Inability to Consent Does Not Diminish the Desirability of Stroke Thrombolysis

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Objective: Some have argued that physicians should not presume to make thrombolysis decisions for incapacitated patients with acute ischemic stroke because the risks and benefits of thrombolysis involve deeply personal values. We evaluated the influence of the inability to consent and of personal health-related values on older adults' emergency treatment preferences for both ischemic stroke and cardiac arrest.
Methods: A total of 2,154 US adults age $\geq$50 years read vignettes in which they had either suffered an acute ischemic stroke and could be treated with thrombolysis, or had suffered a sudden cardiac arrest and could be treated with cardiopulmonary resuscitation. Participants were then asked (1) whether they would want the intervention, or (2) whether they would want to be given the intervention even if their informed consent could not be obtained. We elicited health-related values as predictors of these judgments.
Results: Older adults were as likely to want stroke thrombolysis when unable to consent (78.1%) as when asked directly (76.2%), whereas older adults were more likely to want cardiopulmonary resuscitation when unable to consent (83.6% compared to 75.9%). Greater confidence in the medical system and reliance on statistical information in decision making were both associated with desiring thrombolysis.
Interpretation: Older adults regard thrombolysis no less favorably when considering a situation in which they are unable to consent. These findings provide empirical support for recent professional society recommendations to treat ischemic stroke with thrombolysis in appropriate emergency circumstances under a presumption of consent.
ANN NEUROL 2014;00:000–000

Thrombolysis with intravenous recombinant tissue plasminogen activator (t-PA) within 4.5 hours of ischemic stroke onset improves functional outcomes,[1,2] yet fewer than 5% of patients with acute ischemic stroke receive this intervention.[3] Although many patients are ineligible for thrombolysis because they do not present for care within the therapeutic time window, only 25 to 52% of those who are eligible receive t-PA.[4–7] For these patients, an additional barrier to thrombolysis is that many are unable to consent to treatment because of aphasia or other neurologic deficits,[8] making it ethically controversial to administer thrombolysis in these patients.

The American Academy of Neurology[9] and the American Heart Association/American Stroke Association[10] have recently endorsed the use of thrombolysis in incapacitated patients without surrogate decision makers, according to the rationale that reasonable people would consent to treatment if they could be asked. The ethical and legal presumption of consent is commonly applied for life-saving emergency treatments such as cardiopulmonary resuscitation (CPR).[11–15] In contrast, thrombolysis does not reduce early mortality. Instead, it improves neurological outcomes but also carries an increased risk of intracranial bleeding that may lead to neurological worsening or death. Some have argued that weighing the potential benefits and harms of this therapy involves deeply personal patient values, such that physicians cannot make this decision on behalf of patients without their consent or the input of an available surrogate.[16,17]

We have previously reported that the proportion of older adults who would want treatment with thrombolysis for acute ischemic stroke is comparable to the proportion

View this article online at wileyonlinelibrary.com. DOI: 10.1002/ana.24209

Received May 18, 2014, and in revised form Jun 27, 2014. Accepted for publication Jun 27, 2014.

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who would want treatment with CPR for sudden cardiac arrest.[18] However, given the personal nature of the health-related values involved in such decisions, it is valuable to distinguish the question of whether people would personally choose a treatment from the question of whether they would want health professionals to administer that treatment to them when they are unable to provide informed consent. Because most people want to be involved in medical treatment decisions,[19–22] some who would choose an intervention might nonetheless object to being treated when they cannot provide consent.

To address this issue, we examined older adults' treatment preferences for acute ischemic stroke and sudden cardiac arrest under 2 conditions. In the first, participants were asked if they would want the treatment described, whereas in the second participants were asked if they would want to be given this treatment even though their informed consent could not be obtained. We hypothesized that inability to consent would diminish the desirability of thrombolysis for acute ischemic stroke, but would not diminish the desirability of CPR for sudden cardiac arrest, a scenario in which emergency treatment in the absence of consent is generally accepted. To characterize how these preferences are influenced by personal health-related values, we also assessed participants' attitudes about patient-centered versus physician-centered medical decision making, dependence, longevity, confidence in the medical system, and reliance on statistical information as potential predictors of preferences for thrombolysis or CPR.

