# EDIC EPIDEMIOLOGY OF DIABETES INTERVENTIONS AND COMPLICATIONS

#### EPIDEMIOLOGY OF DIABETES INTERVENTIONS AND COMPLICATIONS

Notification and Further Details of Severe Hypoglycemia Requiring Assistance

T

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 files and the original should be mailed to the Data Coordinating Center.

A.	IDE	NTIFYING INFORMATION				5.	Irrational		(1)
	1.	Clinic Number				б.	Uncontrollable behavior		(1)
	2.	Patient ID Number				7.	Confusion		(1)
	3.	Patient's Initials				8.	Memory loss		(1)
	4.	Date this form completed					Other, specify:		( 1)
			Month Day	Year			None		( 1)
	5.	occurrence or recognition	Month Day			-	OD GLUCOSE DETERMINATION Was the blood glucose measured BEFORE treatment?		Yes Unknown (2) (3)
		Specify date EDIC clinic	Month			2.	By whom a) Patient b) Medical care personnel c) Other	( 1) ( 2) ( 3)	
в.		<ul> <li>a) The event was reported at the What is the EDIC follow-up ye</li> <li>b) The event was reported betweer visits. What is the <u>LAST</u> EDIC follow-up year?</li> <li>NICAL MANIFESTATION (Indicate all or signs white the second sec</li></ul>	ar? 1 two annual 2 symptoms			3	<ul> <li>a) Record measurement:</li> <li><u>OR</u></li> <li>b) If UNKNOWN, check here:</li> <li>Method used: <ul> <li>a) Blood glucose</li> <li>monitoring visual</li> </ul> </li> <li>b) Blood glucose</li> <li>monitoring meter</li> </ul>	_ mg/dl ( 1) ( 1) ( 1) ( 2)	
	1.	Loss of consciousness		( 1)			c) Lab determination (plasma)	(3)	
	2. 3. 4.	Seizure Suspected seizure Unusual difficulty in awakening		( 1) ( 1) ( 1)		5.	Was the blood glucose measured AFTER treatment?	No ( 1)	Yes Unknown (2) (3)
					1				

Patient ID \_\_\_\_\_

Fac	тещ	, ID				
	6	By whom?				
		a) Patient	(1)			
	İ	b) Medical care personnel	(2)	İİ		
		c) Other	(3)			
	7.	a) Record measurement: OR	mg/dl	_		
		b) If UNKNOWN, check here:	( 1)			
	8.	Method used:				
		a) Blood glucose		İ		
		monitoring visual	( 1)			
		b) Blood glucose	(2)			
		monitoring meter	( 2)			
		c) Lab determination (plasma)	(3)			
D.	TRI	EATMENT OF CLINICAL MANIFESTATION				
	_		No	Yes	Unknown	
	1.	Did the symptoms reverse without treatment?	(1)	(2)	(3)	
	2	a) Did the patient receive				
		assistance?	(1)	(2)	(3)	
		b) Was the patient incapable of				
		treating self?	(1)	(2)	(3)	
	3.	Was the patient hospitalized				
		or treated in an emergency room		( 0)	( 2)	
		or other medical facility?				
	4.	Treatment administered: (CHECK	ALL TH	AT AP	,	
		a) intravenous glucose			( 1)	
		b) glucagon			( 1)	
		c) oral carbohydrates			( 1)	

d) Other, describe: (1)

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## E. ASSOCIATED EVENTS

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

INDICATE ALL THAT APPLY: a) death	( 1)
b) neurological insult	
requiring hospitalization	(1)
c) myocardial infarction	(1)
d) stroke	(1)
e) injury to the patient requiring hospitalization	(1)
f) injury to another person	( 1)
g) property damage	( 1)
h) traffic violation	( 1)

### F. USUAL INSULIN TREATMENT

Pat	ient	ID		
G.	PRE	SENCE OF ASSISTANCE		
	1.	Patient's living arrangement at the of the episode being reported:	time	
		With parent or guardian	(	1)
		With other companion/spouse	(	2)
		In dormitory	(	3)
		Alone	(	4)
		Unknown	(	5)
		Other; specify:	(	6)
	2.	<ul><li>Who was with the patient at the time onset of symptoms? (CHECK ALL THAT</li><li>a) Parent, guardian, spouse, child o other person with whom the patien</li></ul>	APPLY) or it	7 \
		usually resides	,	1)
		b) School roommate, classmate or tea		1)
		c) Passerby	·	1)
		d) Other person, specify:		
		e) No one; patient was alone	·	1)
		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?	No Yes Uni	known
		(IF THE PERSON WAS ASLEEP, ANSWER THIS QUESTION "YES" IF THE PERSON WOULD BE CONSIDERED CAPABLE IF AWAKE.)	(1)(2)	(3)
	4.	If YES to Question 3, did this person take any action which might have reduced the severity of this hypoglycemic episode?	No Yes Uni	known
			(1) (2)	

