

EPIDEMIOLOGY OF DIABETES INTERVENTION AND COMPLICATIONS

Ophthalmic Examination and Visual Acuity

Patients are to undergo eye examinations at the 8th, 12th, and 16th anniversary post-DCCT randomization. The ophthalmic follow-up visits should be scheduled to correspond with other regularly scheduled visits whenever possible. Visual acuity is measured and stereo fundus photographs are taken in the course of each eye examination. The following procedures are also required: measurement of intraocular pressure, slit-lamp examination, ophthalmoscopy. Chapter 18 of the Manual of Operations should be consulted for procedures to follow in completing these examinations. The original of this form is to be completed at each scheduled eye examination and sent to the Data Coordinating Center; a copy of the form should be kept in the clinic's files.

A. IDENTIFYING INFORMATION

- 1. EDIC Clinic Number 2. CLINIC _____
- 2. Patient ID Number 3. PATIENT _____
- 3. Patient's Initials 4. INITIALS _____
- 4. Date of examination 5. FORMDATE
Month Day Year
- 5. EDIC year 6. EDIC YEAR _____

B. DISTANCE SUBJECTIVE REFRACTION

Use any visual acuity chart other than
ETDRS Visual Acuity Chart 1 or 2.

IF A SUBJECTIVE REFRACTION CANNOT BE PERFORMED IN ONE OR BOTH EYES AT FOUR METERS BECAUSE OF POOR ACUITY, ATTEMPT THE REFRACTION AT ONE METER. IF A ONE METER REFRACTION IS POSSIBLE, SUBTRACT +0.75 SPHERE FROM THE REFRACTION USED AT ONE METER, AND ENTER THIS RESULT IN QUESTION 2.

- No Yes
- 1a) Was a refraction performed for both eyes? (1) (2)

7. COREFRAC

IF YES, PROCEED TO QUESTION 2.
IF NO, ANSWER THE FOLLOWING ITEMS AND LEAVE BLANK THE RESPONSE TO QUESTION 2 FOR EYE(S) NOT REFRACTED.

Specify reason:

	Right Eye		Left Eye	
	No	Yes	No	Yes
b,c) Poor visual acuity	8. COPVARE (1)	(2)	9. COPVALE (1)	(2)
d,e) Eye(s) enucleated*	10. COENUCRE (1)	(2)	11. COENUCLE (1)	(2)
f,g) Other (specify below)	(1)	(2)	(1)	(2)
	12. COOREFRE		13. COOREFLE	

R - _____
L - _____

*LEAVE BLANK ALL RESPONSES TO QUESTIONS B-2 THROUGH F-7 FOR ENUCLEATED EYE(S).

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- 2. Corrective lenses obtained by subjective refraction for distance:

IF A SUBJECTIVE REFRACTION WAS NOT PERFORMED AT FOUR OR ONE METERS, ENTER THE DISTANCE SUBJECTIVE REFRACTION FROM EITHER THE BASELINE OPHTHALMIC EXAMINATION OR THE LAST OPHTHALMIC EXAMINATION, WHICHEVER IS MORE RECENT. INDICATE WHETHER PLUS OR MINUS SPHERES OR CYLINDERS WERE USED BY CIRCLING THE APPROPRIATE SIGNS. IF SPHERE, CYLINDER, AND AXIS ARE ALL ZERO, RECORD A CHECK MARK () IN THE APPROPRIATE SPACE BELOW:

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	Right Eye	Left Eye
14. COSPHERE	+	+
a,b) Sphere	-	-
16. COCYLRE	+	+
c,d) Cylinder	-	-
e,f) Axis	18. COAXISAE	19. COAXISLE
g,h) Sphere, cylinder, and axis all zero	20. COZERORE (1)	21. COZEROLE (1)

- 3. Is there myopia greater than 7 diopters in one or both eyes?

No Yes
(1) (2)
22. COMYOPIA

C. VISUAL ACUITY MEASUREMENTS

Use ETDRS Visual Acuity CHART 1 for the RIGHT EYE and CHART 2 for the LEFT EYE.

