

DCCT Data Set Documentation: Form 45

**Form 45: Volunteer Understanding Questionnaire (Version A)**

**Purpose:** To evaluate a volunteer's understanding of the briefing material presented during eligibility screening (primarily the Volunteer Information Handbook).

**Collection Schedule:** Eligibility screening only.

**Data Set Name:** F045CMB2

**Structure:** One record per patient per administration.

**Size:** 1702 observations of 17 variables.

**Known Anomalies:** Patients who did not answer every question correctly were deemed temporarily ineligible for randomization and were required to return another day to take Version B of the questionnaire (Form 46). Patients whose eligibility screening became protracted due to "hold" conditions, restarts, etc. may have completed the questionnaire more than once even if they answered all questions correctly the first time.





**DIABETES CONTROL AND COMPLICATIONS TRIAL**  
Volunteer Understanding Questionnaire  
(Version A)

INSTRUCTIONS TO TRIAL COORDINATOR

- This form is to be completed prior to the baseline visit at which the Informed Consent for Randomization (DCCT Form 032) is signed. The patient should
- be given a pencil with an eraser with which to complete the form
- be allowed as much time as he/she needs to complete the form
- complete the form himself/herself without help from another person and without looking at the Research Volunteer's Information Handbook.

When the patient has completed the questionnaire, you should review the questions with him/her to clarify any items to which the patient gave an incorrect answer. Do NOT change any of the responses which the patient gave, however.

If the patient gives the wrong answer to any ONE of the questions, he/she CANNOT be randomized, but must come back another day to take Version B of the questionnaire. If you feel that the patient would benefit from viewing the orientation audiovisual presentation or by re-reading the Research Volunteer's Information Handbook, encourage him/her to do so, and again inform the patient that he/she should ask for clarification of any point he/she does not understand.

Mail the questionnaire to the DCCT Coordinating Center. Retain a copy in the clinic files.

A. IDENTIFYING INFORMATION

- 1 CLINIC<sup>1</sup>. DCCT Clinic Number
- 2 PATIENT<sup>2</sup>. Patient ID Number
- 3 INITIALS<sup>3</sup>. Patient's initials
- 4 FORNDATE<sup>4</sup>. Today's Date

INSTRUCTIONS TO RESEARCH VOLUNTEER

The Volunteer Understanding Questionnaire is based on the Research Volunteer's Information Handbook. The purpose of the questionnaire is to be sure that we have adequately informed you about this study. You should check (✓) the box next to the ONE best answer to each of the questions.

- 1. Doctors specializing in the treatment of diabetes
  - a) have proven that keeping blood glucose levels as close as possible to the levels of people without diabetes will prevent complications ( 1 )

6 DEQ1

- b) have proven that blood glucose levels are unrelated to complications ( 2 )
- c) do not agree that the relationship of blood glucose levels to complications has been proven and further research is needed ( 3 )
- d) believe that the relationship of blood glucose levels to complications is not an important issue keeping in mind all the questions that still have to be answered about diabetes ( 4 )

2. One of the purposes of this study is to determine 7 DEQ2

- a) if a new treatment designed to cure diabetes will be practical and safe over a long period of time ( 1 )
- b) if it is practical and safe to try and keep the blood glucose levels of people with diabetes as close as possible to the levels of non-diabetics over a long period of time ( 2 )

Patient: 0

- c) If the use of the insulin pump is as practical and safe over a long period of time as 3-4 daily injections of insulin ( 3 )
- d) If self blood glucose monitoring is as accurate as urine testing over a long period of time ( 4 )

8 DEQ3. Random assignment means that

- a) the volunteer has an approximately equal chance of being placed in either treatment group ( 1 )
- b) the volunteer can decide which treatment group he or she wishes to be in ( 2 )
- c) the doctor decides which treatment group the volunteer will be assigned to ( 3 )
- d) the volunteer will be assigned to the treatment group which is best ( 4 )

9 DEQ4. The Standard Treatment Group in this study will receive, in addition to diet instruction and diabetes education,

- a) either an insulin pump or three or four injections of insulin a day and will be expected to do daily self blood glucose monitoring ( 1 )
- b) either an insulin pump or three or four injections of insulin a day and will be expected to do daily urine testing only ( 2 )
- c) one or two injections of insulin a day and will be expected to do daily self blood glucose monitoring ( 3 )
- d) one or two injections of insulin a day and will be expected to do daily urine testing ( 4 )

