

Surveys of Stroke Patients and Their Next of Kin on Their Opinions towards Decision-Making and Consent for Stroke Thrombolysis

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Abstract

Introduction: Early initiation of stroke thrombolysis is associated with improved outcomes. Procurement of consent is a key factor in prolonging the door-to-needle duration. This study aimed to determine the attitudes and preferences of stroke patients and their next of kin (NOK) towards decision-making for stroke thrombolysis in Singapore. **Materials and Methods:** We surveyed acute ischaemic stroke patients (n = 171) who presented beyond the 4.5-hour therapeutic window and their NOK (n = 140) using a questionnaire with scenarios on obtaining consent for intravenous thrombolysis. **Results:** In the patient survey, 83% were agreeable for their NOK to decide on their behalf if mentally incapacitated and 74% were agreeable for the doctor to decide if the NOK was absent. In the NOK survey, the majority (81%) wanted to be consulted before mentally capacitated patients made their decision; 72% and 74%, meanwhile, were willing to decide on behalf of a mentally capacitated and mentally incapacitated patient, respectively. In the scenario where a doctor recommended a mentally incapacitated stroke patient to undergo thrombolysis but the family declined, there was a near equal split in preference to follow the family's or doctor's decision in both the patient and NOK surveys. **Conclusion:** The survey found that in the decision-making process for stroke thrombolysis, there was no clear consensus on the preference for the decision maker of the mentally incapacitated patient. In Singapore, there is a strong influence of the NOK in decision-making for thrombolysis.

Ann Acad Med Singapore 2017;46:50-63

Key words: Door-to-needle time, Reperfusion, Therapeutic window

Introduction

Intravenous thrombolysis for acute treatment of ischaemic stroke is proven to reduce disability and increase the likelihood of functional independence. However, it is also associated with increased bleeding risk including devastating symptomatic intracerebral haemorrhage.^{1,2} Earlier initiation of thrombolysis is associated with greater potential benefit.³ There is a narrow 4.5-hour therapeutic window for acute thrombolysis and the American Stroke Association recommends a door-to-needle duration of less than 60 minutes.¹ The urgency to initiate stroke thrombolytic treatment adds a time pressure to the decision-making process. Procurement of consent is a rate-limiting step in achieving the target door-to-needle time.⁴

Stroke often impairs cognition, language and consciousness, thus, limiting the patient's ability to give consent.^{5,6} The Singapore Mental Capacity Act (MCA) states that for emergency life-sustaining treatment for a patient lacking mental capacity, the treating physician is given the responsibility to make the decision according to the patient's best interest.⁷ The MCA also states that the physician should, where practicable, consult anyone engaged in caring for the patient or named by the patient as someone to be consulted. Prior to this study, the common practice in Singapore was to obtain written consent for intravenous thrombolysis administration directly from the next of kin (NOK) of mentally incapacitated stroke patients.⁸ Previous studies on the attitudes towards consent

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for stroke thrombolysis had surveyed non-stroke patients.⁹ In this study, we surveyed the attitudes and preferences of stroke patients and their NOK towards consent and decision-making issues for intravenous stroke thrombolysis and investigated factors associated with their responses.

Materials and Methods

We conducted 2 surveys at the Singapore General Hospital, a large tertiary public hospital in Singapore—one was among consecutive patients admitted for ischaemic stroke and were not eligible for intravenous thrombolysis while the other was among the NOK of these stroke patients. We only included patients who were assessed to be mentally competent by the clinical team. The NOK was the person identified by the patients as the person who would make decisions on their behalf if needed. Basic demographic data of the participants including age, gender, ethnicity, marital status, number of surviving adult relatives and relationship between patient and NOK were collated. A questionnaire containing 5 scenarios was given to the patient participants (Table 1) (Appendix 1). A separate questionnaire with 5 different scenarios was given to the NOK participants (Table 2) (Appendix 2).

Participants either completed the questionnaire independently or with the aid of a research coordinator. Participants were instructed to read the enclosed Patient Information Sheet (PIS) (Appendix 3) prior to completing the questionnaire. Trained research coordinators checked that they had understood the PIS and answered any queries they may have had. Participation was voluntary and informed

consent was obtained from participants. The study was approved by the hospital's Institutional Review Board. We used SPSS version 18 for statistical analyses with chi-square test to assess for associations with the following variables: age, gender, ethnicity, education level, marital status, education level and having a living adult child.