- 1. What is the distance between the patient and the chart (record in meters to nearest 1/10 meter)? 23. CODIST Meters
- 2. Letters correct at four meters distance: AL

CIRCLE EACH LETTER THE PATIENT IDENTIFIES CORRECTLY AND WRITE THE TOTAL CORRECT FOR EACH ROW IN COLUMN AT RIGHT. EACH ROW TOTAL MUST BE ENTERED.
REMEMBER: THE PATIENT STARTS AT THE TOP READING SLOWLY AND GETS ONLY ONE CHANCE AT EACH LETTER. PUSH THE PATIENT UNTIL HE/SHE CLEARLY DEMONSTRATES HE/SHE CANNOT READ OR GUESS LETTERS CORRECTLY.

Patient ID _____

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RIGHT EYE - CHART 1

Acuity Equivalent	Chart 1 letters	Number Correct
20/200	N C K Z O	___ 24. C0200RE4
20/160	R H S D K	___ 25. C0160RE4
20/125	D O V H R	___ 26. C0125RE4
20/100	C Z R H S	___ 27. C0100RE4
20/80	O N H R C	___ 28. C080RE4
20/63	D K S N V	___ 29. C063RE4
20/50	Z S O K N	___ 30. C050RE4
20/40	C K D N R	___ 31. C040RE4
20/32	S R Z K D	___ 32. C032RE4
20/25	H Z O V C	___ 33. C025RE4
20/20	N V D O K	___ 34. C020RE4
20/16	V H C N O	___ 35. C016RE4
20/13	S V H C Z	___ 36. C013RE4
20/10	O Z D V H	___ 37. C010RE4
		38. C04MRE

a) Total number correct at four meters ___

NOTE: DO NOT CHANGE TO CHART 2 UNTIL YOU HAVE CHANGED THE COVER TO THE PATIENT'S RIGHT EYE.

LEFT EYE - CHART 2

Acuity Equivalent	Chart 2 letters	Number Correct
20/200	D S R K N	___ 39. C0200LE4
20/160	C K Z O H	___ 40. C0160LE4
20/125	O N R K D	___ 41. C0125LE4
20/100	K Z V D C	___ 42. C0100LE4
20/80	V S H Z O	___ 43. C080LE4
20/63	H D K C R	___ 44. C063LE4
20/50	C S R H N	___ 45. C050LE4
20/40	S V Z D K	___ 46. C040LE4
20/32	N C V O Z	___ 47. C032LE4
20/25	R H S D V	___ 48. C025LE4
20/20	S N R O H	___ 49. C020LE4
20/16	O D H K R	___ 50. C016LE4
20/13	Z K C S N	___ 51. C013LE4
20/10	C R H D V	___ 52. C010LE4

b) Total number correct at four meters 53. C04MLE

IF THE TOTAL NUMBER OF LETTERS READ CORRECTLY IS GREATER THAN OR EQUAL TO 5 IN EACH EYE, PROCEED TO SECTION D.

IF TOTAL NUMBER OF LETTERS READ CORRECTLY WITH EITHER EYE IS LESS THAN 5, MOVE THE PATIENT TO A DISTANCE OF ONE METER FROM THE CHART AND TEST THE ACUITY AT THIS DISTANCE IN EACH EYE WITH LESS THAN 5 LETTERS CORRECT. ANSWER QUESTIONS 3 AND 4.

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D. INTRAOCULAR PRESSURE

Use Goldmann applanation tonometry

1a,b) Intraocular pressure:

Right Eye
88. COIOPRE _____ mm Hg

Left Eye
89. COIOPLE _____ mm Hg

E. SLIT-LAMP EXAMINATION

1a,b) Is the lens missing?

Right Eye
90. COLENSRE (1) (2)

Left Eye
91. COLENSLE (1) (2)

2a,b) Is there evidence of definite iris neovascularization?

92. COIRISRE (1) (2)

93. COIRISLE (1) (2)

IF YES, GONIOSCOPY SHOULD BE PERFORMED AND THE FOLLOWING ITEM SHOULD BE ANSWERED FOR THAT EYE.

c,d) Is there evidence of angle neovascularization?