10 DEQ5. The Experimental Treatment Group in this study will receive, in addition to diet instruction and diabetes education,

- a) either an insulin pump or three or four injections of insulin a day and will be expected to do daily self blood glucose monitoring ( 1 )
- b) either an insulin pump or three or four injections of insulin a day and will be expected to do daily urine testing only ( 2 )

- c) one or two injections of insulin a day and will be expected to do daily self blood glucose monitoring ( 3 )
  - d) one or two injections of insulin a day and will be expected to do daily urine testing ( 4 )
- 11 DEQ6
- 6. As compared to my current treatment, being in the Standard Treatment Group
    - a) will increase my risk for complications ( 1 )
    - b) will increase my risk of having high blood sugar ( 2 )
    - c) will increase my risk of having low blood sugar ( 3 )
    - d) none of the above ( 4 )

12 DEQ7. As compared to my current treatment, being in the Experimental Treatment Group

- a) will have the added risk of an increased number, and possible increased severity, of hypoglycemic (low blood glucose) reactions ( 1 )
- b) will have the added risk, if I am on the pump, of high blood sugar levels caused by a malfunction of the pump ( 2 )
- c) will have the added risk, if I am on the pump, of developing infections where the needle is inserted ( 3 )
- d) all of the above ( 4 )

13 DEQ8. If I volunteer for this study, I will be expected to participate

- a) possibly one year ( 1 )
- b) possibly three years ( 2 )
- c) possibly eight years ( 3 )
- d) possibly ten years ( 4 )

DEQ13

13. Which of the following complications of diabetes will NOT be measured in this trial?
- a) complications of the eye ( 1 )
  - b) complications of the lung ( 2 )
  - c) complications of the nerve system ( 3 )
  - d) complications of the kidney ( 4 )

19 DEQ14

14. A potential risk of fluorescein angiography (eye photography using colored dye) is
- a) nausea ( 1 )
  - b) discoloration of urine ( 2 )
  - c) serious allergic reaction ( 3 )
  - d) all of the above ( 4 )

20 DENEKNO

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14 DEQ9 9. If I am assigned to the Standard Treatment Group, I can expect to make visits to the center

- a) at least every month ( 1 )
- b) at least every three months ( 2 )
- c) at least every six months ( 3 )
- d) at least every twelve months ( 4 )

15 DEQ10 If I am assigned to the Experimental Treatment Group, I can expect to make visits to the center

- a) at least every month ( 1 )
- b) at least every three months ( 2 )
- c) at least every six months ( 3 )
- d) at least every twelve months ( 4 )

16 DEQ11 11. Which of the following is NOT expected from you if you agree to participate in this study?

- a) to choose whether you want to be assigned to the Experimental or the Standard Treatment Group ( 1 )
- b) to stay in whichever treatment group you are assigned to ( 2 )
- c) to keep all appointments in the clinic and keep all the home records required ( 3 )
- d) (if you are a woman) to avoid planning on becoming pregnant in the next two years ( 4 )

17 DEQ12 12. If I am in the Experimental Treatment Group, I can expect to be initially hospitalized

- a) not at all ( 1 )
- b) one or two days ( 2 )
- c) three to ten days ( 3 )
- d) eleven to fifteen days ( 4 )



CONTENTS PROCEDURE

Data Set Name: DCEXPRT.F045CMB2  
 Member Type: DATA  
 Engine: V608  
 Created: 15:18 Friday, December 1, 1995  
 Last Modified: 15:18 Friday, December 1, 1995  
 Protection:  
 Data Set Type:  
 Label:  
 Observations: 1702  
 Variables: 17  
 Indexes: 0  
 Observation Length: 42  
 Deleted Observations: 0  
 Compressed: NO  
 Sorted: YES

-----Engine/Host Dependent Information-----

Data Set Page Size: 3072  
 Number of Data Set Pages: 25  
 File Format: 607  
 First Data Page: 1  
 Max Obs Per Page: 72  
 Obs in First Data Page: 15  
 Userid : ONITE1  
 File : F045CMB2 DCEXPRT

