate with an increased risk of hyperglycemia and/or diabetes?

* Zyprexa Side Effect Tracking Study (Wave 4) – Aug 2002
Patients developing diabetes while on med
Significant rise in all other med's for Psychs & in Zyprexa for PCPs

Element #1

PCP

Element #1

PSY

Q630 Have any of your patients taking...developed hyperglycemia and/or diabetes?  

Percent answering “YES”  

* Zyprexa Side Effect Tracking Study (Wave 4) – Aug 2002
Q650 When you consider prescribing..., what percentage of the time do you make a conscious decision not to prescribe it due to concerns about hyperglycemia and/or diabetes?

* Zyprexa Side Effect Tracking Study (Wave 4) – Aug 2002
Stated Discontinuation due to Diabetes
Flat to down compared to Wave 3

PCP

PSY

Q660  What percentage of the time do you discontinue use of... due to hyperglycemia and/or diabetes?

* Zyprexa Side Effect Tracking Study (Wave 4) – Aug 2002
Q700 When you consider prescribing..., what percentage of the time do you make a conscious decision not to prescribe it due to concerns about weight gain?

* Zyprexa Side Effect Tracking Study (Wave 4) – Aug 2002
Stated Discontinuation due to Weight Gain
Flat to up compared to Wave 3 for Psychs; up for PCPs

PCP

Risperdal Depakote Zyprexa Seroquel Geodon

- Wave 1 (n=21-73)
- Wave 2 (n=9-87)
- Wave 3 (n=10-93)
- Wave 4 (n=12-91)

PSY

Risperdal Depakote Zyprexa Seroquel Geodon

- Wave 1 (n=222-234)
- Wave 2 (n=165-240)
- Wave 3 (n=197-240)
- Wave 4 (n=196-233)

Q710 What percentage of the time do you discontinue use of...due to weight gain?

* Zyprexa Side Effect Tracking Study (Wave 4) – Aug 2002
Weight gain Manageability
Consistent upward trend in Psychs – Need to accelerate improvement

PCP

PSY

Q730 If a patient treated with... gains weight, is it manageable?

Percent answering “YES”

* Zyprexa Side Effect Tracking Study (Wave 4) – Aug 2002
Overview

- Study Design
- Summary of Results
- Recommendations
- Next Steps
Key Take-aways from this & other recent “Issues” MR

• Embrace our opportunity to impact MDs’ perceptions
  – Address physicians’ fears and anxieties towards Zyprexa and help them feel enabled with they use it
  – Turn our negatives into a positive by exceeding expectations in the solutions we provide our customers
  – Create fears for competitors’ products in both psych and PCP markets to help Zyprexa’s relative perception of tolerability

• Own the weight gain issue and continue to provide our customers with solutions that matter
  – Across all waves, the majority of respondents state they will prescribe more Zyprexa if weight gain can be managed
  – Provide MDs with better solutions: it represents what Lilly & Lilly Neuroscience want to stand for
  – Give MDs a credible response other than switching meds

• Address the physician’s psychological concerns
  – Get better at meeting emotional needs of customers
Overview

- Study Design
- Summary of Results
- Recommendations
- Next Steps
Current & Next Steps

• Done: Reexamine Zyprexa’s Metabolic Side Effect Story for Simplicity and Clarity
  – Determine optimal mix of message focus & expenditures to meet the needs of targeted customer segments
  – Optimize balance between WG & Diabetes solutions in messaging

• Doing: Refine & develop message
  – Determine appropriate content, tone & delivery to include the link to WG for 2003 “side effects” message through standard process
  – Communicate message through multiple channels
  – Address the psychological impact Diabetes has on the physician’s ability to be “in control”

• Need to do: Continue to Support “Solutions For Wellness”
  – Initial field reports indicate strong acceptance
  – More comprehensive data in coming months
Back-up slides
Prevalence among the mentally ill

**PRACTICE SETTING**

<table>
<thead>
<tr>
<th>Practice Setting</th>
<th>Wave 1</th>
<th>Wave 2</th>
<th>Wave 3</th>
<th>Wave 4</th>
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<tr>
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**BASE:** All Physicians