94. COANGLRE (1) (2)

95. COANGLLE (1) (2)

NOTE: BECAUSE GONIOSCOPY MAY INTERFERE WITH CORNEAL CLARITY AND AFFECT THE ABILITY TO TAKE ADEQUATE QUALITY PHOTOGRAPHS, IT IS RECOMMENDED THAT THE PATIENT RETURN FOR A SEPARATE VISIT IF POSSIBLE, OR THAT GONIOSCOPY BE DEFERRED UNTIL AFTER PUPILLARY DILATION AND FUNDUS PHOTOGRAPHY.

F. OPHTHALMOSCOPIC EXAMINATION

1a,b) Was the ophthalmoscopic examination of the fundus satisfactory?

Right Eye

Left Eye

Yes

(1)

(1)

Not entirely satisfactory, but performed

(2)

(2)

Examination could not be performed

(3)

(3)

IF YES FOR BOTH EYES, PROCEED TO QUESTION 2.
IF NOT ENTIRELY SATISFACTORY FOR EITHER EYE OR IF EXAMINATION WAS NOT PERFORMED FOR EITHER EYE, ANSWER THE FOLLOWING ITEM FOR APPROPRIATE EYE.

96. COOPHRE

97. COOPHLE

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c,d) Specify the main reason the fundus examination was unsatisfactory or could not be performed (CHECK ONLY ONE)

Patient refused

Vitreous opacity

Vitreous hemorrhage

Lens opacity

Corneal opacity secondary to neovascular glaucoma

Other corneal opacity

Posterior synechia prevent dilation of pupil

Other (SPECIFY IN THE SPACE PROVIDED)

R - _____

L - _____

IF OPHTHALMOSCOPIC EXAMINATION COULD NOT BE PERFORMED FOR EITHER EYE (I.E., IF QUESTION 1 IS ANSWERED "NOT PERFORMED" FOR BOTH EYES), SKIP QUESTIONS 2 AND 3.
IF THE FUNDUS OF EITHER EYE IS EXAMINED, QUESTIONS 2-7 SHOULD BE ANSWERED FOR THAT EYE.

2a,b) Which statement best describes the clarity of the lens in each eye? (CHECK ONLY ONE)

No lens opacity or some lens opacity but not sufficient to expect reduced visual acuity

Lens opacity sufficient to reduce visual acuity but not to less than 20/100

Lens opacity sufficient to reduce visual acuity to less than 20/100

3a,b) Are vitreous or preretinal hemorrhage present in any areas of the fundus?

IF YES, ANSWER THE FOLLOWING ITEM FOR THAT EYE
IF NO, PROCEED TO QUESTION 4.

98. COREASRE

Right Eye

(1)

(2)

(3)

(4)

(5)

(6)

(7)

(8)

99. COREASLE

Left Eye

(1)

(2)

(3)

(4)

(5)

(6)

(7)

(8)

100. COCLARRE

Right Eye

(1)

(2)

(3)

No Yes
(1) (2)

101. COCLARLE

Left Eye

(1)

(2)

(3)

No Yes
(1) (2)

102. COHEMRE

103. COHEMLE

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c,d) Does hemorrhage obscure one or more disc areas of retina?

Right Eye
No Yes
(1) (2)

Left Eye
No Yes
(1) (2)

104. COOBSCRE

105. COOBSCLE

IF YES, ANSWER THE FOLLOWING ITEMS FOR THAT EYE.
IF NO, PROCEED TO QUESTION 4.

Indicate areas in which vitreous or preretinal hemorrhage obscures one or more disc areas of retina:

e,f) Within seven standard fields

Right Eye
(1)

Left Eye
(1)

106. CO7STDRE

107. CO7STDLE

g,h) Outside seven standard fields but posterior to vortex ampullae

COOUT7RE (1)

COOUT7LE (1)

108. COOUT7RE

109. COOUT7LE

i,j) Anterior to vortex ampullae

COANT7RE (1)

COANT7LE (1)

110. COANT7RE

111. COANT7LE

4a,b) Are new vessels present on or within one disc diameter of the optic nerve head (NVD)?

