

DCCT Data Set Documentation: Form 46

Form 46: Volunteer Understanding Questionnaire (Version B)

Purpose: To re-evaluate understanding of the briefing material presented during eligibility screening among volunteers who answered one or more questions incorrectly on Version A of the questionnaire (Form 45).

Collection Schedule: Eligibility screening only for patients who failed Version A of the questionnaire.

Data Set Name: F046CMB2

Structure: One record per patient per administration.

Size: 572 observations of 17 variables.

Known Anomalies: None.

Comments: Version B of the Volunteer Understanding Questionnaire is a reordered version of the same questions asked in Version A (Form 45). Patients who answered one or more questions incorrectly on Version B could still be randomized at the discretion of the clinic's Principal Investigator.





DIABETES CONTROL AND COMPLICATIONS TRIAL
Volunteer Understanding Questionnaire
(Version B)

INSTRUCTIONS TO TRIAL COORDINATOR

This version of the form is administered only if the patient failed to correctly answer 100% of the questions on Version A (DCCT Form 045). 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 should not be randomized, unless, in the opinion of the clinic staff, the patient has an adequate understanding of the purpose and requirements of the study.

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

A. IDENTIFYING INFORMATION

2 CLINIC 1. DCCT Clinic Number _____

3 PATIENT 7. Patient ID Number _____

INITIALS 3. Patient's Initials _____

FORMDATE 4. Today's Date _____

Month Day Year

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. One of the purposes of this study is to determine
- 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)
- 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)

2. Doctors specializing in the treatment of diabetes 7 DFQ2

- a) have proven that keeping blood glucose levels as close as possible to the levels of people without diabetes will prevent complications (1)
- b) have proven that blood glucose levels are unrelated to complications (2)

10 DFQ5

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)

8 DFQ3 3. The Experimental Treatment Group in this study will receive, in addition to diet instruction and diabetes education, (1)

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 (2)

b) either an insulin pump or three or four injections of insulin a day and will be expected to do daily urine testing only (3)

c) one or two injections of insulin a day and will be expected to do daily self blood glucose monitoring (4)

d) one or two injections of insulin a day and will be expected to do daily urine testing (1)

9 DFQ4 4. The Standard Treatment Group in this study will receive, in addition to diet instruction and diabetes education, (2)

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 (3)

b) either an insulin pump or three or four injections of insulin a day and will be expected to do daily urine testing only (4)

c) one or two injections of insulin a day and will be expected to do daily self blood glucose monitoring (1)

d) one or two injections of insulin a day and will be expected to do daily urine testing (2)

5. 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)

6. If I volunteer for this study, I will be expected to participate 11 DFQ6

a) possibly one year (1)

b) possibly three years (2)

c) possibly eight years (3)

d) possibly ten years (4)

7. Which of the following is NOT expected from you if you agree to participate in this study? 12 DFQ7

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)

13 *DFQ8* Patient - 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)

14 *DFQ9* 9. 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)

15 *DFQ10* 10. 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)

16 *DFQ11* 11. 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)

12. 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)

13. Which of the following complications of diabetes will NOT be measured in this trial? *18 DFQ13*

- 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)

14. If I am in the Experimental Treatment Group, I can expect to be initially hospitalized *19 DFQ14*

- 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.F046CMB2
 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: 572
 Variables: 17
 Indexes: 0
 Observation Length: 136
 Deleted Observations: 0
 Compressed: NO
 Sorted: YES

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

Data Set Page Size: 7168
 Number of Data Set Pages: 12
 File Format: 607
 First Data Page: 1
 Max Obs per Page: 52
 Obs in First Data Page: 34
 Userid : ONITE1
 File : F046CMB2 DCEXPRT