Results

Patient

We surveyed 171 patients (mean age 64 ± 11 years; 66% male; ethnic distribution: 76% Chinese, 13% Malay, 7% Indian and 4% of other ethnicities, consistent with the Singapore population; marital status: 75% married, 11% single, 9% widowed, 4% divorced, 1% separated; educational level: 40% primary, 38% secondary, 22% tertiary; and 74% had a living child aged above 21 years).

In Scenario 1, 58% of patients were willing to receive thrombolysis if recommended by the doctor, with 17% undecided and 25% being unwilling (Table 3). In Scenario 2, in which the patient was mentally incapacitated, 83% were agreeable for their NOK to decide on thrombolysis on their behalf. In Scenario 3, where the patient was mentally incapacitated and the NOK was not present, 74%

Table 1. Patient Questionnaire

Scenario*	Questions
Patient Scenario 1	If you were eligible for thrombolysis and your doctors advised it, how agreeable would you be to receive it?
Patient Scenario 2	How agreeable are you for your NOK to give consent on your behalf?
Patient Scenario 3	Your NOK is not available. How agreeable are you with the doctor's decision to proceed with thrombolysis treatment in your best interests?
Patient Scenario 4	Who would you prefer to make treatment decisions on your behalf?
Patient Scenario 5	If the doctor recommends thrombolysis but your NOK disagrees, would you prefer that treatment is given in accordance with the doctor's advice or the decision of the NOK is accepted and treatment not given?

NOK: Next of kin

*For Scenarios 2 to 5, participants were asked to assume lack of mental capacity.

Table 2. NOK Questionnaire

Scenario**	Questions
NOK Scenario 1	As a family member would you like the doctor to ask for your opinion before your relative makes the treatment decision?
NOK Scenario 2	Your relative is undecided and asks you to make a decision. How willing are you to make the treatment decision on their behalf?
NOK Scenario 3	How comfortable are you in letting the doctors make the decision on behalf of your relative?
NOK Scenario 4	How willing are you to make this treatment decision on your relative's behalf?
NOK Scenario 5a	If you personally suffered an ischaemic stroke and your ability to make decisions is affected, would you prefer that treatment is given in accordance with your doctor's advice or the decision of your NOK is accepted even if they decline consent for the treatment?
NOK Scenario 5b	If you personally suffered an ischaemic stroke and you have the mental capacity to make decisions, who do you think should make the treatment decision?

NOK: Next of kin

**For Scenarios 3 to 4, NOK participants were asked to assume the patient has no mental capacity.

†For Scenarios 5a and 5b, NOK participants were asked on their opinions if they were to personally suffer a stroke.

Table 3. Responses for Patient Scenarios 1 to 3

Scenario	Patient's Response	Strongly Agree n (%)	Agree n (%)	Undecided n (%)	Disagree n (%)	Strongly Disagree n (%)
Patient Scenario 1	If you were eligible for thrombolysis and your doctors advised it, how agreeable would you be to receive it?	26 (15%)	73 (43%)	29 (17%)	38 (22%)	5 (3%)
Patient Scenario 2	If mentally incapacitated, how agreeable are you for your NOK to give consent on your behalf?	41 (24%)	100 (59%)	5 (3%)	20 (12%)	4 (2%)
Patient Scenario 3	Your NOK is not available. How agreeable are you with the doctor's decision to proceed with thrombolysis in your best interests?	28 (17%)	98 (57%)	16 (9%)	24 (14%)	5 (3%)

NOK: Next of kin

would be agreeable for the doctor to decide. There were no associations of age, gender, ethnicity, education level, marital status, education level and having a living child with any of the responses for patient Scenarios 1 to 3, except a lower proportion of Malays (62%) compared to non-Malays (86%) were agreeable for their NOK to decide regarding thrombolysis if they themselves were mentally incapacitated ($P = 0.012$).

