

EPIDEMIOLOGY OF DIABETES INTERVENTION AND COMPLICATIONS

Notification and Further Details of Severe Hypoglycemia Requiring Assistance

This form must be completed each time a patient experiences a severe hypoglycemic episode requiring assistance as specified in Chapter 11 of the Manual of Operations. A copy of this form should be retained in the clinic file and the original should be mailed to the Data Coordinating Center.

A. IDENTIFYING INFORMATION

- 1. Clinic Number 2. CLINIC _____
- 2. Patient ID Number 3. PATIENT _____
- 3. Patient's Initials 4. INITIALS _____
- 4. Date this form completed 5. DBCOMDAT _____
Month Day Year

- 5a. Specify date of occurrence or recognition of hypoglycemic event: 6. FORMDATE _____
Month Day Year

OR

- b) If date uncertain, check here: 7. DRA5B (1)

- 6. Specify date EDIC clinic learned of the event: 8. DBAG _____
Month Day Year

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B. CLINICAL MANIFESTATION (Indicate all symptoms or signs which occurred)

- 1. Loss of consciousness 9. DBB1 (1)
- 2. Seizure 10. DBB2 (1)
- 3. Suspected seizure 11. DBB3 (1)
- 4. Unusual difficulty in awakening 12. DBB4 (1)
- 5. Irrational 13. DBB5 (1)

- 6. Uncontrollable behavior 14. DBB6 (1)
- 7. Confusion 15. DBB7 (1)
- 8. Memory loss 16. DBB8 (1)
- New* 9. Other, specify: 17. DBB9 (1)
- New* 10. None 18. DBB10 (1)

C. BLOOD GLUCOSE DETERMINATION

- 1. Was the blood glucose measured BEFORE treatment? 19. DBC1 (1) (2) (3)
No Yes Unknown

<p>2. By whom?</p> <ul style="list-style-type: none"> a) Patient (1) b) Medical care personnel (2) <u>20. DBC2</u> c) Other (3) <p>3a) Record measurement: _____ mg/dl <u>21. DBC3A</u></p> <p style="text-align: center;">OR</p> <p>b) If UNKNOWN, check here: (1) <u>22. DBC3B</u></p> <p>4. Method used:</p> <ul style="list-style-type: none"> a) Blood glucose monitoring -- visual (1) b) Blood glucose monitoring -- meter (2) <u>23. DBC4</u> c) Lab determination (plasma) (3) 	
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5. Was the blood glucose measured AFTER treatment? 24. DBC5 No (1) Yes (2) Unknown (3)

6. By whom?		
a) Patient	(1)	<u>25. DBC6</u>
b) Medical care personnel	(2)	
c) Other	(3)	
7. a) Record measurement: _____ mg/dl		<u>26. DBC7A</u>
OR		
b) If UNKNOWN, check here:	(1)	<u>27. DBC7B</u>
8. Method used:		
a) Blood glucose monitoring -- visual	(1)	
b) Blood glucose monitoring -- meter	(2)	<u>28. DBC8</u>
c) Lab determination (plasma)	(3)	

E. ASSOCIATED EVENTS

1. Did any of the following occur with the hypoglycemic event described above? 37. DBE1 No (1) Yes (2)

INDICATE ALL THAT APPLY:		
a) death	(1)	<u>38. DBE1A</u>
b) neurological insult requiring hospitalization	(1)	<u>39. DBE1B</u>
c) myocardial infarction	(1)	<u>40. DBE1C</u>
d) stroke	(1)	<u>41. DBE1D</u>
e) injury to the patient requiring hospitalization	(1)	<u>42. DBE1E</u>
f) injury to another person	(1)	<u>43. DBE1F</u>
g) property damage	(1)	<u>44. DBE1G</u>
h) traffic violation	(1)	<u>45. DBE1H</u>

D. TREATMENT OF CLINICAL MANIFESTATION

29. DBD1³⁰ 1. Did the symptoms reverse without treatment? No (1) Yes (2) Unknown (3)
30. DBD2A³² a) Did the patient receive assistance? HCTRF=31 DROP FEDIC 31 DROP (1) (2) (3)
31. DBD2B³³ b) Was the patient incapable of treating self? 33 DROP (1) (2) (3)
32. DBD3 3. Was the patient hospitalized or treated in an emergency room or other medical facility? (1) (2) (3)

4. Treatment administered: (CHECK ALL THAT APPLY)

33. DBD4A a) intravenous glucose 34 (1)
34. DBD4B b) glucagon 37 (1)
35. DBD4C c) oral carbohydrates 39 (1)
36. DBD4D d) Other, describe: 39 (1)

F. USUAL INSULIN TREATMENT

1. On what treatment regimen did the hypoglycemic event occur? 44. DBF1
 a) MDI (1)
 b) pump (2) 50
 c) conventional Both - Dec + Ford? (3)
 2. If a pump patient, is a pump malfunction suspected? 47. DBF2 No (1) Yes (2) Unknown (3) 57
 If YES, describe in detail in a separate report.