**Q300** Do you think hyperglycemia and/or diabetes is more prevalent in patients receiving treatment for mental illness as compared to the general population?
## Diabetic Ketoacidosis

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<th>PCP Wave 3 (Mean n=100)</th>
<th>PCP Wave 4 (Mean n=100)</th>
<th>PSY Wave 3 (Mean n=241)</th>
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* Scale: 1 to 5 where 1 is Never and 5 is Always

**Base: Prescribes medication**

**Q1046** When you prescribe each of the following drugs, how often are you concerned about DKA (diabetic ketoacidosis)?
Reasons for concern about weight gain

Base: Concerned about weight gain in patients that are treated with psychotropic agents

Q510 For which of the following reasons are you concerned about potential weight gain?
Reasons for concern about weight gain

Base: Concerned about weight gain in patients that are treated with psychotropic agents

Q510 For which of the following reasons are you concerned about potential weight gain?
Base: Concerned about weight gain in patients that are treated with psychotropic agents

Q510 For which of the following reasons are you concerned about potential weight gain?
Reasons for concern about weight gain - Cardiovascular Disease

LTC – WAVE 4

Base: Concerned about weight gain in patients that are treated with psychotropic agents Q510 For which of the following reasons are you concerned about potential weight gain?
Discussions about weight gain management

**PCP**

- Wave 1 (n=74)
- Wave 2 (n=85)
- Wave 3 (n=88)
- Wave 4 (n=91)

**PSY**

- Wave 1 (n=235)
- Wave 2 (n=240)
- Wave 3 (n=241)
- Wave 4 (n=233)

1 = Never  
3 = Sometimes  
5 = Always

*Base: Concerned about weight gain in patients that are treated with psychotropic agents

Q520 How often do you discuss the management of weight gain with your patients?
Discussions about weight management

CMHC

1 = Never  3 = Sometimes  5 = Always

Base: Concerned about weight gain in patients that are treated with psychotropic agents
Q520 How often do you discuss the management of weight gain with your patients?
Discussions about weight gain management

LTC – Wave 4

Base: Concerned about weight gain in patients that are treated with psychotropic agents
Q520 How often do you discuss the management of weight gain with your patients?
Counseling about healthy living

**PCP**

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**PSY**

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</tr>
<tr>
<td>Wave 4</td>
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</table>

1 = Never  
3 = Sometimes  
5 = Always

**Base:** Concerned about weight gain in patients that are treated with psychotropic agents

Q530 How often do you offer counseling to your patients starting psychotropic medications about healthy living, exercise, etc.?
Counseling about healthy living

PRIVATE PRACTICE

1 = Never  3 = Sometimes  5 = Always

Base: Concerned about weight gain in patients that are treated with psychotropic agents
Q530 How often do you offer counseling to your patients starting psychotropic medications about healthy living, exercise, etc.?
Counseling about healthy living

LTC – Wave 4

Base: Concerned about weight gain in patients that are treated with psychotropic agents

Q530 How often do you offer counseling to your patients starting psychotropic medications about healthy living, exercise, etc.?
Counseling about healthy living

**PSY SEGMENTS**

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<td>SM (n=20-43)</td>
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</table>

1 = Never
3 = Sometimes
5 = Always

**Base:** Concerned about weight gain in patients that are treated with psychotropic agents

Q530 How often do you offer counseling to your patients starting psychotropic medications about healthy living, exercise, etc.?
Effectiveness of discussions about weight gain

Base: Discuss the management of weight gain with patients or offer counseling to patients starting on psychotropic medications

Q535 Please rate how well your discussions of behavioral interventions work with your patients, either at the time the patient starts the medication or when they begin to gain weight?
Effectiveness of discussions about weight gain

LTC – Wave 4

1 = Not at all well  3 = Well  5 = Extremely well

Base: Discuss the management of weight gain with patients or offer counseling to patients starting on psychotropic medications

Q535 Please rate how well your discussions of behavioral interventions work with your patients, either at the time the patient starts the medication or when they begin to gain weight?