If the patient was mentally incapacitated and given a choice as illustrated in Scenario 4, 58% preferred to follow their NOK's decision and 42% the doctor's. A higher proportion of female patients (71%) as compared to males (53%) would prefer the NOK to make the decision instead of the doctor ($P = 0.026$). If the doctor recommended thrombolysis but the NOK disagreed (Scenario 5), 52% would prefer to follow the NOK's decision while 48% would prefer the doctor's. None of the other responses for patient Scenarios 4 and 5 were associated with age, gender, ethnicity, marital status, education level and having a living child.

NOK

We surveyed 140 NOK of stroke patients (mean age 47 ± 14 years; 39% male; ethnic distribution: 78% Chinese, 11% Malay, 8% Indian and 3% of other ethnicities, consistent with the Singapore population; educational level: 15% primary, 32% secondary and 53% tertiary).

In Scenario 1, 81% of the NOK would like to have their opinion sought before the mentally capacitated patient made any decision on stroke thrombolysis. In Scenario 2, if requested, 72% of NOK were willing to decide on behalf of a mentally competent patient (Table 4). A higher proportion of male NOK (86%) compared to female NOK (64%) were willing to decide on thrombolysis for a mentally capacitated stroke patient ($P = 0.006$). There were no other associations with responses to NOK Scenarios 1 and 2 with age, ethnicity, education level and relationship to patient.

When the patient was mentally incapacitated, 61% of the NOK were comfortable to let doctors decide on stroke thrombolysis (Scenario 3), and 74% were willing to decide

Table 4. Responses for NOK Scenarios 2 to 4

Scenario	NOK Response	Very Willing n (%)	Willing n (%)	Undecided n (%)	Unwilling n (%)	Very Unwilling n (%)
NOK Scenario 2	Your relative is undecided and asks you to make a decision. How willing are you to make the treatment decision on their behalf?	30 (21%)	71 (51%)	26 (19%)	12 (8%)	1 (1%)
NOK Scenario 3	How comfortable are you in letting the doctors make the decision on behalf of your relative if your relative had no mental capacity?	8 (6%)	77 (55%)	16 (11%)	27 (19%)	12 (9%)
NOK Scenario 4	If your relative was mentally incapacitated, how willing are you to make this treatment decision on your relative's behalf?	25 (18%)	78 (56%)	19 (13%)	17 (12%)	1 (1%)

NOK: Next of kin

on behalf of the patient (Scenario 4). These responses to NOK Scenarios 3 and 4 were not associated with age, gender, education level and relationship to patient, except a lower proportion of Malay (50%) compared to non-Malay (77%) NOK were willing to decide on behalf of the patient ($P = 0.034$).

In Scenario 5a, where the NOK hypothetically suffered a stroke, was mentally incapacitated and the doctor recommended intravenous (IV) thrombolysis treatment but their family declined, 46% preferred to follow the doctor's advice to be treated with IV thrombolysis and 54% preferred to follow their family's decision to not be treated. In Scenario 5b, where the NOK hypothetically suffered a stroke and was mentally capacitated, 61% chose the option of making their own decision and 19% each would leave the decision-making to their family and doctor, respectively. None of the responses for NOK Scenarios 5a and 5b were associated with age, gender, ethnicity, relationship to the patient and educational level.

Discussion

This is the first study to investigate the preferences and attitudes of patients and their NOK towards the decision-making process for stroke thrombolysis. The key finding was that there was no consensus for preference with a near equal split for the doctor or the NOK to be the decision maker for a mentally incapacitated stroke patient. This was reflected in both the stroke patient and NOK surveys, even when posed with the situation that the doctor and NOK had differing opinions. The inference is that if a doctor follows the NOK's decision to withhold stroke thrombolysis for a mentally incapacitated stroke patient despite the doctor advising the treatment, the doctor would be not acting according to the patient's wishes about half of the time. More importantly, there is no legal basis within the Singapore MCA for a NOK (regardless of whether the NOK is the patient's donee of a lasting power of attorney with healthcare decision-making authority) to make decisions for a mentally incapacitated patient for emergency treatment.