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos	Format	Label
3	DEQ1	Num	2	6		DOCTORS SPECIALIZING
4	DEQ2	Num	2	8		ONE OF THE STUDY PURPOSES
5	DEQ3	Num	2	10		RANDOM ASSIGNMENT MEANS
6	DEQ4	Num	2	12		STD. RX GROUP WILL RECEIVE
7	DEQ5	Num	2	14		EXP. RX GROUP WILL RECEIVE
8	DEQ6	Num	2	16		COMPARED TO CURRENT RX, STD. RX
9	DEQ7	Num	2	18		COMPARED TO CURRENT RX, EXP. RX
10	DEQ8	Num	2	20		EXPECTED TO PARTICIPATE
11	DEQ9	Num	2	22		STD. RX MAKE VISITS
12	DEQ10	Num	2	24		EXP. RX MAKE VISITS
13	DEQ11	Num	2	26		WHICH IS NOT EXPECTED
14	DEQ12	Num	2	28		EXP. RX INITIALLY HOSPITALIZED
15	DEQ13	Num	2	30		WHICH COMPLICATION NOT MEASURED
16	DEQ14	Num	2	32		A RISK OF FLUORESCIN
2	FORM	Num	3	3		DCCT FORM NUMBER
1	FSASDATE	Num	3	0	MMDYY8.	FORMDATE AS SAS DATE VALUE
17	MASK_PAT	Num	8	34		Patient ID number

-----Sort Information-----

Sortedby: MASK\_PAT  
 Validated: YES  
 Character Set: EBCDIC

\* \* D I S T R I B U T I O N A L S U M M A R Y \* \*

Variable Attributes	Statistic	<-----Primary Retinopathy----->				<-----Secondary Retinopathy----->				<---Treatment Group--->			
		<--Int-->	<--Cnv-->	<--Total-->	<--Int-->	<--Cnv-->	<--Total-->	<--Int-->	<--Cnv-->	<--Total-->	<--Int-->	<--Cnv-->	<--Total-->
<b>DOCTORS SPECIALIZING</b>													
Variable Name: DEQ1													
N		391.00	419.00	810.00	464.00	426.00	890.00	855.00	845.00	1700.00			
Nmiss		0.00	0.00	0.00	0.00	2.00	2.00	0.00	2.00	2.00			
Value (1) %		5.12	6.21	5.68	3.23	5.63	4.36	4.09	5.92	5.00			
Value (2) %		0.26	0.00	0.12	0.43	0.47	0.45	0.35	0.24	0.29			
Value (3) %		92.58	92.12	92.35	95.47	93.47	94.49	94.15	92.78	93.47			
Value (4) %		2.05	1.67	1.85	0.86	0.47	0.67	1.40	1.07	1.24			
<b>EXP. RX MAKE VISITS</b>													
Variable Name: DEQ10													
N		391.00	418.00	809.00	464.00	427.00	891.00	855.00	845.00	1700.00			
Nmiss		0.00	1.00	1.00	0.00	1.00	1.00	0.00	2.00	2.00			
Value (1) %		98.98	96.41	97.65	97.84	96.72	97.31	98.36	96.57	97.47			
Value (2) %		1.02	3.35	2.22	1.94	3.28	2.58	1.52	3.31	2.41			
Value (3) %		0.00	0.24	0.12	0.00	0.00	0.00	0.00	0.12	0.06			
Value (4) %		0.00	0.00	0.00	0.22	0.00	0.11	0.12	0.00	0.06			
<b>WHICH IS NOT EXPECTED</b>													
Variable Name: DEQ11													
N		391.00	419.00	810.00	464.00	427.00	891.00	855.00	846.00	1701.00			
Nmiss		0.00	0.00	0.00	0.00	1.00	1.00	0.00	1.00	1.00			
Value (1) %		97.70	98.81	98.27	98.92	99.06	98.99	98.36	98.94	98.65			
Value (2) %		1.02	0.00	0.49	0.22	0.23	0.22	0.58	0.38	0.35			
Value (3) %		0.26	0.72	0.49	0.00	0.00	0.00	0.12	0.35	0.24			
Value (4) %		1.02	0.48	0.74	0.86	0.70	0.79	0.94	0.59	0.76			
<b>EXP. RX INITIALLY HOSPITALIZED</b>													
Variable Name: DEQ12													
N		391.00	419.00	810.00	464.00	428.00	892.00	855.00	847.00	1702.00			
Nmiss		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00			
Value (1) %		0.00	0.48	0.25	0.00	0.70	0.34	0.00	0.59	0.29			
Value (2) %		3.58	4.77	4.20	4.74	2.57	3.70	4.21	3.66	3.94			
Value (3) %		95.91	94.75	95.31	94.83	96.26	95.52	95.32	95.51	95.42			
Value (4) %		0.51	0.00	0.25	0.43	0.47	0.45	0.47	0.24	0.35			
<b>WHICH COMPLICATION NOT MEASURED</b>													
Variable Name: DEQ13													
N		391.00	419.00	810.00	464.00	428.00	892.00	855.00	847.00	1702.00			
Nmiss		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00			
Value (1) %		0.00	0.00	0.00	0.22	0.00	0.11	0.12	0.00	0.06			
Value (2) %		99.49	99.05	99.26	98.71	97.90	98.32	99.06	98.47	98.77			
Value (3) %		0.51	0.00	0.25	0.00	0.23	0.11	0.23	0.12	0.18			
Value (4) %		0.00	0.95	0.49	1.08	1.87	1.46	0.58	1.42	1.00			
<b>A RISK OF FLUORESCENT</b>													
Variable Name: DEQ14													
N		390.00	418.00	808.00	464.00	427.00	891.00	854.00	845.00	1699.00			
Nmiss		1.00	1.00	2.00	0.00	1.00	1.00	1.00	2.00	3.00			
Value (1) %		3.33	2.15	2.72	3.45	4.68	4.04	3.40	3.43	3.41			
Value (2) %		3.33	3.35	3.34	1.51	2.81	2.13	2.34	3.08	2.71			
Value (3) %		1.79	3.11	2.48	3.88	2.81	3.37	2.93	2.96	2.94			
Value (4) %		91.54	91.39	91.46	91.16	89.70	90.46	91.33	90.53	90.94			



