

Letters

RESEARCH LETTER

Testing the Presumption of Consent to Emergency Treatment for Acute Ischemic Stroke

In life-threatening emergencies involving incapacitated patients without surrogates, clinicians may intervene without obtaining informed consent, applying the presumption that reasonable people would consent to treatment in such circumstances. Whether this rationale applies to the treatment of acute ischemic stroke with intravenous thrombolysis is controversial because this intervention improves functional outcomes but is not life preserving.¹

Nonetheless, the presumption of consent to thrombolysis for ischemic stroke has recently been endorsed by profes-

sional societies.^{2,3} Previous empirical studies of preferences for emergency treatment have been limited to surveys of convenience samples that were not demographically representative. We evaluated the presumption of consent by comparing preferences for treatment of acute ischemic stroke with thrombolysis and treatment of sudden cardiac arrest with cardiopulmonary resuscitation (CPR; in which the presumption of consent is generally accepted) in a nationally representative sample of older US adults.

Methods | This experiment was conducted between February 19 and March 3, 2013, as part of a broader study of treatment preferences using the GfK KnowledgePanel, a probability-based panel designed to be representative of the US population.⁴

Table 1. Demographic and Health Predictors of Treatment Preferences for Ischemic Stroke Among Adults Aged 50 Years or Older (n=545)

	Want Thrombolysis		Odds Ratio (95% CI)	
	Unweighted Count, No.	Weighted % (95% CI) ^a	Univariable ^b	Multivariable ^c
Sex				
Male (n = 260)	211	84.5 (78.3-89.2)	1 [Reference]	1 [Reference]
Female (n = 285)	208	69.2 (61.6-75.9)	0.41 (0.24-0.70)	0.43 (0.24-0.77)
Age per decade (median, 60-69 y)			1.29 (0.95-1.75)	
Race/ethnicity				
White, non-Hispanic (n = 433)	341	78.2 (72.5-83.0)	1 [Reference]	1 [Reference]
Black, non-Hispanic (n = 51)	30	53.9 (36.8-70.1)	0.33 (0.15-0.70)	0.39 (0.14-1.06)
Other, non-Hispanic (n = 14)	11	92.5 (70.8-98.4)	3.42 (0.66-17.83)	4.04 (0.55-29.77)
Hispanic (n = 33)	26	79.7 (58.8-91.5)	1.09 (0.38-3.15)	0.82 (0.28-2.41)
Mixed, non-Hispanic (n = 14)	11	48.2 (18.5-79.2)	0.26 (0.06-1.10)	0.34 (0.08-1.46)
Marital status				
Married (n = 346)	273	81.2 (75.2-86.0)	1 [Reference]	1 [Reference]
Widowed (n = 45)	36	82.6 (68.1-91.4)	1.10 (0.46-2.66)	1.96 (0.63-6.09)
Divorced (n = 76)	51	54.0 (39.4-67.9)	0.27 (0.14-0.54)	0.43 (0.20-0.90)
Never married (n = 44)	30	61.3 (41.0-78.3)	0.37 (0.15-0.90)	0.42 (0.16-1.10)
Other (n = 34)	29	84.8 (66.3-94.0)	1.29 (0.43-3.88)	1.74 (0.55-5.48)
Annual household income per \$25 000 (median, \$50 000-\$74 999)			1.32 (1.11-1.58)	
Employment status				
Employed (n = 233)	180	77.0 (69.1-83.4)	1 [Reference]	
Retired (n = 216)	176	79.4 (71.1-85.8)	1.15 (0.63-2.11)	
Disabled (n = 42)	25	60.0 (40.1-77.0)	0.45 (0.18-1.10)	
Other or unemployed (n = 54)	38	72.9 (56.5-84.8)	0.80 (0.35-1.84)	
Educational attainment per category ^d			1.78 (1.31-2.44)	1.83 (1.35-2.48)
Overall physical health per category ^e			1.23 (0.92-1.63)	
Previous diagnosis				
Myocardial infarction (n = 26)	23	92.0 (70.2-98.2)	3.70 (0.74-18.39)	3.77 (0.61-23.08)
Stroke (n = 16)	11	56.1 (26.0-82.4)	0.38 (0.10-1.44)	0.46 (0.16-1.31)
Regular religious attendance (n = 219)	173	78.3 (70.3-84.6)	1.23 (0.72-2.10)	
Has health care advance directive (n = 221)	186	83.6 (76.3-89.0)	2.05 (1.17-3.60)	

^a Weighted to represent the total population of US adults aged 50 years or older on the basis of the US Current Population Survey.

