

Data Supplement 2

Safety of Community Use of TPA in Acute Stroke Clinical Data Collection Form

Database ID (automatic) (1)

Chart Reviewer (Initials): ____ (2)

Source Record: Paper Electronic Combined Existing Data Base No Chart (3)

STUDY HOSPITAL DATA SOURCE

1. Hospital Foote Hurley SJMH UMMC (4)

2. Hospital Record # _____ (5)

PATIENT INFORMATION

3. Last Name _____ (6)

4. First Name _____ (7)

5. MI _ (8)

6. Birthdate (mm/dd/yyyy) (_ / _ / _) (9)

7. Gender Male /Female (10)

8. Race "White(non-Hispanic)";"Black";"Asian";"Hispanic";
"Other";"Unknown" (11)

9. Home Address

a. Street: _____ ND (12)

b. City: _____ ND (13)

c. State (MI) _____ ND (14)

d. Zip (5 digit) _____ ND (15)

e. Telephone ____ - ____ - _____ ND (16)

10. Work Address

a. Street: _____ ND (17)

b. City: _____ ND (18)

c. State (MI) _____ ND (19)

d. Zip (5 digit) _____ ND (20)

e. Telephone ____ - ____ - _____ ND (21)

11. Social Security (____ - ____ - _____) ND (22)

STROKE ONSET INFORMATION

12. Stroke Onset Date (mm/dd/yyyy) (_ / _ / _) (23)

13. Stroke Onset Time (24 hr clock) (_ : _) (24)

14. Location at Onset "Home"; "Work"; "Hospital"; "Car";

"Nursing Home or Assisted Living Facility"
 Other"; "Unknown" (25)

HOSPITAL TO HOSPITAL TRANSFER INFORMATION

15. Was this patient involved in a Hospital-to-Hospital Transfer? Yes / No (26)

IF TRANSFER = "YES", COMPLETE THE FOLLOWING

- a. Initial Hospital _____ (27)
- b. Initial Hospital Mode of Arrival "Ground Ambulance"; "Air Ambulance"; "Car";
 "Inpatient"; "Other"; "Not documented" (28)

IF MODE OF ARRIVAL = "GROUND OR AIR AMBULANCE" COMPLETE THE FOLLOWING:

- i. EMS 1 Dispatch Date ____ / ____ / ____ ND (29)
- ii. EMS 1 Dispatch Time (__ : __) ND (30)
- iii. EMS 1 On-Scene Time (__ : __) ND (31)
- iv. EMS 1 Depart Scene Time (__ : __) ND (32)
- v. EMS 1 Initial Hospital Arrival Time (__ : __) ND (33)

OTHERWISE, CONTINUE

- c. Initial hospital ED Arrival Time (__ : __) ND (34)
- d. Initial hospital ED MD Contact Time (__ : __) ND (35)
- e. Initial hospital ED CT Time (__ : __) ND (36)
- f. Was TPA given prior to transfer? Yes / No ND (37)

IF ANSWER = "YES", COMPLETE THE FOLLOWING:

- i. Initial hospital ED tPA Time (__ : __) ND (38)
- ii. Bolus dose _____ mg ND (39)
- iii. Infusion dose _____ mg ND (40)
- iv. Total dose(may be calculated) _____ mg ND (41)

IF ANSWER = "NO", CONTINUE

STUDY HOSPITAL DATA

16. Mode of Arrival to Study Hospital "Ground Ambulance"; "Air Ambulance"; "Car"; "Inpatient";
 "Ambulatory"; "Other"; "Not documented" (42)

IF MODE OF ARRIVAL = GROUND AMBULANCE, COMPLETE THE FOLLOWING

- a. EMS 2 Dispatch Date ____ / ____ / ____ ND (43)
- b. EMS 2 Dispatch Time (__ : __) ND (44)
- c. EMS 2 On-Scene Time (__ : __) ND (45)
- d. EMS 2 Depart Scene Time (__ : __) ND (46)
- e. EMS 2 Study Hospital Arrival Time (__ : __) ND (47)