Patients and Methods

Study Participants

The study was conducted on the Time-Sharing Experiments in the Social Sciences platform, utilizing the Web-enabled GfK (Nuremberg, Germany) KnowledgePanel, a probability-based panel designed to be representative of the US population.[23] Before 2009, households were selected for this panel using random-digit dialing based on a sample frame of US residential landline telephone service; after 2009, a residential address-based sampling frame was used to account for the growing number of mobile phone–only households. Households that were selected for the panel but lacked Internet access were provided with a computer and Internet connection. Between February 19 and March 3, 2013, 3,418 online questionnaires were fielded to US adults aged 50 years and older.

Experimental Design and Study Oversight

To examine the influence of the inability to consent on emergency treatment preferences for stroke and cardiac arrest, we designed a population-based survey experiment. This study design has been recently developed in the social sciences and combines the empirical rigor of laboratory-based psychological methods with the generalizability of population-based survey methods.[24] In population-based survey experiments, investigators randomly assign different conditions to subjects that are sampled to represent a target population of interest.

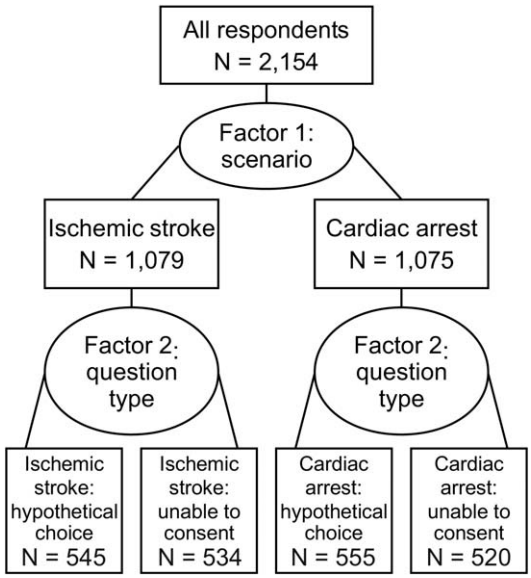

FIGURE 1: Study design. US adults aged 50 years or older were randomly assigned to read 1 of 4 vignettes according to a 2 × 2 fully crossed between-subjects factorial design.

In our study, older US adults were assigned to read 1 of 4 vignettes, according to a randomized 2 × 2 fully crossed, between-subjects factorial design (Fig 1). Half were presented a scenario in which they had suffered a severe acute ischemic stroke and were quickly brought to a hospital, and the other half were presented a scenario in which they had suffered an out-of-hospital cardiac arrest and were quickly attended by paramedics. Ischemic stroke vignettes included data on probabilistic risks and benefits of treatment with thrombolysis as well as a graphical representation of these data from a decision aid used to guide informed consent discussions.[25] Because randomized clinical trial data do not exist for risks and benefits of CPR, the cardiac arrest vignettes included data on probabilistic outcomes after paramedic-initiated CPR[26] using a similar graphical tool, designed under the assumption that the mortality of sudden cardiac arrest without treatment is 100%. In each of these clinical scenarios, half of the participants were then asked to make a hypothetical choice using a 4-point Likert scale (definitely yes/probably yes/probably no/definitely no) with the prompt, "Would you want treatment with [this medicine]/[CPR] for your condition?" The other half were asked specifically whether they would want to be treated if informed consent and surrogate input were unavailable, using the same 4-point Likert scale with the prompt, "Imagine that the [doctors]/[paramedics] cannot communicate with you because of your [stroke]/[heart attack], and also cannot find your family or friends to ask them whether you would want this treatment. Even though the [doctors]/[paramedics] are not able to obtain your consent, would you want them to treat you with [this medicine]/[CPR]?" Personal health-related values regarding