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Patients developing hyperglycemia/diabetes by medication

**CMHC**

- Wave 1 (n=77)
- Wave 2 (n=81)
- Wave 3 (n=81)
- Wave 4 (n=79)

**PRIVATE**

- Wave 1 (n=86)
- Wave 2 (n=80)
- Wave 3 (n=80)
- Wave 4 (n=76)

**INSTITUTIONAL**

- Wave 1 (n=72)
- Wave 2 (n=80)
- Wave 3 (n=80)
- Wave 4 (n=75)

Base: Prescribes medication

Q630 Have any of your patients taking... developed hyperglycemia and/or diabetes?

Percent answering “YES”

Risperdal ★ Depakote ★ Zyprexa
Seroquel ★ Geodon
Patients developing hyperglycemia/diabetes by medication
Zyprexa PCP slightly > than others while Psych > than expected

LTC – Wave 4

<table>
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<tr>
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<th>LTC - PCP (n=76)</th>
<th>LTC - PSY (n=75)</th>
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<tr>
<td>Risperdal</td>
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<td>Seroquel</td>
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<tr>
<td>Geodon</td>
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</tbody>
</table>

Base: Prescribes medication
Q630 Have any of your patients taking... developed hyperglycemia and/or diabetes?
Percent answering “YES”
Patients developing hyperglycemia/diabetes by medication

PSY SEGMENTS

Rule Bound

Wave 3 (n=40)

Wave 4 (n=30)

- Risperdal
- Depakote
- Zyprexa
- Seroquel
- Geodon

Base: Prescribes medication

Q630 Have any of your patients taking... developed hyperglycemia and/or diabetes?

Percent answering “YES”
Number of patients developing hyperglycemia/diabetes by medication

**PSY**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Wave 1 (n=222-234)</th>
<th>Wave 2 (n=165-240)</th>
<th>Wave 3 (n=197-240)</th>
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<tr>
<td>Risperdal</td>
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</tr>
<tr>
<td>Seroquel</td>
<td></td>
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</table>

*Note: PCPs not tracked due to small sample sizes.*

**Base:** Have patients taking...develop hyperglycemia/diabetes

**Q640** Within the past year, approximately how many of your patients receiving...developed hyperglycemia and/or diabetes?
Number of patients developing hyperglycemia/diabetes by medication

**LTC – Wave 4**

![Bar chart showing comparison between Depakote and Zyprexa for LTC - PCP (n=33) and LTC - PSY (n=47).]

*Note: Insufficient incidence to report data for other drugs.*

**Base:** Have patients taking...develop hyperglycemia/diabetes  
**Q640** Within the past year, approximately how many of your patients receiving...developed hyperglycemia and/or diabetes?
Percentage of [target medication] patients with hyperglycemia/diabetes

PSY

Note: PCPs not tracked due to small sample sizes.

Base: Have patients taking...develop hyperglycemia/diabetes
Q645 What percentage of your...treated patients does this represent?
Percentage of [target medication] patients with hyperglycemia/diabetes

LTC – Wave 4

Note: Insufficient incidence to report data for other drugs.

Base: Have patients taking...develop hyperglycemia/diabetes

Q645 What percentage of your...treated patients does this represent?
Concerns about hyperglycemia/diabetes prevents prescription

PRIVATE PRACTICE

<table>
<thead>
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<th>Wave</th>
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<td>Wave 1</td>
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<td>Wave 4</td>
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**Base: Prescribes Medication**

**Q650** When you consider prescribing Zyrexa, what percentage of the time do you make a conscious decision not to prescribe it due to concerns about hyperglycemia and/or diabetes?

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Patients developing hyperglycemia/diabetes by medication

**PSY SEGMENTS**

**High Flyer**

![Bar chart for PSY SEGMENTS]

- **Risperdal**
- **Depakote**
- **Zyprexa**
- **Seroquel**
- **Geodon**

**Base: Prescribes Medication**

**Q650** When you consider prescribing Zyprexa, what percentage of the time do you make a conscious decision not to prescribe it due to concerns about hyperglycemia and/or diabetes?

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Discontinues medication due to hyperglycemia/diabetes

PRIVATE PRACTICE

Base: Prescribes medication
Q660 What percentage of the time do you discontinue use of... due to hyperglycemia and/or diabetes?