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

#	Variable	Type	Len	Pos	Format	Label
2	DFQ1	Num	8	8		ONE OF THE STUDY PURPOSES
3	DFQ2	Num	8	16		DOCTORS SPECIALIZING
4	DFQ3	Num	8	24		EXP. RX GROUP WILL RECEIVE
5	DFQ4	Num	8	32		STD. RX GROUP WILL RECEIVE
6	DFQ5	Num	8	40		RANDOM ASSIGNMENT MEANS
7	DFQ6	Num	8	48		EXPECTED TO PARTICIPATE
8	DFQ7	Num	8	56		WHICH IS NOT EXPECTED
9	DFQ8	Num	8	64		COMPARED TO CURRENT RX, EXP. RX
10	DFQ9	Num	8	72		STD. RX MAKE VISITS
11	DFQ10	Num	8	80		EXP. RX MAKE VISITS
12	DFQ11	Num	8	88		A RISK OF FLUORESCENIN
13	DFQ12	Num	8	96		WHICH COMPLICATION NOT MEASURED
14	DFQ13	Num	8	104		EXP. RX INITIALLY HOSPITALIZED
15	DFQ14	Num	8	112		DCCT FORM NUMBER
16	FSASDATE	Num	8	120	MMDDYY8.	FORMDATE AS SAS DATE VALUE
17	MASK_PAT	Num	8	128		Patient ID number

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

Sortedby: MASK_PAT
 Validated: YES
 Character Set: EBCDIC

*** DISTRIBUTIONAL SUMMARY ***

Variable Attributes	Statistic	<--Int-->	<--Cnv-->	<-Total->	<--Int-->	<--Cnv-->	<-Total->	<--Treatment Group-->	<--Cnv-->	<Overall>
ONE OF THE STUDY PURPOSES										
Variable Name: DFQ1	N	124.00	158.00	282.00	144.00	145.00	289.00	268.00	303.00	571.00
	Nmiss	0.00	1.00	1.00	0.00	0.00	0.00	0.00	1.00	1.00
	Value (1) %	0.00	1.27	0.71	0.69	3.45	2.08	0.37	2.31	1.40
	Value (2) %	98.39	98.73	98.58	99.31	93.10	96.19	98.88	96.04	97.37
	Value (3) %	1.61	0.00	0.71	0.00	3.45	1.73	0.75	1.65	1.23
STD. RX MAKE VISITS										
Variable Name: DFQ10	N	124.00	159.00	283.00	144.00	145.00	289.00	268.00	304.00	572.00
	Nmiss	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Value (1) %	2.42	0.63	1.41	3.47	0.69	2.08	2.99	0.66	1.75
	Value (2) %	94.35	99.37	97.17	93.75	97.93	95.85	94.03	98.68	96.50
	Value (3) %	1.61	0.00	0.71	1.39	1.38	1.38	1.49	0.66	1.05
	Value (4) %	1.61	0.00	0.71	1.39	0.00	0.69	1.49	0.00	0.70
EXP. RX MAKE VISITS										
Variable Name: DFQ11	N	124.00	159.00	283.00	144.00	145.00	289.00	268.00	304.00	572.00
	Nmiss	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Value (1) %	98.39	98.74	98.59	100.00	95.17	97.58	99.25	97.04	98.08
	Value (2) %	0.81	1.26	1.06	0.00	4.83	2.42	0.37	2.96	1.75
	Value (3) %	0.81	0.00	0.35	0.00	0.00	0.00	0.37	0.00	0.17
A RISK OF FLUORESCIN										
Variable Name: DFQ12	N	123.00	158.00	281.00	144.00	145.00	289.00	267.00	303.00	570.00
	Nmiss	1.00	1.00	2.00	0.00	0.00	0.00	1.00	1.00	2.00
	Value (1) %	0.81	1.27	1.07	4.86	0.69	2.77	3.00	0.99	1.93
	Value (2) %	3.25	6.33	4.98	4.86	2.76	3.81	4.12	4.62	4.39
	Value (3) %	0.81	0.63	0.71	0.00	0.69	0.35	0.37	0.66	0.53
	Value (4) %	95.12	91.77	93.24	90.28	95.86	93.08	92.51	93.73	93.16
WHICH COMPLICATION NOT MEASURED										
Variable Name: DFQ13	N	124.00	159.00	283.00	144.00	145.00	289.00	268.00	304.00	572.00
	Nmiss	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Value (1) %	0.81	0.00	0.35	0.00	0.00	0.00	0.37	0.00	0.17
	Value (2) %	99.19	95.60	97.17	100.00	96.55	98.27	99.63	96.05	97.73
	Value (3) %	0.00	3.14	1.77	0.00	0.00	0.00	0.00	1.64	0.87
	Value (4) %	0.00	1.26	0.71	0.00	3.45	1.73	0.00	2.30	1.22
EXP. RX INITIALLY HOSPITALIZED										
Variable Name: DFQ14	N	124.00	159.00	283.00	144.00	145.00	289.00	268.00	304.00	572.00
	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	0.00	0.00	0.00	0.00	0.00	0.00
	Value (2) %	12.90	8.81	10.60	14.58	8.97	11.76	13.81	8.88	11.19
	Value (3) %	87.10	89.31	88.34	84.03	86.21	85.12	85.45	87.83	86.71
	Value (4) %	0.00	1.89	1.06	0.69	4.83	2.77	0.37	3.29	1.92

