

Diabetes Prevention Trial - Type 1

HYPOGLYCEMIA REPORTING FORM

All observations or self reporting of presumed or definite hypoglycemia should be recorded on the adverse events reporting form as well as this form.

Subject ID #:

Subject Initials:
F M L

Date: / /
M M D D Y Y

Name of person completing form (please print): _____

Date of Occurrence: / / Time of Occurrence: : (Use 24 hour clock)
M M D D Y Y

Signs/Symptoms

1. Did any of the following symptoms occur?

1=No
2=Yes
3=Don't Know

1=No
2=Yes
3=Don't Know

- Paleness
- Sweating
- Trembling or Shakes
- Rapid heart beat
- Numbness around lips or hands
- Nervousness or restlessness
- Personality change or irritability
- Dizziness or feeling faint
- Fainting or loss of consciousness

- Vision changes
- Headache
- Unable to talk or speak clearly
- Saying things that did not make sense
- Slurred speech
- Seizures
- Staggering
- Poor Coordination
- Change in school performance
- Other (specify _____)

2. Was the onset of the symptoms while awake or asleep? 1=Awake 2=Asleep

3. Where was the subject when the symptoms occurred? 1=Home 4=Driving automobile
2=Work 5=Other _____
3=School 6=Unknown

Treatment

4. Did eating or drinking something sweet make the symptoms go away?
 1=No 2=Yes 3=Did not eat when symptoms occurred 4=Don't know

5. What other treatment was received? 1=Glucagon 2=IV Glucose 3=Other _____ 4=Unknown 5=None
Did this treatment make the symptoms go away? 1=No 2=Yes 3=Don't know

6. Did anyone help the subject with the treatment? 1=No 2=Yes, EMT 3=Yes, ER 4=Yes, other person 5=Don't know

H Y

DMU Use Only

Date rcvd: _____

Blood Sugar

7. Was the blood sugar measured before treatment of symptoms? 1=No 2=Yes 3=Don't know

If yes, (a) what was the blood sugar measurement?

(b) How was it measured? 1=Visual 2=Meter 3=Lab

Complete questions 8 & 9 only for Parenteral Antigen/Experimental Treatment Group subjects

8. Was there any change in the time that insulin was given? 1=No 2=Yes 3=Don't know

If yes, when was insulin given? 1=Later than usual 2=Earlier than usual

9. Was there a change in the number of units of insulin given? 1=No 2=Yes 3=Don't know

If yes, (a) what was the number of units of insulin given?

(b) was this amount more or less than the amount usually given? 1=More 2=Less

Complete question 10 only for Oral Antigen subjects

10. Was >1 pill of oral medication taken within 24 hours? 1=No 2=Yes 3=Don't know

If yes, how many?

Events Prior to Symptoms

11. Was there anything unusual about your activity during the four hours before the symptoms began?

1=No 2=Yes 3=Don't know

If yes, what was activity level? 1=More than usual 2=Less than usual

12. How much did you eat during the 4 hours before the symptoms began?

1=Usual amount 2=Lesser amount 3=More than usual 4=Eating was delayed 5=Missed a meal/snack 6=Unknown

13. Did you drink any alcoholic beverages up to 24 hours before symptoms began? 1=No 2=Yes 3=Don't know

If yes, did you drink any alcoholic beverage in the four hours just before the event began? 1=No 2=Yes

14. Did you take any drugs up to 24 hours before the symptoms began? 1=No 2=Yes 3=Don't know

If yes, did you take any drugs in the four hours just before the symptoms began? 1=No 2=Yes 3=Don't know

If yes, specify, _____

15. Were you under serious emotional stress in the week prior to the event? 1=No 2=Yes 3=Don't know

Associated Sequelae

16. Did any of the following occur at the same time as the hypoglycemic event?

1=No
2=Yes
3=Don't Know

- Neurologic insult requiring hospitalization
- Injury to subject requiring hospital admission
- Injury to another person requiring medical assistance
- Vehicular accident or property damage

1=No
2=Yes
3=Don't Know

- Traffic violation
- Myocardial infarction
- Stroke

17. Clinic action taken (if change in dose, be sure to record on encounter form): _____