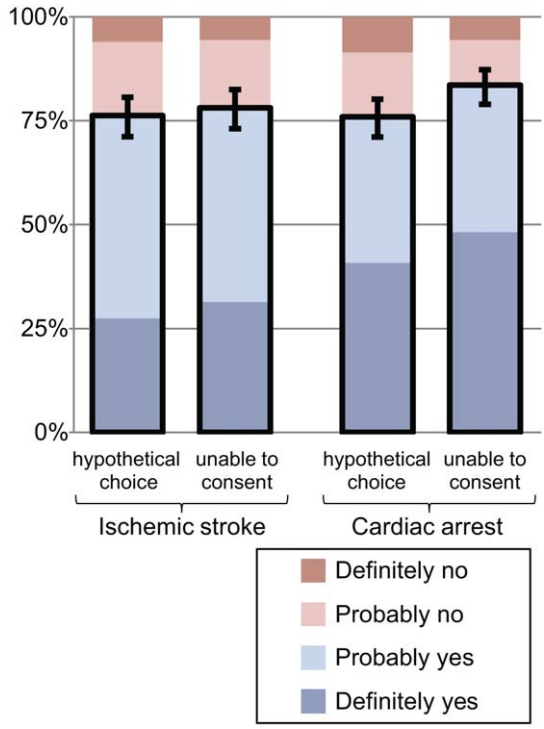

FIGURE 2: Emergency treatment preferences, by condition. Black outlines and error bars represent the dichotomized treatment preference (whether the intervention was desired), whereas shaded areas show the Likert-scaled intensity of these preferences. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

medical decision making,[22] disability and longevity,[19] confidence in the medical system, and reliance on statistical information in decision making were elicited using a 6-point Likert scale. The survey vignettes with associated graphics and questions, as well as the complete study data set, are freely available at www.tessexperiments.org/data/chiong300.html.

The institutional review board at the University of California, San Francisco approved this study. Participants provided informed consent before they were presented with the study instrument.

Statistical Analysis

Questionnaire responses were weighted to match the US population aged 50 years and older based on the United States Current Population Survey using a 3-step strategy to offset known selection deviations in panel recruitment, other sources of sampling error due to recruitment methods and panel attrition, and study-specific factors such as nonresponse and undersampling or oversampling resulting from the study-specific sample design. Data on participants' demographic characteristics were obtained from previous KnowledgePanel surveys. Likert-scaled treatment preferences were dichotomized to yes/no for analysis (the full scale is retained for illustrative purposes in Fig 2), and Likert-scaled measures of personal health-related values were dichotomized to agree/disagree. For the primary analysis, the influence of an inability to consent on preferences for thrombolysis and CPR was assessed with logistic regression; we subsequently tested for interactions between scenario (stroke or cardiac arrest) and the inability to consent regarding treatment preferences using bivariate logistic regression. In secondary analyses, we evaluated the influence of personal health-related values, the inability to consent, and interactions between health-related values and the inability to consent regarding treatment preferences for thrombolysis and CPR using bivariate logistic regression models that included responses from both the hypothetical choice and inability to consent conditions. All statistical analyses were conducted using Stata 12.1 (StataCorp, College Station, TX); a 2-tailed p value of <0.05 was considered significant.

Results

Characteristics of the Participants

Of 3,418 fielded questionnaires, 2,154 (63.0%) were completed. Respondents were demographically representative of US adults age 50 years and older, and there were no significant demographic differences across the 4 conditions (Table 1).