Our group has shown previously that the majority of Singapore neurologists are willing to make decisions on stroke thrombolysis for mentally incapacitated stroke patients.⁸ A published study found that the inability to give consent did not reduce a person's desire for stroke thrombolysis.¹⁰ Following this study, our institution has revised our protocol for stroke thrombolysis from taking consent from the NOK for a mentally incapacitated stroke patient to the current practice of the doctors making the decision in the best interest of such patients. In addition to being consistent with the MCA, this new protocol will hasten the decision-making process and in turn, reduce the

door-to-needle duration for thrombolysis.

There are important issues to bear in mind with regard to surrogate consent. When faced with the hypothetical situation of being a stroke patient, 61% of the NOK participants wanted to make their own decision regarding stroke thrombolysis if mentally capacitated, although 81% of these individuals, in their real-life role as a NOK, wanted to be consulted on the mentally capacitated stroke patient's decision for thrombolysis. This shows the difference between decision-making as a NOK or surrogate. It has been shown previously that a higher proportion of relatives acting as proxy decision makers (rather than the stroke patients themselves) were uncertain about the thrombolysis decision.¹¹

Both the patient and NOK surveys reported in this study indicated the strong influence of the NOK in Singapore in the decision-making for thrombolysis. About half of the stroke patients surveyed would rather follow the NOK's decision and have the treatment withheld even if the doctor had recommended it. The NOK were also very keen to be consulted for their opinions during the decision-making process and majority of the NOK surveyed were comfortable and willing to make the decision on behalf of a mentally incapacitated patient. Doctors in Singapore should bear this in mind and include the NOK in discussions regarding thrombolysis for stroke patients, even though the final decision should be made by the patient if mentally capacitated and by the doctor in the patient's best interest if the patient is mentally incapacitated.

For most of the scenarios, there were no associations between patient demographics with responses; thus, it would not be possible to anticipate preferences for any particular patient subgroup. Ethnicity and gender were factors influencing the attitudes towards consent processes for stroke thrombolysis in 2 scenarios each. Malays, as a patient, were less likely to be agreeable to accept a decision made by the NOK; as a NOK, they were less likely to be willing to make decisions for the mentally incapacitated patient. In the scenario as a mentally incapacitated patient, a higher proportion of females than males would prefer their NOK to decide the treatment for them instead of the doctor; as a NOK, a lower proportion of females were willing to decide for a mentally capacitated stroke patient. The reasons for these associations were not investigated in this study and should be explored in future research.

The main strength of this study is that the participants were acute stroke patients themselves and had experienced stroke symptoms. Thus, they would closely represent the preferences and attitudes of patients having to make decisions about stroke thrombolysis. Furthermore, we obtained opinions from both stroke patients and their NOK.

However, there were some limitations. In this study, we studied stroke patients who were not eligible for thrombolysis and respondents were not approached during the hyperacute period, thus they were not under the same time pressure as in real-life thrombolysis decision-making situations. Respondents, though, were given information on thrombolysis and were told that the decision-making for this treatment was time-sensitive. The completion of the questionnaire by the patient and NOK was not always done concurrently. The NOK surveyed was the person identified by the patient as the surrogate decision maker, although this may vary in real-life situations depending on availability. We did not explore differences between responses from a spouse, sibling or parent nor the influence of stroke severity on opinions provided. The information conveyed regarding thrombolysis included a standardised patient information leaflet but there were no visual aids. The study involved ethnic Asian participants in Singapore, a small city-nation in Southeast Asia, and the preference and attitudes found may differ in other ethnic groups and countries.

Conclusion

This study of stroke patients and their NOK found that in the decision-making process for stroke thrombolysis, there is no clear consensus on the preference for the decision maker for the mentally incapacitated patient. In Singapore, there is a strong influence of the NOK in decision-making for thrombolysis.