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## Target medications and weight fluctuations

<table>
<thead>
<tr>
<th>PCP</th>
<th>Wave 1</th>
<th>Wave 2</th>
<th>Wave 3</th>
<th>Wave 4</th>
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<th>Wave 2</th>
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Base: Prescribes medication

**Q671** What percentage of your patients receiving...lose weight, have no change in weight, gain weight?

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Zyprexa MDL 1596: Confidential-Subject to Protective Order

ZY200191359
Page 48
## Target medications and weight fluctuations

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**Base:** Prescribes medication

Q671 What percentage of your patients receiving... lose weight, have no change in weight, gain weight?
Target medications and weight fluctuations

**LTC – Wave 4**

**Lose Weight**
- LTC - PCP (n=7-74)
- LTC - PSY (n=68-75)

**Gain Weight**
- LTC - PCP (n=7-74)
- LTC - PSY (n=68-75)

**Base: Prescribes medication**

Q671 What percentage of your patients receiving... lose weight, have no change in weight, gain weight?
Base: Prescribes medication
Q700 When you consider prescribing..., what percentage of the time do you make a conscious decision not to prescribe it due to concerns about weight gain?

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Concerns about weight gain prevents prescription

**LTC – Wave 4**

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**Base: Prescribes medication**

**Q700** When you consider prescribing..., what percentage of the time do you make a conscious decision not to prescribe it due to concerns about weight gain?

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52
Discontinues medication due to weight gain

CMHC
PRIVATE
INSTITUTIONAL

Base: Prescribes medication
Q710 What percentage of the time do you discontinue use of...due to weight gain?
Base: Prescribes medication

Q710 What percentage of the time do you discontinue use of...due to weight gain?
Discontinues ZYPREXA due to weight gain

**Base: Prescribes medication**
Q710 What percentage of the time do you discontinue use of ZYPREXA due to weight gain?

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**PSY SEGMENTS**

- Skeptical Exp. - Adult
- Rule Bound
- Skeptical Exp. - Child & Adult
- High Flyer
- Selective Majority

- Wave 3 (n=15-48)
- Wave 4 (n=20-46)
## Patient types to avoid

### PCP

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**Base: Prescribes medication**

**Q720** When choosing to prescribe..., which of the following patient types are you most likely to avoid?
Patient types to avoid - OVERWEIGHT PATIENTS and ZYPREXA

Base: Prescribes medication
Q720 When choosing to prescribe ZYPREXA, which of the following patient types are you most likely to avoid?
Base: Prescribes medication

Q720 When choosing to prescribe..., which of the following patient types are you most likely to avoid?
Manageability of weight gain

LTC – Wave 4

BASE: Prescribes medication

Q730 If a patient treated with... gains weight, is it manageable?
Weight gain manageability and prescribing behavior

Percentage of *PSYCHIATRISTS* whose prescribing would increase if weight gain were more manageable with the specified drug

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*Note: PCPs not tracked due to small sample sizes.*

**Base: Weight gain is not manageable**

Q770  If weight gain with...were more manageable, would your prescribing of it increase?
Products displaced by increased prescriptions of ZYPREXA

**PSY**

Note: PCPs not tracked due to small sample sizes.

**Base:** Prescribing of Zyprexa would increase if weight gain were more manageable

**Q780** What product(s) would be replaced by the increase in prescribing of...?
For each physician, Zyprexa share was calculated based on behavioral data indicating the percentage of a physician’s annual antipsychotic prescriptions that are written for Zyprexa. A Zyprexa share equal to .5 indicates that half of all antipsychotic scripts written by Physician X are written for Zyprexa. This variable represents an individual-level indicator of Zyprexa’s market share.

The table below indicates that perceptions about avoiding and discontinuing Zyprexa—be it for hyperglycemia/diabetes or weight gain—are highly correlated and best evaluated together rather than individually. Bivariate analyses indicate that as perceptions of avoiding Zyprexa increase, so do perceptions of discontinuing Zyprexa. Surprisingly, none of these variables, neither individually nor in composite, are significantly correlated with the proportion of antipsychotic prescriptions that are written for Zyprexa.

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<th>Discontinue H/D</th>
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* = p<0.05