

**To:** CN=Joe Jansen/OU=AM/O=LLY@Lilly  
**CC:** CN=Patrizia Cavazzoni/OU=AM/O=LLY@Lilly; CN=Jared G Kerr/OU=AM/O=LLY@Lilly  
**Date:** 10/02/2002 11:07:27 AM  
**From:** CN=Jared G Kerr/OU=AM/O=LLY  
**Subject:** Add to Clintrace section along with other MLS comments from Jared

The remaining 907 adverse event reports were categorized as cases suggestive of hyperglycemia or diabetes mellitus. Out of these, a total of 716 adverse event reports were identified through clinical evaluation to be non-severe cases of glucose dysregulation, as they did not involve death, coma, or acidosis. The remaining 191 cases were identified to be potentially severe glucose adverse events, involving death, coma or acidosis. A detailed clinical evaluation was undertaken for these 191 potentially severe glucose adverse events. A majority (142/191) of these severe spontaneous adverse event reports ascertained to be cases of glucose dysregulation were confounded by the presence of definite other etiologic factors (54/191) or possible other etiologic contributing factors (88/191) known to affect glucose homeostasis (including baseline risk factors for diabetes, medical conditions that have been established to affect glucose homeostasis, or concomitant treatment with drugs known to be associated with glucose dysregulation). A lack of information in the adverse event report precluded the assessment of any etiologic factor in 47/191 cases of potentially severe glucose adverse events. For 2 cases out of 191 potentially severe glucose related adverse events, no apparent etiology other than treatment with olanzapine was identified.

FOR PC:

The 2 NOAE cases listed above were the following:

**Case 1: Case # 2.07 (GBS010709212)**

DKA and Coma

Little data, No concoms, No prior Hx, Peak glucose unknown, Positive Dechallenge

**Case 2: Case # 1.87 (USA020211401)**

Pancreatitis (577 amylase; 2399 lipase; xx TGs)

No concomitants, Peak Glucose: 517, RF: Race and dyslipidemia, Non-compliant olanzapine use, Positive Dechallenge

Sincerely,

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