Influence of Inability to Consent on Emergency Treatment Preferences

Contrary to our hypothesis, older adults were no less likely to desire thrombolysis when unable to consent (78.1%) than when asked directly (76.2%; odds ratio [OR] = 1.1, 95% confidence interval [CI] = 0.76–1.6, $p = 0.57$). Older adults were significantly more likely to want treatment with CPR when unable to consent (83.6% vs 75.9%; OR = 1.6, 95% CI = 1.1–2.4, $p = 0.02$). There was a trend toward a qualitative interaction between clinical scenario (stroke or cardiac arrest) and the inability to consent on treatment preferences; more older adults desired thrombolysis than CPR when making a hypothetical personal choice, but more older adults desired CPR than thrombolysis if unable to consent (see Fig 2; $p = 0.18$).

The influence of inability to consent on treatment preferences for both emergency treatments was generally consistent across demographic subgroups (Fig 3). One exception was the influence of inability to consent on preferences for thrombolysis within subgroups defined by marital status. The inability to consent made thrombolysis less desirable for widowed older adults, but more desirable for divorced older adults.

Across educational subgroups, the increased desirability of thrombolysis in the absence of consent was most pronounced among older adults who did not complete high school. We have previously reported that older adults with lower educational attainment were less likely

TABLE 1. Demographic Characteristics of Study Population, by Condition[a]

Characteristic	Ischemic Stroke: Hypothetical Choice, n = 545	Ischemic Stroke: Unable to Consent, n = 534	Cardiac Arrest: Hypothetical Choice, n = 555	Cardiac Arrest: Unable to Consent, n = 520
Female gender, % (No.)	53.3 (285)	53.8 (286)	53.6 (298)	52.8 (275)
Age, % (No.)				
50–59 years	41.6 (243)	41.1 (221)	41.5 (244)	42.2 (218)
60–69 years	31.1 (179)	31.1 (200)	31.4 (196)	31.3 (173)
70–79 years	22.3 (101)	20.7 (89)	20.8 (91)	19.7 (101)
≥80 years	5.1 (22)	7.1 (24)	6.3 (24)	6.9 (28)
Race or ethnicity, % (No.)				
White, non-Hispanic	75.0 (433)	75.8 (415)	76.2 (442)	75.8 (412)
Black, non-Hispanic	10.2 (51)	10.2 (54)	10.0 (44)	10.3 (52)
Other, non-Hispanic	4.8 (14)	5.0 (14)	3.6 (14)	4.9 (13)
Hispanic	9.1 (33)	8.4 (35)	9.4 (37)	8.2 (31)
Mixed, non-Hispanic	1.0 (14)	0.7 (16)	0.8 (18)	0.8 (12)
Marital status, % (No.)				
Married	60.5 (346)	58.9 (336)	59.4 (367)	58.1 (325)
Widowed	10.6 (45)	10.1 (50)	11.8 (47)	7.1 (35)
Divorced	13.3 (76)	15.3 (81)	13.2 (66)	18.2 (90)
Never married	8.9 (44)	8.0 (34)	10.1 (47)	11.0 (45)
Other	6.7 (34)	7.8 (33)	5.5 (28)	5.6 (25)
Annual household income, % (No.)				
<$25,000	21.9 (98)	21.9 (99)	22.3 (86)	21.8 (103)
$25,000–$49,999	24.5 (122)	23.9 (118)	24.6 (153)	24.8 (116)
$50,000–$74,999	17.4 (111)	17.6 (119)	17.6 (105)	17.6 (101)
$75,000–$99,999	12.1 (60)	15.2 (78)	13.6 (73)	17.5 (86)
$100,000–$124,999	9.7 (59)	9.2 (48)	10.7 (67)	7.5 (53)
≥$125,000	14.5 (95)	12.2 (72)	11.3 (71)	10.9 (61)
Employment status, % (No.)				
Employed	38.0 (233)	44.3 (252)	39.2 (236)	41.0 (221)
Retired	43.4 (216)	38.3 (195)	40.2 (211)	40.6 (210)
Disabled	8.6 (42)	7.1 (38)	9.8 (53)	11.0 (52)
Other unemployed	10.0 (54)	10.4 (49)	10.9 (55)	7.4 (37)
Highest educational attainment, % (No.)				
Less than high school	13.1 (38)	12.4 (40)	11.7 (55)	12.2 (34)
Completed high school	33.0 (165)	33.1 (176)	33.5 (173)	33.4 (172)
Some college	25.6 (156)	25.8 (146)	26.0 (157)	25.7 (146)
Bachelor degree or higher	28.3 (186)	28.8 (172)	28.9 (170)	28.7 (168)