^b Calculated with simple logistic regression. An odds ratio of greater than 1 indicates a greater likelihood of wanting emergency treatment, whereas an odds ratio of less than 1 indicates a lower likelihood of wanting treatment.

^c Multivariable logistic regression model generated using backward stepwise selection at a *P* value threshold of .20.

^d Included as an ordinal predictor (<high school, n = 38; completed high school, n = 165; some college, n = 156; ≥bachelor's degree, n = 186) after testing for linearity.

^e Included as an ordinal predictor (poor, n = 9; fair, n = 94; good, n = 176; very good, n = 211; excellent, n = 50) after testing for linearity.

Table 2. Demographic and Health Predictors of Treatment Preferences for Cardiac Arrest Among Adults Aged 50 Years or Older (n=555)

	Want CPR		Odds Ratio (95% CI)	
	Unweighted Count, No.	Weighted % (95% CI) ^a	Univariable ^b	Multivariable ^c
Sex				
Male (n = 257)	201	77.7 (70.2-83.8)	1 [Reference]	
Female (n = 298)	221	74.4 (67.8-80.1)	0.83 (0.50-1.40)	
Age per decade (median, 60-69 y)			0.69 (0.53-0.90)	0.82 (0.62-1.09)
Race/ethnicity				
White, non-Hispanic (n = 442)	332	74.7 (69.2-79.4)	1 [Reference]	
Black, non-Hispanic (n = 44)	35	81.4 (60.6-92.5)	1.48 (0.50-4.34)	
Other, non-Hispanic (n = 14)	9	60.9 (27.3-86.6)	0.53 (0.12-2.24)	
Hispanic (n = 37)	30	85.6 (69.3-93.9)	2.02 (0.74-5.50)	
Mixed, non-Hispanic (n = 18)	16	84.3 (47.2-97.0)	1.82 (0.30-11.18)	
Marital status				
Married (n = 367)	277	75.6 (69.5-80.7)	1 [Reference]	
Widowed (n = 47)	34	63.2 (44.4-78.7)	0.55 (0.24-1.26)	0.81 (0.36-1.85)
Divorced (n = 66)	50	80.8 (67.2-89.6)	1.36 (0.62-2.96)	1.20 (0.55-2.54)
Never married (n = 47)	37	78.6 (62.7-88.9)	1.19 (0.51-2.74)	0.97 (0.40-2.34)
Other (n = 28)	24	91.3 (74.9-97.4)	3.40 (0.93-12.45)	2.70 (0.71-10.03)
Annual household income per \$25 000 (median, \$50 000-\$74 999)			1.06 (0.91-1.22)	
Employment status				
Employed (n = 236)	185	80.1 (73.0-85.7)	1 [Reference]	
Retired (n = 211)	151	69.9 (61.6-77.2)	0.58 (0.33-1.00)	
Disabled (n = 53)	41	76.7 (57.9-88.7)	0.82 (0.31-2.13)	
Other or unemployed (n = 55)	45	82.2 (65.7-91.8)	1.15 (0.44-3.03)	
Educational attainment per category ^d			1.03 (0.81-1.31)	
Overall physical health per category ^e			1.38 (1.05-1.84)	1.43 (1.08-1.90)
Previous diagnosis				
Myocardial infarction (n = 28)	21	70.2 (44.8-87.2)	0.72 (0.24-2.15)	
Stroke (n = 13)	11	93.9 (70.8-99.0)	4.91 (0.77-31.50)	8.20 (1.03-65.29)
Regular religious attendance (n = 210)	157	74.2 (66.1-80.9)	0.87 (0.52-1.44)	
Has health care advance directive (n = 220)	152	67.0 (58.7-74.4)	0.43 (0.26-0.72)	0.47 (0.28-0.79)

^a Weighted to represent the total population of US adults aged 50 years or older on the basis of the US Current Population Survey.