Right Eye
No Yes Quest.
(1) (2) (3)

Left Eye
No Yes Quest.
(1) (2) (3)

112. CONVDRE

113. CONVDLE

IF YES, ANSWER THE FOLLOWING ITEM FOR THAT EYE.
IF NO, PROCEED TO QUESTION 5.

c,d) Are the vessels greater than or equal to DRS Standard Photo 10A?

No Yes
(1) (2)

CO5NVDLE
No Yes
(1) (2)

114. CO5NVDRE

115. CO5NVDLE

5a,b) Are new vessels elsewhere present?

No Yes Quest.
(1) (2) (3)

CONVELE
No Yes Quest.
(1) (2) (3)

116. CONVERE

117. CONVELE

IF YES, ANSWER THE FOLLOWING ITEMS FOR THAT EYE.
IF NO, PROCEED TO QUESTION 6.

c,d) Are there new vessels within the seven standard fields?

No Yes
(1) (2)

CO7NVELE
No Yes
(1) (2)

118. CO7NVERE

119. CO7NVELE

e,f) Are there new vessels outside the seven standard fields?

COOUT7RE (1) (2)

COOUT7LE (1) (2)

120. COOUT7RE

121. COOUT7LE

g,h) Are the new vessels greater than or equal to 1/2 DA in size in any 30 degree field?

CO5NVERE (1) (2)

CO5NVELE (1) (2)

122. CO5NVERE

123. CO5NVELE

6a,b) Is there retinal thickening within one disc diameter of the center of the macula, i.e., within a circle two disc diameters in diameter centered on the macula?

Right Eye
No Yes Quest.
(1) (2) (3)

Left Eye
No Yes Quest.
(1) (2) (3)

CO7HIKRE (1) (2) (3)

124. CO7HIKLE

IF YES OR QUESTIONABLE, ANSWER THE FOLLOWING ITEMS FOR THAT EYE.
IF NO, PROCEED TO QUESTION 7.

c,d) Is the center of the macular involved?

COCNTKRE (1) (2) (3)

COCNTKLE (1) (2) (3)

126. COCNTKRE

127. COCNTKLE

e,f) Are cystoid changes present?

(1) (2) (3)

(1) (2) (3)

128. COCYSTRE

129. COCYSTLE

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7a,b) Are high risk characteristics present?

IF YES, ANSWER THE FOLLOWING ITEM FOR THAT EYE.
IF NO, PROCEED TO QUESTION 8.

c,d) Do you plan to perform photocoagulation?

IF YES, PROCEED TO QUESTION 8.
IF NO, ANSWER THE FOLLOWING ITEM FOR THAT EYE.

e,f) Why do you not plan photocoagulation in the eye(s)
with high risk characteristics? (CHECK ALL THAT APPLY)

1 Patient refuses

2 Unable to treat due to hemorrhage

3 Unable to treat for other reason*

*Specify reason: _____

4 Would prefer not to treat

5 Other; specify: _____

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P.11 8a,b) Is there any other major ophthalmoscopic abnormality such as
retinal detachment, photocoagulation scars, fibrous/glial
proliferations, vein occlusion, etc.?

IF YES, DESCRIBE:

Right Eye
No Yes

130. COHRCRE (1) (2)

132. COPLANRE (1) (2)

134. COREFRE (1)

136. COUNHMRE (1)

138. COUNORRE (1)

140. COPREFRE (1)

142. COOLASRE (1)

Right Eye
No Yes
(1) (2)

144. COABNRE

Left Eye
No Yes

(1) (2)

131. COHRCLE

(1) (2)

132. COPLANLE

(1) 135. COREFLE

(1) 137. COUNHMLE

(1) 139. COUNORLE

(1) 141. COPREFLE

(1) 143. COOLASLE

Left Eye
No Yes

(1) (2)

145. COABNLE

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Type or print name of Ophthalmologist performing eye examination:

Certification
Numbers (if any)

____ - ____ - 146. COOPRTHNO

Type or print name of individual performing visual acuity examination:

____ - ____ - 147. COEXAMNO

Type or print name of Study Coordinator or other person who reviewed
the form for completeness:

____ - ____ - 148. COREVIEW

149. CO WEEKNO