REFERENCES

1. Jauch EC, Saver JL, Adams HP Jr, Bruno A, Connors JJ, Demaerschalk BM, et al. Guidelines for the early management of patients with acute ischaemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke* 2013;44:870-947.
2. Wardlaw JM, Murray V, Berge E, Del Zoppo GJ. Thrombolysis for acute ischaemic stroke. *Cochrane Database Syst Rev* 2009;4:CD000213.
3. Lees KR, Bluhmki E, von Kummer R, Brodt TG, Toni D, Grotta JC, et al. Time to treatment with intravenous alteplase and outcome in stroke: an updated pooled analysis of ECASS, ATLANTIS, NINDS and EPITHET trials. *Lancet* 2010;375:1695-703.
4. Kwan J, Hand P, Sandercock P. A systematic review of barriers to delivery of thrombolysis for acute stroke. *Age Ageing* 2004;33:116-21.
5. Rose DZ, Kasner SE. Informed consent: the rate-limiting step in acute stroke trials. *Front Neurol* 2011;2:65.
6. Eissa A, Krass I, Bajorek BV. Barriers to the utilisation of thrombolysis for acute ischaemic stroke. *J Clin Pharm Ther* 2012;37:399-409.
7. Singapore Statutes Online. Mental Capacity Act (Chapter 177A). Available at: <http://statutes.agc.gov.sg/aol/search/display/view.w3p;ident=3fb55a4c-06dc-4a94-bc7a-b07a59ab0540;query=DocId%3A7f933c47-8a34-47d1-8d0a-0a457d6fa1c2%20%20Status%3Ainforce%20Depth%3A0;rec=0#legis>. Accessed on 10 March 2015.
8. Talabucon LP, Menon S, Toh AJ, Oh DC, De Silva DA. Attitudes and practices on the consent process and decision-making for intravenous stroke thrombolysis: physicians' perspective. *Ann Acad Med Singapore* 2013;42:567-74.
9. Chiong W, Kim AS, Huang IA, Farahany NA, Josephson SA. Testing the presumption of consent to emergency treatment for acute ischemic stroke. *JAMA* 2014;311:1689-91.
10. Chiong W, Kim AS, Huang IA, Farahany NA, Josephson SA. Inability to consent does not diminish the desirability of stroke thrombolysis. *Ann Neurol* 2014;76:296-304.
11. Ciccone A, Sterzi R, Crespi V, Defanti CA, Pasetti C. Thrombolysis for acute ischemic stroke: the patient's point of view. *Cerebrovasc Dis* 2001;12:335-40.

Appendix 1

Patient Questionnaire

Attitudes and Perceptions on the Informed Consent Process / Decision-making on Intravenous Tissue Plasminogen Activator (IV tPA).

You have been invited to participate in this survey because you have recently suffered a stroke. This survey aims to determine the attitudes and perceptions of the informed consent process, as well as factors that influence decision-making for the clot-busting drug treatment for stroke. There is no right or wrong answer. Your answers will be kept strictly confidential.

You may complete the form on your own by ticking (☑) the box. Alternatively, our trial coordinator can assist you by writing down your verbal answers. Please direct any questions you may have to the trial coordinator.

☐
SC

1. Please indicate the language or dialect that you are most fluent with. (You may choose more than one answer)

- ☐ 1) English ☐ 4) Tamil
☐ 2) Mandarin ☐ 5) Others including dialect: _____
☐ 3) Malay

☐
Lng

2. Marital status

- ☐ 1) Single ☐ 4) Divorced
☐ 2) Married ☐ 5) Separated
☐ 3) Widowed

☐
Sta

3. Do you have any surviving children aged 21 and above?

- ☐ 1) Yes
☐ 2) No

☐
Chi

4. Do you have any surviving siblings (brothers/sisters)?

- ☐ 1) Yes
☐ 2) No

☐
Sib

An ischemic stroke occurs when a blood vessel in the brain is blocked. Thrombolysis treatment – a clot-busting drug called alteplase - attempts to unblock the blood vessel. This drug must be given within 4.5 hours of the stroke onset. The advantage of this treatment is that it increases the likelihood of patients recovering their physical and mental abilities. Delay in initiating this treatment reduces its benefits and increases the bleeding risk. The main complication of this treatment is bleeding in the brain. You were not offered this clot busting drug treatment. This may be because you were admitted beyond the proven time window or it may be due to contraindications based on your medical history and laboratory findings.

Attitudes and Perceptions on the Informed Consent Process / Decision-making on Intravenous Tissue Plasminogen Activator (IV TPA).

Please read the Patient Information Sheet before answering the following questions.

Scenario 1: If you were suitable and eligible for this clot busting drug treatment and your doctors advised it, how agreeable would you be to receive it?

