

**To:** CN=Robert W Baker/OU=AM/O=LLY@Lilly  
**Date:** 01/10/2001 03:52:10 PM  
**From:** CN=Margaret O Sowell NONLILLY/OU=AM/O=LLY  
**Subject:** Re: Hyperglycemia sell sheet

Robert-

I had an opportunity to look at the proposed sell sheets for hyperglycemia. As you know I'm still new to the Zyprexa issues and to the Lilly process so forgive me if some of my comments are naive. Much of what I suggest may have already been considered and discarded ... please forgive....

First Page:

treatment emergent hyperglycemia and diabetes (figure)...these are estimates rates correct, based on the continuous statistical analysis not absolute rates?

2nd and 3rd bullets ...would it be simpler to combine and maybe put in table the mean increases in glucose rather than saying olanz was higher by small amt than rsp, higher than haldol by littler bigger snmbwer, and less than cloz....if want only one figure maybe this rather than estinated rates of events????

last bullet is clinically most relevant....i think....

Second Page:

Want to simplify to make points more clear????

Bullets one and 2....combine....

Something like " Hyperglycemia and diabetes are very common in the general adult population of the US with prevalences of ~ 7 to 8% based on a recent epidemiological survey ...ref".

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Bullet 3 .....Compared to the general population, patients with schizophrenia and bipolar disorder have an increased prevalence of type 2 diabetes (~ 2 to 4 times higher.....add your refs.....) that appears to have preceded the widespread use of atypical antipsychotic drugs...(add Dixon, L et al "Prevalence and correlates of diabetes in national Schizophrenia Samples....Schizophrenia Bulletin 26(4): 903-912, 2000).

Bullet 4.....Many different factors contribute to individuals risk for hyperglycemia or diabetes.....rather than a number of factors influence glucose control..?????

figure as shown except change to "High FAT diet rather than high lipid diet"

Under the figure I got a little confused....

Last bullet ...not sure I understand as is stated the principle statement....

? even though patients gain more weight w/ olz and cloz there was not increased rate (incidence???? of hyperglycemic events at any threshold..(????)...this wasn't true for cloz was it ....I'm afraid that I have missed something major in the high powered stats discussions...Baseline BMI and baseline glc are predictors (is that right term) for hyperglycemic event ...weren't they better predictors that weight gain during therapy?????? (theoreticallythey should be, I would think)

Is it reassuring that 80% of subjects with hyperglycemia not getting fatter on olanzapine....?

My first thought was ...Oh, olanzapine does something else "BAD" that increases glucose.....I at least expect weight to be linked with glucose....What does John H. thinks about this....

The last bullet is reassuring.....

methods look like they match original manuscript rather than current form.....

Physician guidelines....Not sure this is ready for prime time unless we're just giving them the ADA recommendations as a courtesy card kind of thing...

first bullet, incorporate ADA recommendations for who to screen (at risk group)...anyone who.....

then how to screen guidelines per ADA... with schizo group FBS are hard to get so do you also want to mention that random's can be used..... can DM symptom interpretation also be an issue...polydipsia and polyuria might not stand out in psychiatrists practice?????

Bigger question.....are we( Lilly) making guideline recommendations that are different from the ADA in any way 'cause of the special patient population (i.e.....we just told the docs that schizo and BPD has 2-4X increased prevalence of type 2 DM.....maybe they should screen ALL there patients????)

what to tell the pschiatrists to do with abnormal results...My personal feeling is that every diabetic patient should see a diabetologist/endocrinologist at least once....i do acknowledge that this is a theoretical not a practical goal.....

I have carried on for quite a while.  
hope I've said something that is helpful ...Again please forgive me if I've naively missed the point, repeated myself, etc....

thanks for opportunity to give some feedback