\* DISTRIBUTIONAL SUMMARY \*

Variable Attributes	Statistic	<--Int-->	<--Cnv-->	<--Total-->	<--Int-->	<--Cnv-->	<--Total-->	<--Int-->	<--Cnv-->	<--Total-->
<b>ONE OF THE STUDY PURPOSES</b>										
Variable Name: DEQ2	N	391.00	418.00	809.00	464.00	427.00	891.00	855.00	845.00	1700.00
	Nmiss	0.00	1.00	1.00	0.00	1.00	1.00	0.00	2.00	2.00
	Value (1) %	1.79	1.44	1.61	0.86	1.17	1.01	1.29	1.30	1.29
	Value (2) %	97.44	97.61	97.53	98.06	97.62	97.76	97.78	97.51	97.65
	Value (3) %	0.51	0.48	0.49	1.08	0.94	1.01	0.82	0.71	0.76
	Value (4) %	0.26	0.48	0.37	0.00	0.47	0.22	0.12	0.47	0.29
<b>RANDOM ASSIGNMENT MEANS</b>										
Variable Name: DEQ3	N	391.00	418.00	809.00	464.00	428.00	892.00	855.00	846.00	1701.00
	Nmiss	0.00	1.00	1.00	0.00	0.00	0.00	0.00	1.00	1.00
	Value (1) %	99.23	100.00	99.63	99.14	99.07	99.10	99.18	99.53	99.35
	Value (2) %	0.00	0.00	0.00	0.22	0.00	0.11	0.12	0.00	0.06
	Value (3) %	0.26	0.00	0.12	0.00	0.00	0.00	0.12	0.00	0.06
	Value (4) %	0.51	0.00	0.25	0.65	0.93	0.78	0.58	0.47	0.53
<b>STD. RX GROUP WILL RECEIVE</b>										
Variable Name: DEQ4	N	391.00	418.00	809.00	464.00	428.00	892.00	855.00	846.00	1701.00
	Nmiss	0.00	1.00	1.00	0.00	0.00	0.00	0.00	1.00	1.00
	Value (1) %	0.26	0.24	0.25	0.65	0.47	0.56	0.47	0.35	0.41
	Value (2) %	0.00	0.48	0.25	0.22	0.23	0.22	0.12	0.35	0.24
	Value (3) %	21.23	20.57	20.89	16.16	8.88	12.67	18.48	14.66	16.58
	Value (4) %	78.52	78.71	78.62	82.97	90.42	86.55	80.94	84.63	82.77
<b>EXP. RX GROUP WILL RECEIVE</b>										
Variable Name: DEQ5	N	391.00	419.00	810.00	464.00	428.00	892.00	855.00	847.00	1702.00
	Nmiss	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Value (1) %	97.44	96.66	97.04	96.77	97.20	96.97	97.08	96.93	97.00
	Value (2) %	2.05	2.86	2.47	2.59	2.57	2.58	2.34	2.72	2.53
	Value (3) %	0.51	0.48	0.49	0.65	0.23	0.45	0.58	0.35	0.47
<b>COMPARED TO CURRENT RX, STD. RX</b>										
Variable Name: DEQ6	N	391.00	419.00	810.00	463.00	427.00	890.00	854.00	846.00	1700.00
	Nmiss	0.00	0.00	0.00	1.00	1.00	2.00	1.00	1.00	2.00
	Value (1) %	0.77	0.00	0.37	0.65	0.00	0.34	0.70	0.00	0.35
	Value (2) %	1.79	1.67	1.73	2.38	1.64	2.02	2.11	1.65	1.88
	Value (3) %	1.28	2.15	1.73	3.24	2.81	3.03	2.34	2.48	2.41
	Value (4) %	96.16	96.18	96.17	93.74	95.55	94.61	94.85	95.86	95.35
<b>COMPARED TO CURRENT RX, EXP. RX</b>										
Variable Name: DEQ7	N	391.00	418.00	809.00	462.00	427.00	889.00	853.00	845.00	1698.00
	Nmiss	0.00	1.00	1.00	2.00	1.00	3.00	2.00	2.00	4.00
	Value (1) %	6.65	6.46	6.55	5.84	5.15	5.51	6.21	5.80	6.01
	Value (2) %	0.26	0.00	0.12	0.22	0.23	0.22	0.23	0.12	0.18
	Value (3) %	1.53	1.91	1.73	2.38	3.28	2.81	1.99	2.60	2.30
	Value (4) %	91.56	91.63	91.59	91.56	91.33	91.45	91.56	91.48	91.52