* * * 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-->
DOCTORS SPECIALIZING Variable Name: DFQ2	N	124.00	159.00	283.00	143.00	144.00	287.00	144.00	144.00	288.00	267.00	303.00	570.00
	Mmiss	0.00	0.00	0.00	1.00	1.00	2.00	1.00	1.00	2.00	1.00	1.00	2.00
	Value (1) %	8.87	10.06	9.54	4.90	13.19	9.06	6.74	6.74	11.55	6.74	11.55	9.30
	Value (2) %	1.61	0.00	0.71	0.00	0.35	0.75	0.35	0.35	0.75	0.35	0.35	0.53
	Value (3) %	87.10	89.31	88.34	95.10	86.11	90.59	91.39	87.79	89.47	91.39	87.79	89.47
	Value (4) %	2.42	0.63	1.41	0.00	0.00	0.00	1.12	0.33	0.70	1.12	0.33	0.70
EXP. RX GROUP WILL RECEIVE Variable Name: DFQ3	N	124.00	159.00	283.00	144.00	145.00	289.00	145.00	145.00	290.00	268.00	304.00	572.00
	Mmiss	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Value (1) %	98.39	96.86	97.53	100.00	95.86	97.92	99.25	96.38	97.73	99.25	96.38	97.73
	Value (2) %	0.81	2.52	1.77	0.00	4.14	2.08	0.37	0.37	0.75	0.37	0.37	0.75
	Value (3) %	0.81	0.00	0.35	0.00	0.00	0.00	0.00	0.00	0.17	0.00	0.00	0.17
	Value (4) %	0.00	0.63	0.35	0.00	0.00	0.00	0.00	0.33	0.17	0.00	0.33	0.17
STD. RX GROUP WILL RECEIVE Variable Name: DFQ4	N	124.00	158.00	282.00	144.00	145.00	289.00	145.00	145.00	290.00	268.00	303.00	571.00
	Mmiss	0.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	1.00
	Value (1) %	1.61	0.00	0.71	0.69	0.69	0.35	1.12	0.35	0.53	1.12	0.35	0.53
	Value (2) %	0.00	1.90	1.06	1.39	0.69	1.04	0.75	1.32	1.05	0.75	1.32	1.05
	Value (3) %	36.29	39.87	38.30	32.64	30.34	31.49	34.33	35.31	34.85	34.33	35.31	34.85
	Value (4) %	62.10	58.23	59.93	65.28	68.97	67.13	63.81	63.37	63.57	63.81	63.37	63.57
RANDOM ASSIGNMENT MEANS Variable Name: DFQ5	N	124.00	159.00	283.00	144.00	145.00	289.00	145.00	145.00	290.00	268.00	304.00	572.00
	Mmiss	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Value (1) %	100.00	99.37	99.65	100.00	97.93	98.96	100.00	98.68	99.30	100.00	98.68	99.30
	Value (4) %	0.00	0.63	0.35	0.00	2.07	1.04	0.00	1.32	0.70	0.00	1.32	0.70
EXPECTED TO PARTICIPATE Variable Name: DFQ6	N	121.00	159.00	280.00	144.00	145.00	289.00	145.00	145.00	290.00	265.00	304.00	569.00
	Mmiss	3.00	0.00	3.00	0.00	0.00	0.00	0.00	0.00	0.00	3.00	0.00	3.00
	Value (2) %	2.48	6.29	4.64	0.69	1.38	1.04	1.51	3.95	2.81	1.51	3.95	2.81
	Value (3) %	41.32	45.91	43.93	27.78	37.24	32.53	33.96	41.78	38.14	33.96	41.78	38.14
	Value (4) %	56.20	47.80	51.43	71.53	61.38	66.44	64.53	54.28	59.05	64.53	54.28	59.05
WHICH IS NOT EXPECTED Variable Name: DFQ7	N	124.00	159.00	283.00	144.00	144.00	288.00	144.00	144.00	288.00	268.00	303.00	571.00
	Mmiss	0.00	0.00	0.00	0.00	1.00	1.00	0.00	1.00	1.00	0.00	1.00	1.00
	Value (1) %	96.77	98.11	97.53	99.31	94.64	96.88	98.13	96.37	97.20	98.13	96.37	97.20
	Value (2) %	0.81	0.63	0.71	0.00	0.69	0.35	0.37	0.66	0.53	0.37	0.66	0.53
	Value (3) %	1.61	0.63	1.06	0.00	1.39	0.69	0.75	0.99	0.88	0.75	0.99	0.88
	Value (4) %	0.81	0.63	0.71	0.69	3.47	2.08	0.75	1.98	1.40	0.75	1.98	1.40
COMPARED TO CURRENT RX, EXP. RX Variable Name: DFQ8	N	124.00	159.00	283.00	144.00	145.00	289.00	145.00	145.00	290.00	268.00	304.00	572.00
	Mmiss	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Value (1) %	8.06	6.29	7.07	2.78	1.38	2.08	5.22	3.95	4.55	5.22	3.95	4.55
	Value (2) %	0.81	0.63	0.71	0.69	0.00	0.35	0.75	0.33	0.52	0.75	0.33	0.52
	Value (3) %	0.81	0.00	0.35	0.00	2.07	1.04	0.37	0.99	0.70	0.37	0.99	0.70
	Value (4) %	90.32	93.08	91.87	96.53	96.55	96.54	93.66	94.74	94.23	93.66	94.74	94.23