Patient ID _____

G. PRESENCE OF ASSISTANCE

1. Patient's living arrangement at the time of the episode being reported:

- With parent or guardian (1)
- With other companion/spouse (2)
- 49. = 11
DBG1 In dormitory (3)
- Alone (4)
- Unknown (5)
- Other; specify: _____ (6)

2. Who was with the patient at the time of onset of symptoms? (CHECK ALL THAT APPLY)

- 49. - 12
DBG2A a) Parent, guardian, spouse, child or other person with whom the patient usually resides (1)
- 50. - 13
DBG2B b) School roommate, classmate or teacher (1)
- 51. - 14
DBG2C c) Passerby (1)
- 52. - 15
DBG2D d) Other person, specify: _____ (1)
- 53. - 16
DBG2E e) No one; patient was alone (1)
- 54. - 17
DBG2F f) Unknown; patient cannot recall (1)

3. If the patient was not alone (Question 2), was the person who was present during the onset of symptoms capable of recognizing that the patient was experiencing a hypoglycemic reaction?

(IF THE PERSON WAS ASLEEP, ANSWER THIS QUESTION "YES" IF THE PERSON WOULD BE CONSIDERED CAPABLE IF AWAKE.)

No Yes Unknown
(1) (2) (3)

55. DBG3 18

4. If YES to Question 3, did this person take any action which might have reduced the severity of this hypoglycemic episode?

No Yes Unknown
56. DBG4 19 (1) (2) (3)

5. If YES to Question 4, what did this person do? (CHECK ALL THAT APPLY)

- 57.
DBG5A a) Administer oral carbohydrates (1)
- 58.
DBG5B b) Administer glucagon (1)
- 59.
DBG5C c) Called paramedics New (1)
- 60.
DBG5D d) Unknown. (1)
- 61.
DBG5E e) Other, specify: _____ (1)

H. DIURNAL FREQUENCY

1. Indicate the time of the onset of the episode (best estimate):

- 62. DBH1A a) ²⁴12:00 a.m. -- 4:00 a.m. (1)
- 4:00 a.m. -- 8:00 a.m. (2)
- 8:00 a.m. -- 12:00 p.m. (3)
- 12:00 p.m. -- 4:00 p.m. (4)
- 4:00 p.m. -- 8:00 p.m. (5)
- 8:00 p.m. -- 12:00 a.m. (6)
- Unknown (7)

63. DBH1B b) ²⁵Record the time if known: _____ : _____ o'clock
am (1) pm (2)

64. DBH1C ²⁶Or check here if unknown: _____ (3)

2. Onset of hypoglycemia occurred while patient was

- asleep 65. DBH2 (1) New
- awake (2)

I. DESCRIPTION OF EVENT

1. Patient's location at onset of episode: 66. DBI1 ²⁷
- Home -- awake (1)
 - asleep, (2)
 - Work (3)
 - School (4)
 - Automobile (5)
 - Leisure activity outside home -- sports (6)
 - other social activity (7)
 - Other outside home -- awake (8)
 - asleep (9)
 - Unknown (10)

2. If patient was awake,

- a) Were warning signs or symptoms present prior to the episode? 67. DBI2A (1) (2) (3) 28
- b) If YES, were these recognized as symptoms of hypoglycemia by the patient? 68. DBI2B (1) (2) (3) 29
- c) Another person? 69. DBI2C (1) (2) (3) 30

J. POTENTIAL CONTRIBUTING FACTORS

1. Characterize the patient's exercise preceding the hypoglycemic event:

- a) Exercise during the same four-hour period in H.1 70. DBI1A ³¹ (1) (2) (3) (4) (5)
- b) Was this unusual for this patient? 71. DBI1B ³² (1) (2) (3)
- c) Exercise during the previous 24 hours excluding the four-hour period in H.1 72. DBI1C ³³ (1) (2) (3) (4) (5)
- d) Was this unusual for this patient? 73. DBI1D ³⁴ (1) (2) (3)