^b Calculated with simple logistic regression. An odds ratio of greater than 1 indicates a greater likelihood of wanting emergency treatment, whereas an odds ratio of less than 1 indicates a lower likelihood of wanting treatment.

^c Multivariable logistic regression model generated using backward stepwise selection at a *P* value threshold of .20.

^d Included as an ordinal predictor (<high school, n = 55; completed high school, n = 173; some college, n = 157; ≥bachelor's degree, n = 170) after testing for linearity.

^e Included as an ordinal predictor (poor, n = 11; fair, n = 88; good, n = 205; very good, n = 207; excellent, n = 34) after testing for linearity.

Adults aged 50 years or older were randomly assigned to read 1 of 2 scenarios: in one they experienced a severe acute ischemic stroke and were brought to a hospital, and in the other they experienced an out-of-hospital cardiac arrest and were attended to by paramedics.

The stroke scenario included a graphical depiction of probabilistic risks and benefits of treatment with thrombolysis.⁵ The cardiac arrest scenario included a similar depiction of probabilistic outcomes after paramedic-initiated CPR.⁶ All participants were then asked whether they would want the treatment described, using a 4-point Likert scale (definitely yes, probably yes, probably no, or definitely no).

The institutional review board at the University of California, San Francisco, approved this study. All participants provided informed consent.

Responses were weighted to match the US population aged 50 years or older. Likert-scaled treatment preferences were dichotomized to yes or no for analysis. The influence of the clinical scenario (ischemic stroke vs cardiac arrest) on treatment preference was assessed using logistic regression.

In secondary analyses, we evaluated demographic and health predictors of treatment preference in both stroke and cardiac arrest using logistic regression. Exploratory multivariable logistic regression models were generated using backward stepwise selection at a *P* value threshold of .20. Statistical analyses were conducted using Stata version 12.1 (StataCorp). Two-tailed *P* < .05 was considered significant.

Results | In the broader treatment preferences study, 2154 (63.0%) of 3418 fielded questionnaires were completed; half (n = 1100) of these participants were randomized to the 2 study conditions in the present experiment. Participants were demographically representative of US adults aged 50 years or older, with no significant differences between conditions (Table 1 and Table 2).

In population-weighted analyses, 76.2% (95% CI, 71.2%-80.6%) of older adults (419 of 545 participants) wanted thrombolysis for acute ischemic stroke, whereas 75.9% (95% CI, 71.1%-80.2%) of older adults (422 of 555 participants)

wanted CPR for sudden cardiac arrest ($P = .93$). In multivariable models, female sex, divorced marital status, and lower educational attainment predicted refusal of thrombolysis (Table 1). Poorer physical health, previous stroke, and possession of a health care advance directive predicted refusal of CPR (Table 2).

Discussion | When an incapacitated older patient's treatment preferences are unknown and surrogate decision makers are unavailable, there are equally strong empirical grounds for presuming individual consent to thrombolysis for stroke as for presuming individual consent to CPR. Because the presumption of consent is generally accepted for CPR, this finding provides empirical support for policy positions recently taken by professional societies that favor the use of thrombolysis for stroke in emergency circumstances under a presumption of consent.

Even though such emergency presumptions are supported by the treatment preferences of most older adults, it is noteworthy that nearly one-quarter of older adults would not want either intervention. Also, our experiment was only designed to address the empirical basis of the ethical and legal presumption of consent. Policies regarding the applicability of this presumption must also be informed by normative considerations such as the role of clinical judgment and the values of life and independence.

Winston Chiong, MD, PhD
 Anthony S. Kim, MD, MAS
 Ivy A. Huang
 Nita A. Farahany, PhD, JD
 S. Andrew Josephson, MD

Author Affiliations: Department of Neurology, University of California, San Francisco (Chiong, Kim, Huang, Josephson); School of Law, Duke University (Farahany).

Corresponding Author: Winston Chiong, MD, PhD, University of California, 675 Nelson Rising Ln, Ste 190, San Francisco, CA 94158 (winston.chiong@ucsf.edu).