TABLE 1: Continued

Characteristic	Ischemic Stroke: Hypothetical Choice, n = 545	Ischemic Stroke: Unable to Consent, n = 534	Cardiac Arrest: Hypothetical Choice, n = 555	Cardiac Arrest: Unable to Consent, n = 520
Census region, % (No.)				
Northeast	18.8 (111)	18.9 (100)	19.0 (110)	18.9 (101)
Midwest	22.2 (139)	21.3 (130)	22.5 (127)	22.3 (130)
South	37.2 (182)	37.4 (193)	35.8 (194)	36.7 (182)
West	21.9 (113)	22.4 (111)	22.8 (124)	22.1 (107)
Religious attendance, % (No.)				
Never	17.5 (99)	19.7 (107)	20.6 (106)	20.6 (99)
Occasionally	40.0 (227)	42.6 (232)	44.5 (238)	46.2 (224)
Once a week or more	42.6 (219)	37.7 (194)	34.9 (210)	33.3 (194)
Overall physical health, % (No.)				
Excellent	8.2 (50)	8.3 (43)	6.7 (34)	6.5 (37)
Very good	36.5 (211)	35.5 (200)	34.7 (207)	36.7 (199)
Good	31.9 (176)	41.3 (207)	38.2 (205)	37.9 (186)
Fair	21.1 (94)	12.3 (67)	17.9 (88)	16.3 (81)
Poor	2.3 (9)	2.6 (15)	2.4 (11)	2.6 (10)
Other characteristics, % (No.)				
Previous diagnosis of heart attack	6.2 (26)	6.4 (34)	5.1 (28)	8.1 (33)
Previous diagnosis of stroke	3.6 (16)	2.3 (14)	2.6 (13)	3.1 (16)
Has healthcare advance directive	39.4 (221)	37.9 (211)	40.7 (220)	44.5 (232)

[a]Reported percentages are weighted to represent the total population of US adults age 50 years or older on the basis of the United States Current Population Survey. Raw counts (reported in parentheses) indicate the actual number of study participants prior to weighting.

to want thrombolysis[18]; this finding persists even when patients are unable to consent (with educational attainment treated as ordinal predictor after testing for linearity; OR = 1.4, 95% CI 1.1–1.9, $p = 0.012$), despite the finding that older adults in the lowest educational attainment group viewed thrombolysis more favorably when unable to consent than when making a hypothetical personal choice.

Associations with Personal Health-Related Values

Consistent with earlier population-based research on patient preferences in medical decision making,[22,27] an overwhelming majority of older adults want their physicians to present them with treatment options (Table 2), but smaller majorities also prefer to rely on their physicians' knowledge and decisions. A majority of older adults also fear becoming dependent on others for their daily needs, although a majority would also want to live a long life regardless of health and independence. Confidence in the medical system was high, although reliance on statistical information in decision making was low (see Table 2). Generally these measures were not strongly correlated with one another, except for measures of preferring to rely on physician knowledge and decisions (phi coefficient = 0.58); weaker positive associations were also observed between confidence in the medical system and relying on physician knowledge (phi = 0.32), wanting to be presented with options (phi = 0.27), and relying on physician decisions (phi = 0.29). Comparable rho coefficients were also obtained using Spearman rank correlations of the original nondichotomized Likert-scaled responses.