- ☐ 1) Strongly agree
☐ 2) Agree
☐ 3) Undecided or unsure what to do
☐ 4) Disagree
☐ 5) Strongly disagree

Reasons: _____

☐

S1

Stroke can affect mental functioning. Hence some patients are not able to make decisions for themselves due to their stroke symptoms. The following scenarios 2-5 are based on such potential situations.

Scenario 2: The doctor has discussed this clot-busting drug treatment with your family or next of kin and advised that in the circumstances this treatment is in your best interests. Your family or next of kin gave consent for you to receive this treatment. Do you agree with your family or next of kin's decision? (Please give your reasons in the space below.)

- ☐ 1) Strongly agree
☐ 2) Agree
☐ 3) Undecided
☐ 4) Disagree
☐ 5) Strongly disagree

Reasons: _____

☐

S2

Scenario 3: Your family or next of kin were not available to discuss the treatment options with your doctors. The doctors decided to give you the clot busting treatment because they thought it was in your best interests. Do you agree with the doctors' decision? (Please specify your reasons in the space provided below.)

- ☐ 1) Strongly agree
☐ 2) Agree
☐ 3) Undecided
☐ 4) Disagree
☐ 5) Strongly disagree

Reasons: _____

☐

S3

Attitudes and Perceptions on the Informed Consent Process / Decision-making on Intravenous Tissue Plasminogen Activator (IVTPA).

Scenario 4: The stroke has affected your mental functioning so you are unable to make a decision whether to accept or reject the clot-busting drug treatment. If this had happened to you, whom would you prefer to make that decision on your behalf? (Please specify your reasons in the space provided.)

S4

- ☐ 1) Family or next of kin ☐ 2) Doctor

Reasons:

Scenario 5: The stroke has affected your mental functioning so you are unable to make a decision whether to accept or reject the clot-busting drug treatment. The doctor has advised you should be treated with the clot-busting drug called alteplase. The doctor has discussed this treatment with your family or next of kin and advised that in the circumstances this treatment is in your best interests. Your family or next of kin declined consent for you to receive this treatment. You would prefer that:

S5

- ☐ 1) The treatment is given in accordance with the doctor's advice
☐ 2) The decision of my family or next of kin is accepted and treatment not given

6. When you read through the Patient Information Sheet, how did you find it?

- ☐ 1) Very easy to understand ☐ 4) Confusing
☐ 2) Easy to understand ☐ 5) Very confusing
☐ 3) Adequate to understand

PIS2

7. Do you think the Patient Information Sheet is useful if ever you will make a decision about the clot busting treatment?

- ☐ 1) Not useful, it will make my decision harder ☐ 3) Unsure if useful or not
☐ 2) Useful, it will make my decision easier

PIS3

8. Was the Patient Information Sheet...

- ☐ 1) Too long
☐ 2) Length about right
☐ 3) Too short, requires more information

PIS4

9. Which is your preferred format of the Patient Information Sheet?

- ☐ 1) Written
☐ 2) Illustrated
☐ 3) Both written and illustrated

PIS5

10. The current Patient Information Sheet is in English. Would you prefer it to be translated into a language you are more comfortable with?

- ☐ 1) Yes
☐ 2) No
☐ 3) Does not matter as long as it was adequately explained or verbally translated to me
☐ 4) Not applicable as English is my primary language

PIS6

Attitudes and Perceptions on the Informed Consent Process / Decision-making on Intravenous Tissue Plasminogen Activator (IV tPA).

What other information do you think is important when making a decision regarding this clot-busting drug treatment, but is lacking or needs more emphasis in the Patient Information Sheet?

Thank you for participating in this survey. If you have any comments about this clot-busting drug treatment or about the informed consent process, or suggestions to improve this survey questionnaire, please write them in the space provided below.

Appendix 2

NOK Questionnaire

Attitudes and Perceptions on the Informed Consent Process / Decision-making on Intravenous Tissue Plasminogen Activator (IV TPA).

You have been invited to participate in this survey because your relative has recently suffered a stroke. This survey aims to determine the attitudes and perceptions of the informed consent process, as well as factors that influence decision-making for the clot-busting drug treatment for stroke. There is no right or wrong answer. Your answers will be kept strictly confidential.