Notes: (VM=DUIGPROD 191: F046CMB2 LISTING) (VM=FARNOLD 191: DOCUMENT SAS)

* * DISTRIBUTIONAL SUMMARY * *

Variable Attributes	Statistic	<--Int-->	<--Cnv-->	<-Total->	<--Int-->	<--Cnv-->	<-Total->	<--Int-->	<--Cnv-->	<-Total->	<--Int-->	<--Cnv-->	<-Total->	<Overall-->
COMPARED TO CURRENT RX, STD. RX	N	124.00	159.00	283.00	143.00	145.00	288.00	267.00	304.00	571.00	1.00	0.00	1.00	571.00
Variable Name: DFC9	Nmiss	0.00	0.00	0.00	1.00	0.00	1.00	1.00	0.00	1.00	1.00	0.00	1.00	1.00
	Value (1) %	2.42	0.63	1.41	0.70	2.76	1.74	1.50	1.64	1.58	1.50	1.64	1.58	1.58
	Value (2) %	8.06	1.89	4.59	5.59	0.00	2.78	6.74	0.99	3.68	6.74	0.99	3.68	3.68
	Value (3) %	1.61	0.63	1.06	2.80	2.07	2.43	2.25	1.32	1.75	2.25	1.32	1.75	1.75
	Value (4) %	87.90	96.86	92.93	90.91	95.17	95.06	89.51	96.05	92.99	89.51	96.05	92.99	92.99
DCCT FORM NUMBER	N	124.00	159.00	283.00	144.00	145.00	289.00	268.00	304.00	572.00	0.00	0.00	0.00	572.00
Variable Name: FORM	Nmiss	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Value (461) %	15.32	8.81	11.66	14.58	13.79	14.19	14.93	11.18	12.94	14.93	11.18	12.94	12.94
	Value (462) %	84.68	91.19	88.34	85.42	86.21	85.81	85.07	88.82	87.06	85.07	88.82	87.06	87.06

Notes: (VMP=DOUGPROD 191: F046CMB2 LISTING)
 (VMP=ARNOLD 191: DOCUMENT SAS)