Older adults who are confident in the medical system and who rely on statistical information in decision making

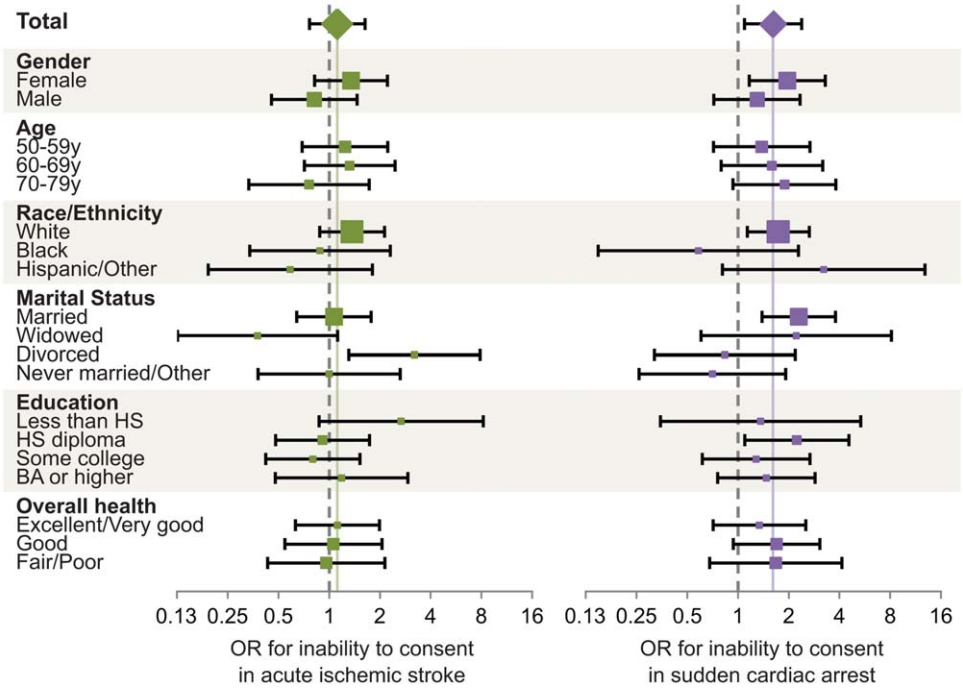

FIGURE 3: Influence of an inability to consent on the desirability of treatment, by demographic. BA = bachelor degree; HS = high school; OR = odds ratio. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

were more likely to want treatment with thrombolysis. Older adults who desire longevity and who do not fear loss of independence were more likely to want CPR (see Table 2). Personal health-related values did not significantly modify the influence of the inability to consent on treatment preferences for thrombolysis or CPR. (Stratified ORs and interaction measures are displayed in Supplementary Tables 1–3 for personal health-related values with $p \leq 0.20$ for interaction with the inability to consent.)

Discussion

In a demographically representative, national population-based survey experiment, the inability to consent to treatment did not make older adults less likely to want emergency thrombolysis for acute ischemic stroke. Our study also reveals associations between older adults' preferences for emergency treatment and their personal health-related values; also of note, our respondents' elicited values were broadly consistent with measures reported in earlier population-based studies.[22,27] Although earlier normative work on the presumption of consent to thrombolysis has focused on a tradeoff between the potential benefit of improved neurologic outcome and the potential harms of intracranial bleeding and death,[16,17] we found no significant associations between participants' attitudes about the values of functional independence or longevity and preferences for thrombolysis. Similarly, we found no significant associations between an interest in patient-directed medical decision making and preferences for thrombolysis. Instead, desiring thrombolysis was associated with confidence in the medical system and reliance on statistical information in decision making. Although our measures of these 2 attitudes were not correlated with one another, both attitudes may involve a willingness to place trust in specialized biomedical knowledge and expertise.

Although valuing independence or longevity was not associated with preferences for thrombolysis, older adults who do not fear functional dependence and who value longevity were more likely to want CPR for cardiac arrest. This finding is consistent with the observation that CPR may be life-saving but also carries a risk of survival with severe neurological disability. Although it has been claimed that consent to thrombolysis involves an essentially personal weighing of the values of independence and longevity, our findings suggest that these 2 personal values more strongly influence consent to CPR than consent to thrombolysis.