Notes: (vm=DEQ6)PROD 191: F045CMB2 (LISTING) (vm=ARNOLD 191: DOCUMENT SAS)

\* \* \* \* \* D I S T R I B U T I O N A L S U M M A R Y \* \* \* \* \*

Variable Attributes	Statistic	<--Int-->	<--Cnv-->	<-Total->	<--Int-->	<--Cnv-->	<-Total->	<--Int-->	<--Cnv-->	<-Total->	<--Int-->	<--Cnv-->	<-Total->
<b>EXPECTED TO PARTICIPATE</b>													
Variable Name: DEOB													
N		386.00	419.00	805.00	462.00	428.00	890.00	848.00	847.00	1695.00			
Nmiss		5.00	0.00	5.00	2.00	0.00	2.00	7.00	0.00	7.00			
Value (1) %		0.52	0.24	0.37	0.22	0.93	0.56	0.35	0.59	0.47			
Value (2) %		4.66	3.82	4.22	2.16	3.04	2.58	3.30	3.42	3.36			
Value (3) %		44.56	46.30	45.47	37.01	40.42	38.65	40.45	43.33	41.89			
Value (4) %		50.26	49.64	49.94	60.61	55.61	58.20	55.90	52.66	54.28			
<b>STD. RX MAKE VISITS</b>													
Variable Name: DEQ9													
N		391.00	419.00	810.00	464.00	428.00	892.00	855.00	847.00	1702.00			
Nmiss		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00			
Value (1) %		1.53	1.91	1.73	4.96	1.17	3.14	3.39	1.53	2.47			
Value (2) %		97.44	96.18	96.79	93.75	97.66	95.63	95.44	96.93	96.16			
Value (3) %		0.77	1.19	0.99	1.08	0.93	1.01	0.94	1.06	1.00			
Value (4) %		0.26	0.72	0.49	0.22	0.23	0.22	0.23	0.47	0.35			
<b>DCCT FORM NUMBER</b>													
Variable Name: FORM													
N		391.00	419.00	810.00	464.00	428.00	892.00	855.00	847.00	1702.00			
Nmiss		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00			
Value (451) %		23.53	23.87	23.70	38.58	33.88	36.32	31.70	28.93	30.32			
Value (452) %		76.47	76.13	76.30	61.42	66.12	63.68	68.30	71.07	69.68			

Notes: (VM=DOUGPROD 191: F045CNB2 LISTING)  
 (VM=ARNOLD 191: DOCUMENT SAS)