IF MODE OF ARRIVAL = AIR AMBULANCE, COMPLETE THE FOLLOWING

- f. Helicopter Liftoff date ____ / ____ / _____ ND (48)
- g. Helicopter Liftoff Time (__ : __) ND (49)
- h. Helicopter Arrive On-Scene (__ : __) ND (50)
- i. Helicopter Depart Scene (__ : __) ND (51)
- j. Helicopter Arrive Destination (__ : __) ND (52)

OTHERWISE, CONTINUE

PHYSICIAN TREATMENT DATA

- 17. ED Treating Attending (last name) _____ ND (53)
- 18. ED Treating Attending (first name) _____ ND (54)
- 19. ED Treating Resident (last name) _____ none
(55)
- 20. ED Treating Resident (first name) _____ none
(56)
- 21. Method of Neurology Consult in ED? "in person";"by phone";"consult obtained, method unknown";
"no consult identified" (57)
- 22. Method of BIG Consult in ED? "in person";"by phone";"consult obtained, method unknown";
"no consult identified" (58)
- 23. BIG Team Member Consulted? "W.Barsan";"S.Hickenbottom";"R.McCurdy";"C.Schultz";
"P.Scott"; "R.Silbergleit";"R.Smith";"J.Kutcher";"D.Brown";
"L.Morgenstern"; "M.Wang";"T.Smith"; "J. Majersik"; "D.
Zahuranec"; "Unknown"; "Unknown Investigators" (59)

ED INTERVAL TIMES

- 24. Study hospital ED Arrival Date: ____ / ____ / _____ ND (60)
- 25. Study hospital ED Arrival Time (__ : __) ND (61)
- 26. Study hospital ED First MD Contact (__ : __) ND (62)
- 27. Study hospital CT Time (__ : __) ND (63)
- 28. Study hospital TPA Time (__ : __) ND (64)

PAST MEDICAL HISTORY

- 29. Prior Stroke Yes / No (65)
- 30. Prior TIA Yes / No (66)
- 31. Diabetes (I or II) or documented current use of glucose lowering medication Yes / No (67)
- 32. Hypertension or documented current use of anti-hypertensive medication Yes / No (68)
- 33. Elevated Cholesterol or documented current use of lipid lowering medication Yes / No (69)
- 34. Coronary Artery Disease (documented CAD, MI, angina, CABG, angioplasty, stent) Yes / No (70)

- 35. CHF Yes / No (71)
- 36. Atrial Fibrillation Yes / No (72)
- 37. Valvular Heart Disease Yes / No (73)
- 38. Smoking within previous year before stroke Yes / No (74)
- 39. Current anti-platelet therapy (aspirin, ticlid, plavix, dipyridamole, or combinations) Yes / No (75)
- 40. Current beta-blocker therapy Yes / No (76)
- 41. Any other pre-existing medical conditions? Yes / No (77)

PRE-STROKE FUNCTIONAL STATUS

- 42. Pre-stroke modified Rankin Scale (circle) "0"; "1"; "2"; "3"; "4"; "5" (78)

BLOOD GLUCOSE INFORMATION

- 43. Pre-treatment Blood Glucose: _____ mg/dL (79)

BLOOD PRESSURE INFORMATION

- 44. Pre-TPA treatment BP (closest to TPA treatment time) _____ / _____ (80)
- 45. Pre-TPA treatment BP Time (__ : __) (81)
- 46. 1 hr post-TPA treatment BP (closest to 1-hour) _____ / _____ (82)
- 47. 1 hr post-TPA treatment BP Time (__ : __) (83)
- 48. 24 hr post-TPA treatment BP (closest to 24-hours) _____ / _____ (84)
- 49. 24 hr post-TPA treatment BP time (__ : __) (85)

STROKE SEVERITY INFORMATION

- 50. Last Documented pre-treatment NIHSS _____ none (86)
 - 51. Estimated pre-treatment NIHSS _____ (87)
- (use Estimated Pre-Treatment NIHSS scoring form and attach)

TPA ELIGIBILITY

- 52. Clinical diagnosis of Stroke True / False (88)
- 53. Stroke symptoms not clearing True / False (89)
- 54. Not minor symptoms True / False (90)
- 55. Symptoms not suggesting SAH True / False (91)
- 56. Time to TPA \leq 180 minutes True / False (92)