One unexpected finding is that when informed consent cannot be obtained, a greater proportion of older adults would want emergency CPR. This finding is a situational exception to the general maxim that people desire involvement in their health care decision making.[19–22] It also suggests paradoxically that some individuals who would decline CPR if asked would still want to receive CPR if their informed refusal could not be obtained. A possible explanation is that some participants may have interpreted the question regarding the absence of informed consent as a question about what medical

TABLE 2. Associations between Personal Health-Related Values and Emergency Treatment Preferences[a]

Value Statement	Ischemic Stroke: OR (95% CI)	Interaction with Inability to Consent, *p*	Cardiac Arrest: OR (95% CI)	Interaction with Inability to Consent, *p*
I prefer to rely upon my doctor's knowledge and not try to find out about my condition on my own. Agree: 62.4%	1.0 (0.61–1.7), $p = 0.93$	0.20	1.3 (076–2.0), $p = 0.37$	0.73
I prefer that my doctor offers me choices and asks my opinion. Agree: 93.8%	0.58 (0.18–1.8), $p = 0.36$	0.22	1.8 (0.74–4.6), $p = 0.19$	0.66
I prefer to leave the decisions about my medical care up to my doctor. Agree: 59.2%	1.5 (0.87–2.5), $p = 0.15$	0.61	1.5 (0.92–2.5), $p = 0.10$	0.53
I am afraid of becoming dependent on my family or a nursing home for my daily needs. Agree: 75.2%	0.97 (0.52–1.8), $p = 0.91$	0.99	0.53 (0.28–0.98), $p = 0.04$	0.92
I would like to live a long life, regardless of how healthy or independent I am. Agree: 53.4%	0.92 (0.54–1.6), $p = 0.77$	0.75	3.1 (1.8–5.4), $p < 0.001$	0.48
When I go to a hospital or doctor's office, I am confident that I will receive good care. Agree: 85.2%	2.2 (1.1–4.4), $p = 0.03$	0.72	1.6 (0.89–2.9), $p = 0.11$	0.51
I do not believe in using statistics to make important life decisions. Agree: 71.4%	0.44 (0.25–0.78), $p = 0.005$	0.12	1.2 (0.73–2.1), $p = 0.43$	0.20

[a]Participants responses to each of these statements were dichotomized (to agree/disagree). Bivariate logistic regression models were generated for each health-related value including participants' dichotomized responses (agree/disagree) to the statement, whether the participant received the treatment question emphasizing the inability to consent, and the interaction between these 2 terms as predictors of whether participants desired the described treatment. An odds ratio > 1 indicates a greater likelihood of desiring emergency treatment when participants agreed with the statement, whereas an odds ratio < 1 indicates a lower likelihood of desiring treatment when participants agreed with the statement.
CI = confidence interval; OR = odds ratio.

professionals should do in cases where informed consent is unobtainable rather than about what the participant personally would want (because in the context of these vignettes, these preferences could not be elicited). If so, then some older adults may judge that clinicians should err on the side of intervention in such cases, even if they themselves would not want the intervention.

We recognize several limitations. First, our study was only designed to address empirical issues pertinent to the ethical and legal presumption of consent, such as whether older adults' preferences for thrombolysis or CPR are influenced by the inability to consent to treatment. Further normative considerations do and should inform policy choices about the applicability and scope of such presumptions—including clinical judgment, patient quality of life, norms governing medical optimism, and the role of advance directives. Moreover, the vignettes elicited respondent preferences under situations of complete inability to consent due to aphasia. Our findings may not generalize to ischemic strokes that affect other components of decision-making capacity, such as by diminishing patients' ability to understand the benefits and harms of treatment.