Author Contributions: Dr Chiong had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Chiong, Kim, Farahany, Josephson.

Acquisition, analysis, or interpretation of data: Chiong, Kim, Huang.

Drafting of the manuscript: Chiong, Huang.

Critical revision of the manuscript for important intellectual content: Chiong, Kim, Farahany, Josephson.

Statistical analysis: Chiong, Kim.

Obtained funding: Chiong.

Study supervision: Josephson.

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Kim reported receiving grants from SanBio Inc outside the submitted work. No other disclosures were reported.

Funding/Support: This work was supported by grant K23AGO43553 from the National Institute on Aging, grant KL2TR000143 from the National Center for Advancing Translational Sciences, and by funding through the American Brain Foundation Clinical Research Training Fellowship Program. Data collection was provided by Time-sharing Experiments in the Social Sciences with National Science Foundation grant 0818839 (Jeremy Freese, PhD, and James Druckman, PhD, principal investigators). Time-sharing Experiments in the Social Sciences provided data collection using the GfK KnowledgePanel and survey weights for matching participants' responses to the US Current Population Survey.

Role of the Sponsors: The sponsors had no role in the design of the study; analysis and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: We gratefully acknowledge the technical contributions of Carolyn Chu, Stefan Subias, and other staff of GfK; and the assistance of Amy J. Markowitz, JD, and John M. Neuhaus, PhD (both with the University of California, San Francisco), in drafting the manuscript. None received compensation for their contributions.

1. Rubin EB, Bernat JL. Consent issues in neurology. *Neurol Clin*. 2010;28(2):459-473.

2. American Academy of Neurology. American Academy of Neurology policy on consent issues for the administration of IV tPA. http://www.aan.com/uploadedFiles/Website_Library_Assets/Documents/6.Public_Policy/1.Stay_Informed/2.Position_Statements/3.PDFs_of_all_Position_Statements/IV.pdf. Accessed August 28, 2013.

3. Jauch EC, Saver JL, Adams HP Jr, et al; American Heart Association Stroke Council; Council on Cardiovascular Nursing; Council on Peripheral Vascular Disease; Council on Clinical Cardiology. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2013;44(3):870-947.

4. Callegaro M, DiSogra C. Computing response metrics for online panels. *Public Opin Q*. 2008;72(5):1008-1032.

5. Gadhia J, Starkman S, Ovbiagele B, Ali L, Liebeskind D, Saver JL. Assessment and improvement of figures to visually convey benefit and risk of stroke thrombolysis. *Stroke*. 2010;41(2):300-306.

6. McNally B, Robb R, Mehta M, et al; Centers for Disease Control and Prevention. Out-of-hospital cardiac arrest surveillance—Cardiac Arrest Registry to Enhance Survival (CARES), United States, October 1, 2005–December 31, 2010. *MMWR Surveill Summ*. 2011;60(8):1-19.

COMMENT & RESPONSE

Financial Relationships Between Medical Communication Companies and Industry

To the Editor I believe Dr Rothman and colleagues¹ misrepresented the Accreditation Council for Continuing Medical Education (ACCME) system and the rules safeguarding continuing medical education (CME) from industry influence. The authors asserted that the organizations in their report are all ACCME accredited and that the organizations also provide marketing services to industry, including “prelaunch and branding campaigns.” I do not believe these assertions are true, for the following reasons.

First, 2 of the 18 organizations analyzed in Table 3 (Clinical Care Options and Institute for Medical Education and Research) were not accredited by the ACCME in 2010. Second, organizations that provide marketing for industry are not eligible for ACCME accreditation.² Third, the authors implied that organizations involved in industry marketing collaborate with ACCME-accredited providers to develop accredited CME. The ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities prohibit such arrangements. No organization that is involved in marketing products can control the content of accredited CME.²

In addition, the authors stated that “Industry contracts with [accredited providers] are not publicly available.” The ACCME, in fulfillment of its public interest purpose and mission, requires transparency from accredited providers regarding commercial support. I believe it is important that every written agreement for every commercial support grant in all