IF TIME TO TPA > 180 MINUTES, COMPLETE THE FOLLOWING

- a. Was this a known time deviation by the Attending MD? Yes / No (93)
- b. Was patient and/or family approval obtained? Yes / No (94)
- 57. No head trauma (3 mo) True / False (95)

- 58. No prior stroke (3 mo) True / False (96)
- 59. No MI (3 mo) True / False (97)
- 60. No significant GI or GU hemorrhage (21d) True / False (98)
- 61. No major surgery (14d) True / False (99)

IF FALSE, COMPLETE THE FOLLOWING

- a. Name of surgical procedure: _____ (100)
- b. Was this a known deviation by the Attending MD? Yes/ No (101)
- c. Was the patient/family approval obtained? Yes/ No (102)
- 62. No non-compressible arterial puncture (7d) True / False (103)
- 63. No prior ICH / SAH True / False (104)
- 64. BP not > 185 systolic or 110 diastolic True / False (105)
- 65. No evidence active bleeding or acute trauma (fracture) on exam True / False (106)
- 66. Not taking oral anticoagulant, or if taking, INR ≤1.7 True / False (107)
- 67. If on heparin, aPTT normal True / False (108)
- 68. Platelet count > 100k True / False (109)
- 69. Glucose > 50 mg/dl True / False (110)
- 70. No seizure True / False (111)

ED PRE-TREATMENT MEDICATION (list drug only, no dose information needed)

- (112) 71. PreTx Med 1 _____ none
- (113) 72. PreTx Med 2 _____ none
- (114) 73. PreTx Med 3 _____ none
- (115) 74. PreTx Med 4 _____ none
- (116) 75. PreTx Med 5 _____ none

ED PROCEDURES

- 76. Intubation Yes / No (117)
- 77. Foley Catheter Yes / No (118)
- 78. NG placement Yes / No (119)

TREATMENT

- 79. Intravenous thrombolysis Yes / No (120)

IF ANSWER = “YES”, complete the following for the intravenous medication ONLY

- a. Bolus dose _____ mg ND (121)
- b. Infusion dose _____ mg ND (122)
- c. Total dose(may be calculated) _____ mg ND (123)

80. Combination IV / IA thrombolysis Yes / No (124)

IF ANSWER = “YES”, complete the following for the intravenous medication ONLY

- a. Bolus dose _____ mg ND (125)
- b. Infusion dose _____ mg ND (126)
- c. Total dose may be calculated) _____ mg ND (127)

81. Intra-arterial thrombolysis Yes / No (128)

NEUROIMAGING (ALL PRE- OR POST-TREATMENT IMAGING DURING FIRST 10 DAYS OF INDEX HOSPITALIZATION)

Head CT Scans

Head CT #1

82. Was Head CT # 1 study performed? Yes / No (129)

IF ANSWER = “NO” SKIP TO NEXT NEUROIMAGING STUDY BELOW

83. Head CT # 1 Date (__ / __ / ____) (130)

84. Head CT # 1 Time (__ : __) (131)

85. Head CT # 1 Presence or possibility of intracranial hemorrhage Yes / No
(132)

86. Head CT # 1 Presence of intracranial lesion other than current/previous ischemic stroke Yes / No
(133)

IF ANSWER TO EITHER OF PREVIOUS TWO QUESTIONS = “YES” COMPLETE THE FOLLOWING:

- a. Copy of all CTs/MRIs in the first 10 days obtained? Yes / No
(134)
- b. Copy of original radiology interpretations of all CTs/MRIs obtained? Yes / No
(135)

Head CT #2

87. Was Head CT # 2 study performed? Yes / No (136)

IF ANSWER = “NO” SKIP TO NEXT NEUROIMAGING STUDY BELOW

88. Head CT # 2 date (__ / __ / ____) (137)

89. Head CT # 2 time (__ : __) (138)

90. Head CT # 2 Presence or possibility of intracranial hemorrhage Yes / No
(139)

91. Head CT # 2 Presence of intracranial lesion other than current or previous ischemic stroke Yes /
No (140)

IF ANSWER TO EITHER OF PREVIOUS TWO QUESTIONS = “YES” COMPLETE THE FOLLOWING:

- a. Copy of all CTs/MRIs in the first 10 days obtained? Yes / No
(141)
- b. Copy of original radiology interpretations of all CTs/MRIs obtained? Yes / No
(142)

Head CT #3

92. Was Head CT # 3 study performed? Yes / No (143)

IF ANSWER = “NO” SKIP TO NEXT NEUROIMAGING STUDY BELOW

- 93. Head CT # 3 date (__ / __ / ____) (144)
- 94. Head CT # 3 time (__ : __) (145)
- 95. Head CT # 3 Presence or possibility of intracranial hemorrhage Yes / No
(146)
- 96. Head CT # 3 Presence of intracranial lesion other than current or previous ischemic stroke Yes /
No (147)

IF ANSWER TO EITHER OF PREVIOUS TWO QUESTIONS = “YES” COMPLETE THE FOLLOWING:

- a. Copy of all CTs/MRIs in the first 10 days obtained? Yes / No
(148)
- b. Copy of original radiology interpretations of all CTs/MRIs obtained? Yes / No
(149)

Head CT # 4

97. Was Head Ct # 4 study performed? Yes / No (150)

IF ANSWER = “NO” SKIP TO NEXT NEUROIMAGING STUDY BELOW

- 98. Head CT # 4 date (__ / __ / ____) (151)
- 99. Head CT # 4 time (__ : __) (152)
- 100. Head CT # 4 Presence or possibility of intracranial hemorrhage Yes / No (153)
- 101. Head CT # 4 Presence of intracranial lesion other than current/previous ischemic stroke Yes /
No (154)

IF ANSWER TO EITHER OF PREVIOUS TWO QUESTIONS = “YES” COMPLETE THE FOLLOWING:

- a. Copy of all CTs/MRIs in the first 10 days obtained? Yes / No
(155)
- b. Copy of original radiology interpretations of all CTs/MRIs obtained? Yes / No
(156)

MRI Scanning

MRI of Brain #1

102. Was MRI # 1 study performed? Yes / No (157)

IF ANSWER = “NO” SKIP TO NEXT NEUROIMAGING STUDY BELOW

103. MRI # 1 Date (_ _ / _ _ / _ _ _ _) (158)
104. MRI # 1 Time (_ _ : _ _) (159)
105. MRI # 1 Presence or possibility of intracranial hemorrhage Yes / No (160)
106. MRI # 1 Presence of intracranial lesion other than current/previous ischemic stroke Yes / No
(161)

IF ANSWER TO EITHER OF PREVIOUS TWO QUESTIONS = “YES” COMPLETE THE FOLLOWING:

- a. Copy of all CTs/MRIs in the first 10 days obtained? Yes / No
(162)
- b. Copy of original radiology interpretations of all CTs/MRIs obtained? Yes / No
(163)
107. MRA of Brain (intracranial vessels) study completed? Yes / No
(164)

MRI of Brain # 2

108. Was MRI # 2 study performed? Yes / No (165)

IF ANSWER = “NO” SKIP TO NEXT NEUROIMAGING STUDY BELOW

109. MRI # 2 Date (_ _ / _ _ / _ _ _ _) (166)
110. MRI # 2 Time (_ _ : _ _) (167)
111. MRI # 2 Presence or possibility of intracranial hemorrhage Yes / No
(168)
112. MRI # 2 Presence of intracranial lesion other than current or previous ischemic stroke Yes / No
(169)

IF ANSWER TO EITHER OF PREVIOUS TWO QUESTIONS = “YES” COMPLETE THE FOLLOWING:

- a. Copy of all CTs/MRIs in the first 10 days obtained? Yes / No
(170)
- a. Copy of original radiology interpretations of all CTs/MRIs obtained? Yes / No
(171)
113. MRA of Brain (intracranial vessels) study completed? Yes / No
(172)

ADDITIONAL STUDIES

114. Carotid Ultrasound Yes / No (173)
115. Transthoracic Echo Yes / No (174)
116. Transesophageal Echo Yes / No (175)
117. CT Angiography Yes / No (176)

IF ANSWER = “YES” COMPLETE THE FOLLOWING:

- a. CT Angio Date (_ _ / _ _ / _ _ _ _) (177)
- b. CT Angio Time (_ _ : _ _) (178)

- c. CT Angio Presence or possibility of intracranial hemorrhage (179) Yes / No
- d. CT Angio Presence of intracranial lesion other than current/previous ischemic stroke (180) Yes / No

IF ANSWER TO EITHER OF PREVIOUS TWO QUESTIONS = "YES" COMPLETE THE FOLLOWING:

- i. Copy of CT angio obtained (181) Yes / No
- ii. Copy of original radiology interpretation of CT angio obtained* (182) Yes / No

118. CT with Xenon Yes / No (183)

IF ANSWER = "YES" COMPLETE THE FOLLOWING:

- a. CT Xenon Date (__ / __ / ____) (184)
- b. CT Xenon Time (__ : __) (185)
- c. CT Xenon Presence or possibility of intracranial hemorrhage (186) Yes / No
- d. CT Xenon Presence of intracranial lesion other than current or previous ischemic stroke (187) Yes/ No

IF ANSWER TO EITHER OF PREVIOUS TWO QUESTIONS = "YES" COMPLETE THE FOLLOWING:

- i. Copy of all CTs/MRIs in first 10 days obtained (188) Yes / No
- ii. Copy of original radiology interpretations of all CTs/MRIs obtained (189) Yes / No

119. EEG Yes / No (190)

120. MRA of neck (extracranial vessels) Yes/ No (191)

121. Angiography Yes / No (192)

If "YES" then answer the following:

- a. Angio Date (__ / __ / ____) (193)
- b. Angio Findings: "normal"; "abnormal" (194)
(if other than "normal", copy angio report)

Otherwise, continue

TPA TREATMENT COMPLICATIONS

- 122. CNS Hemorrhage Yes / No (195)
- 123. CNS Hemorrhage Time "≤36 hours from treatment"; "> 36 hours from treatment" (196)
- 124. CNS Hemorrhage Clinical Type "Symptomatic"; "Asymptomatic" (197)
- 125. Major Systemic Hemorrhage Yes / No (198)

INPATIENT CARE

- 126. No anti-platelet drug use for 24 hours post-treatment (199) True / False
- 127. No anti-coagulant drug use within 24 hours post-treatment (200) True / False
- 128. Blood pressure maintained below 185 systolic and 110 diastolic for 24 hours post-treatment* (201) True / False/
Unable to assess (201)

DISCHARGE INFORMATION

- 129. Discharge Date (__ / __ / ____) (202)
- 130. Discharged to: "Home";"Rehabilitation Facility";"Nursing Home or Assisted Living";"Other Acute Care Hospital";"Death" (203)
- 131. MRS at Discharge 0; 1; 2; 3; 4; 5; 6 (204)
- 132. Outcome at Discharge vs. ED admission "Normal";"Improved";"Unchanged";"Worse";"Death" (205)
- 133. Discharge Dx #1 (narrative) _____ none (206)
- 134. Discharge Dx #2 _____ none (207)
- 135. Discharge Dx #3 _____ none (208)
- 136. Discharge Dx #4 _____ none (209)
- 137. Discharge Dx #5 _____ none (210)
- 138. Discharge Dx #6 _____ none (211)
- 139. ICD-9 Code #1 _____ (212)
- 140. ICD-9 Code #2 _____ (213)
- 141. ICD-9 Code #3 _____ (214)
- 142. ICD-9 Code #4 _____ (215)
- 143. ICD-9 Code #5 _____ (216)
- 144. Comments: (217)

DATABASE MAINTENANCE

144. COMPLETED FIRST INDIVIDUAL CHART DATA ENTRY _____	Yes / No	INITIALS
145. COMPLETED SECOND INDIVIDUAL CHART DATA ENTRY _____	Yes / No	INITIALS
146. INDIVIDUAL CHART DATA ENTRY VERIFICATION COMPLETED _____	Yes / No	INITIALS
147. INDIVIDUAL PATIENT DATA VERIFICATION COMPLETED _____	Yes / No	INITIALS
148. FINAL DATABASE ENTRY COMPLETED _____	Yes / No	