In addition, although our vignettes depicted realistic situations using best available data on emergency treatment for ischemic stroke and cardiac arrest, the clinical scenarios presented were not fully analogous. For instance, differences in outcomes due to thrombolysis

from a randomized trial were presented in the stroke scenario, whereas absolute outcomes after CPR from observational studies were presented in the cardiac arrest scenario. Because a placebo-controlled trial of CPR would be unethical, differential data for CPR outcomes do not exist; absolute outcomes from observational studies of thrombolysis are not as relevant to our question, because some patients with strokes spontaneously improve without treatment. Similarly, the stroke scenario concerns treatment by physicians, whereas the cardiac arrest scenario concerns treatment by paramedics, which reflects the different clinical circumstances of these emergencies. Future studies that account for these differences in presentation, using contrived scenarios, may reveal other factors that influence treatment preferences.

The Internet-based testing platform allowed us to derive population-based estimates of treatment preferences in a large, nationally representative sample; however, it also limited our ability to explore the bases for these preferences. Other studies have explored attitudes underlying patients' treatment preferences regarding thrombolysis in acute ischemic stroke in demographically nonrepresentative samples,[19,28,29] in some cases employing qualitative and mixed methods in addition to the quantitative methods employed in our study.

In summary, although an overwhelming majority of older adults generally want to be presented with treatment options and asked their opinion, most older adults would want emergency treatment for ischemic stroke and cardiac arrest, and the desirability of such treatment is not diminished by the inability to give consent. We have previously reported that the proportion of older adults who desire thrombolysis for stroke is comparable to the proportion of older adults who desire CPR for sudden cardiac arrest.[18] Together, these findings provide empirical support for recent professional society recommendations favoring the use of thrombolysis for acute ischemic stroke in appropriate emergency circumstances under a presumption of consent. First, when an older adult's treatment preferences are unknown, he or she is just as likely to want treatment with thrombolysis as to want CPR, an intervention for which the presumption of consent is widely accepted. Second, although individual treatment preferences for thrombolysis reflect personal health-related values, the desirability of thrombolysis is not diminished in circumstances where patients are unable to consent to treatment.

At the same time, it must be acknowledged that for both thrombolysis and CPR, almost a quarter of older adults would not choose these interventions for themselves when informed of the likely outcomes. This finding is a reminder that the presumption of consent to emergency treatment is a pragmatic ethical and legal norm that allows medical professionals to provide care that most of their patients would want in situations where informed individual consent cannot be obtained. As a norm limited to such circumstances, this presumption of consent should only be applied when truly informed consent cannot be obtained from the patient and when surrogates are unavailable. This presumption should also yield to other evidence regarding the individual patient's wishes, or to medical judgment about the appropriateness of the intervention in the individual patient's case.[30] Finally, the finding that a sizable minority would not want interventions directed at their own medical benefit suggests caution in extending presumptions of consent to medical decisions that are not directed at the patient's own medical benefit, such as organ donation,[31] participation in emergency clinical research,[32] and the involvement of medical trainees in clinical care.[33,34]

Acknowledgment

This work was supported by grant K23AG043553 from the NIH National Institute on Aging, grant KL2TR000143 from the National Center for Advancing Translational Sciences, and the American Brain Foundation Clinical Research Training Fellowship Program. Data collection was provided by Time-Sharing Experiments in the Social Sciences (National Science Foundation grant 0818839; Jeremy Freese, PhD and James Druckman, PhD, principal investigators).

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

We thank Carolyn Chu, Stefan Subias, and other staff at GfK for technical contributions; and Amy J. Markowitz, JD, for assistance in drafting the manuscript.

Authorship

W.C. 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; W.C., S.A.J., and A.S.K conceived the study; W.C. and A.S.K. compiled and analyzed the data, with interpretive input from N.A.F. and I.A.H.; W.C. and I.A.H. made initial drafts of tables, figures, and results. W.C. led in writing the article with contributions from all other authors.

Potential Conflicts of Interest

A.S.K.: grants, SanBio.

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