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	5.	If YES to Question 4, what did this person do? (CHECK ALL THAT APPLY)			
		a) Administer oral carbohydrates	(	1)	
		b) Administer glucagon	(	1)	
		c) Called paramedics	(	1)	
		d) Unknown	(	1)	
		e) Other, specify:	(	1)	
н.	DIU	RNAL FREQUENCY			
	1.	Indicate the time of the onset of the episode (best estimate):			
		a) 12:00 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)	
		b) Record the time if known:: o'o	210	ock	
		am	(	1)	
		mq	(	2)	
		Or check here if unknown:	(	3)	
	2.	Onset of hypoglycemia occurrred while patient was			
		asleep	(	1)	
		awake	(	2)	

Patient ID \_\_\_\_\_ 2. If patient was awake, I. DESCRIPTION OF EVENT 1. Patient's location at onset of episode: a) Were warning signs or symptoms present prior to No Yes Unknown Home -- awake (1) the episode? (1)(2)(3) asleep (2) b) If YES, were these Work (3) recognized as symptoms of hypoglycemia by the No Yes Unknown School (4) (1) (2) (3) patient? Automobile (5) c) Another person? (1)(2)(3) Leisure activity outside home -- sports (6) other social activity (7) Other outside home -- awake (8) asleep (9) Unknown (10)

## J. POTENTIAL CONTRIBUTING FACTORS

1.	Characterize the patient's exercise preceding the hy a) Exercise during the same four-hour period in H.1	ypoglyce	emic eve	nt: None ( 1)		-	Moderate (3)	Strenuous Unkno (4) (5)	own
				No	Yes	Unkno	wn		
	b) Was this unusual for this patient?			( 1)	(2)	(3)			
	c) Exercise during the previous 24 hours excluding period in H.1	the four	-hour	None ( 1)	Sedent ( 2	-	oderate (3)	Strenuous Unknow (4) (5)	wn
				No	Yes	Unkno	wn		
	d) Was this unusual for this patient?			( 1)	(2)	(3)			
2.	Characterize the patient's diet preceding this hypogevent: (Check all that apply)	glycemic	Missed			Delaye	d	Ate Less Than Usual	
		Meal	Snack	Unknown	Meal	Snack	Unknowi		own
	a) During the same four-hour period in H.1	(1)	( 1)	(1)	(1)	( 1)	( 1)	(1)(1)(1)	
	b) Previous 24 hours excluding the four-hour period								
	in H.1	(1)	(1)	(1)	(1)	(1)	(1)	(1)(1)(1)	
3.	a) Were there any deviations from usual insulin dos algorithm preceding this hypoglycemic event?	e or				No	Yes Ui	nknown	
	During the same four-hour period as in H.1					(1)	(2)	(3)	
	During the previous 24 hours excluding the four-	nour per	iod in	н.1		(1)	(2)	(3)	

Patient ID \_\_\_\_\_

3.	b) Were there any deviations from the timing or scheduling of insulin?	7.
	During the same four-hourNo Yes Unknownperiod as in H.1(1) (2) (3)	
	During the previous 24 hours excluding the four-hour period in H.1 (1)(2)(3)	
4.	Was there sexual activity preceding this hypoglycemic event?	
	a) During the same four-hour No Yes Unknown period in H.1 (1) (2) (3)	
	b) During the previous 24 hours excluding the four-hour period in H.1 (1) (2) (3)	
5.	Any alcohol or other recreational drug consumption preceding hypoglycemic event?	
	a) During the same four-hour period in H.1 (1) (2) (3)	
	<pre>b) During the previous 24 hours excluding the four-hour period in H.1 (1) (2) (3)</pre>	8.
б.	Glucose monitoring (blood or urine) preceding hypoglycemic event	
	a) How is the patient monitoring his/her diabetes?	
	Self blood glucose monitoring (1) (2) (3)	
	Urine glucose monitoring (1) (2) (3)	
	<pre>b) Number of tests performed during prior week</pre>	9.
	c) Were any tests performed during the 24 hours prior to episode? (1) (2) (3)	
	<pre>d) If applicable, did the patient    perform 3:00 a.m. blood glucose    testing in week prior to episode? (1) (2) (3)</pre>	
	e) Record 3:00 a.m. value	
	I I	

	lationship to menstrual cycle: F NOT APPLICABLE, MALE OR NO MENSES	, GO	TO QUE:	STION 8)
a)	Was the patient menstruating at the time of the episode?		Yes ( 2)	
b)	Was the patient's usual form of birth control at the time of this episode oral contraceptives?			Unknown (3)
C)	Characterize the patient's cycle			Unknown (3)
	If regular, estimate the usual leng of cycle (e.g., 28 days)	gth		days
d)	Does the patient's blood or urine glucose fluctuate around the time of menses?	-	Yes ( 2)	Unknown (3)
	If YES, explain:			
pot	s there any recent stress or other cential psychological disturbances the week prior to the episode?			
Spe	ecify:			
	re other potentially contributing ctors present?	-	Yes ( 2) 	
   P:	lease list:			
1		İ		

Patient ID \_\_\_\_\_

10. a)	Does the patient usually carry something to treat reactions?		Unknown (3)	
	Specify:	 		
1- )		 		
(ם	Did the patient have something to treat reactions with him at the time of this episode?		Unknown (3)	
Deveen				Coutification Number
Person	completing form:			Certification Number