You may complete the form on your own by ticking (☑) the box. Alternatively, our trial coordinator can assist you by writing down your verbal answers. Please direct any questions you may have to the trial coordinator.

1. Age: _____

2. Gender: ☐ 1) Female ☐ 2) Male

3. Race/ethnicity

☐ 1) Chinese ☐ 3) Indian
☐ 2) Malay ☐ 4) Mixed/Others (please indicate) _____

4. Please indicate the language or dialect that you are most fluent with. (You may choose more than one answer)

☐ 1) English ☐ 3) Malay ☐ 5) Others including dialect: _____
☐ 2) Mandarin ☐ 4) Tamil

5. What is your relationship to the patient?

☐ 1) Parent ☐ 3) Child ☐ 5) Others (please indicate): _____
☐ 2) Sibling ☐ 4) Spouse

☐

SC

☐

Age

☐

Sex

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Rac

☐

Lng

☐

Rel

An ischemic stroke occurs when a blood vessel in the brain is blocked. Thrombolysis treatment – a clot-busting drug called alteplase - attempts to unblock the blood vessel. This drug must be given within 4.5 hours of the stroke onset. The advantage of this treatment is that it increases the likelihood of patients recovering their physical and mental abilities. Delay in initiating this treatment reduces its benefits and increases the bleeding risk. The main complication of this treatment is bleeding in the brain. Please read the Patient Information Sheet before answering the following questions.

Scenario 1

The doctors have assessed your relative (the patient) and advised that he/she should be treated with the clot-busting drug treatment called alteplase. The doctor has discussed this treatment with your relative and advised that in the circumstances this treatment is in your relative's best interests. Your relative is prepared to make the treatment decision. As a family member, would you like the doctor to ask for your opinion before your relative makes the treatment decision?

☐ 1) Yes
☐ 2) No, because the patient is competent, and can therefore decide on his / her own

☐

1

Attitudes and Perceptions on the Informed Consent Process / Decision-making on Intravenous Tissue Plasminogen Activator (IV TPA).

Scenario 2

The doctors have assessed your relative (the patient) and advised that he/she should be treated with the clot-busting drug called alteplase. The doctor has discussed this treatment with your relative and advised that in the circumstances this treatment is in your relative's best interests. Your relative (the patient) is undecided and asks you as family member to make a decision on his/her behalf. How willing are you to make the decision about this clot busting drug treatment for your relative? (Please specify your reasons in the space provided below.)

☐

2

- | | |
|--|--|
| ☐ 1) Very willing | ☐ 4) Unwilling |
| ☐ 2) Willing | ☐ 5) Very unwilling |
| ☐ 3) Undecided or unsure what to do | |

Reasons:

Scenario 3

The stroke has affected your relative's mental functioning and he/she is unable to make a decision whether to accept or reject the clot-busting drug treatment called alteplase. The doctors advised that in the circumstances this treatment is in your relative's best interests. How comfortable are you in letting the doctors make the decision on behalf of your relative and give him/her the clot-busting drug treatment? (Please specify your reasons in the space provided below.)

☐

3

- | | |
|--|--|
| ☐ 1) Very comfortable | ☐ 4) Uncomfortable |
| ☐ 2) Comfortable | ☐ 5) Very uncomfortable |
| ☐ 3) Undecided or unsure what to do | |

Reasons:

Scenario 4

The stroke has affected your relative's mental functioning and he/she is unable to make a decision whether to accept or reject the clot-busting drug treatment called alteplase. The doctors advised that in the circumstances this treatment is in your relative's best interests. How willing are you to make this treatment decision on your relative's behalf and sign an informed consent on his/her behalf?

☐

4

- | | |
|--|--|
| ☐ 1) Very willing | ☐ 4) Unwilling |
| ☐ 2) Willing | ☐ 5) Very unwilling |
| ☐ 3) Undecided or unsure what to do | |

Reasons:

Attitudes and Perceptions on the Informed Consent Process / Decision-making on Intravenous Tissue Plasminogen Activator (IV tPA).