2. Characterize the patient's diet preceding this hypoglycemic event: (Check all that apply)

- a) During the same four-hour period in H.1
- | | | | | | | | | |
|---------------------------------|-------|---------|------------------------|-------|---------|----------------------|------|---------|
| Meal | Snack | Unknown | Meal | Snack | Unknown | No | Yes | Unknown |
| (1) | (1) | (1) | (1) | (1) | (1) | (1) | (1) | (1) |
| <u>DBI2A1 - DBI2A3</u> | | | <u>DBI2A4 - DBI2A6</u> | | | <u>DBI2A7 DBI2A9</u> | | |
| ⁸³⁻⁹¹ (1) (1) (1) | | | (1) (1) (1) | | | (1) (1) (1) | | |

3. a) Were there any deviations from usual insulin dose or algorithm preceding this hypoglycemic event?

- During the same four-hour period as in H.1 92. DBI3A1 (1) (2) (3) 53
- During the previous 24 hours excluding the four-hour period in H.1 93. DBI3A2 (1) (2) (3) 54

3b) Were there any deviations from the timing or scheduling of insulin?

During the same four-hour period as in H.1 94. DBJ3B1 (1) (2) (3) ⁵⁵

During the previous 24 hours excluding the four-hour period in H.1 95. DBJ3B2 (1) (2) (3) ⁵⁶

4. Was there sexual activity preceding this hypoglycemic event?

a) During the same four-hour period in H.1 96. DBJ4A (1) (2) (3) ⁵⁷

b) During the previous 24 hours excluding the four-hour period in H.1 97. DBJ4B (1) (2) (3) ⁵⁸

5. Any alcohol or other recreational drug consumption preceding hypoglycemic event?

a) During the same four-hour period in H.1 98. DBJ5A (1) (2) (3) ⁵⁹

b) During the previous 24 hours excluding the four-hour period in H.1 99. DBJ5B (1) (2) (3) ⁶⁰

6. Glucose monitoring (blood or urine) preceding hypoglycemic event

^{New} a) How is the patient monitoring his/her diabetes?
Self blood glucose monitoring 100. DBJ6A1 (1) (2) (3) ^{New}
Urine glucose monitoring 101. DBJ6A2 (1) (2) (3) ^{New}

^{X (NEW)} b) Number of tests performed during prior week 102. DBJ6B ⁶¹

c) Were any tests performed during the 24 hours prior to episode? 103. DBJ6C (1) (2) (3) ⁶²

d) If applicable, did the patient perform 3:00 a.m. blood glucose testing in week prior to episode? 104. DBJ6D (1) (2) (3) ⁶³

e) Record 3:00 a.m. value _____ 105. DBJ6E ⁶⁴

7. Relationship to menstrual cycle: (IF NOT APPLICABLE, MALE OR NO MENSES, GO TO QUESTION 8)

a) Was the patient menstruating at the time of the episode? 106. DBJ7A (1) (2) (3) ⁶⁵

b) Was the patient's usual form of birth control at the time of this episode oral contraceptives? 107. DBJ7B (1) (2) (3) ⁶⁶

c) Characterize the patient's cycle 108. DBJ7C1 (1) (2) (3) ⁶⁷
If regular, estimate the usual length of cycle (e.g., 28 days) 109. DBJ7C2 _____ days

d) Does the patient's blood or urine glucose fluctuate around the time of menses? 110. DBJ7D (1) (2) (3) ⁶⁸

If YES, explain: _____

8. Was there any recent stress or other potential psychological disturbances in the week prior to the episode? 111. DBJ8 ⁷⁰
No Yes Unknown
(1) (2) (3)

Specify: _____

9. Were other potentially contributing factors present? 112. DBJ9 ⁷¹
No Yes Unknown
(1) (2) (3)

Please list: _____

Patient ID _____

10a) Does the patient usually carry something to treat reactions? No Yes Unknown
72 (1) (2) (3) 113. DBJ10A

Specify: _____

b) Did the patient have something to treat reactions with him at the time of this episode? No Yes Unknown
73 (1) (2) (3) 114. DBJ10B

Person completing form:

Certification Number

_____ 115. CERTIF

116 WEEKNO