The next 2 scenarios are your views if you personally suffered an ischemic stroke

Scenario 5a: You have suffered an ischemic stroke. The doctor has advised you should be treated with the clot-busting drug called alteplase. The stroke has affected your mental functioning so you are unable to make a decision whether to accept or reject the clot-busting drug treatment. The doctors have discussed this treatment with your family or next of kin and advised that in the circumstances you should be treated with alteplase. You would prefer that:

☐

5a

- ☐ 1) The treatment is given in accordance with your doctor's advice
☐ 2) The decision of my family or next of kin is accepted, even if they decline consent for me to be treated with alteplase

Scenario 5b: You have suffered an ischemic stroke. The doctor has advised you should be treated with the clot-busting drug called alteplase. The doctor has assessed that you have the mental capacity to make the decision whether to accept or decline treatment. Who do you think should make this treatment decision?

☐

5b

- ☐ 1) You
☐ 2) The doctor
☐ 3) Your family members or next of kin

Reasons:

6. When you read through the Patient Information Sheet, how did you find it?

- ☐ 1) Very easy to understand
☐ 2) Easy to understand
☐ 3) Adequate to understand
☐ 4) Confusing
☐ 5) Very confusing

☐

PIS2

7. Do you think the Patient Information Sheet is useful when making a decision about the clot busting treatment?

- ☐ 1) Not useful, it will make my decision harder
☐ 2) Useful, it will make my decision easier
☐ 3) Unsure if useful or not

☐

PIS3

8. Is the Patient Information Sheet...

- ☐ 1) Too long
☐ 2) Length about right
☐ 3) Too short, requires more information

☐

PIS4

9. Which is your preferred format of the Patient Information Sheet?

- ☐ 1) Written
☐ 2) Illustrated
☐ 3) Both written and illustrated

☐

PIS5

Attitudes and Perceptions on the Informed Consent Process / Decision-making on Intravenous Tissue Plasminogen Activator (IV TPA).

10. The current Patient Information Sheet is written in English. Would you prefer it to be translated into a language you are more comfortable with?

- ☐ 1) Yes
☐ 2) No
☐ 3) Does not matter as long as it was adequately explained or verbally translated to me
☐ 4) Not applicable as English is my primary language



PIS6

What other information do you think is important when making a decision regarding this clot-busting drug treatment, but is lacking or needs more emphasis in the Patient Information Sheet?

Thank you for participating in this survey. If you have any comments about this clot-busting drug treatment or about the informed consent process, or suggestions to improve this survey questionnaire, please write them in the space provided below.

Appendix 3

Patient Information Sheet

INTRAVENOUS ALTEPLASE FOR ACUTE ISCHAEMIC STROKE

Patient Information Sheet

What is Alteplase?

Alteplase acts as an agent to dissolve clots by breaking up the blockage in blood vessels.

Why do I need this treatment?

You have been diagnosed with stroke due to blockage in one of the blood vessels supplying blood to your brain. If alteplase is given within 4 and a half hours from the onset of the stroke, you are more likely to achieve recovery to the extent of independence in carrying out self-care activities (e.g. toileting, feeding, walking) within 3 months as compared to 30 - 45% who achieve functional independence with standard stroke therapy. Your physician will assess your suitability to receive this alteplase treatment. As the assessment is based on the information which you provide, you are encouraged to co-operate in providing accurate information to the best of your knowledge.

What does it involve?

Alteplase will be given into your vein (intravenous) over 1 hour.

What are the risks of the treatment?

The main complication arising from alteplase is bleeding, both inside and outside the brain. The risk of bleeding inside the brain with alteplase is up to 10 times higher than standard stroke therapy. This degree of risk is dependent on the severity of stroke and time from stroke onset, and will be explained to you by your physician. Some patients may die from this complication despite medical care, however the overall 3-month risk of death is similar between patients who receive this treatment and those who do not. Despite the risk of bleeding, patients who receive alteplase are still more likely to be functionally independent at 3 months compared to standard stroke therapy.

Less than 5% of patients will develop an allergic reaction to alteplase. Allergic reactions may range from rashes, breathing difficulties, drop in blood pressure and death. Medication and ventilatory support may be required.

What can I expect after the treatment?

You will be admitted to the Neurology high-dependency or intensive care ward and monitored closely over the few days following the treatment, especially in the first 24 hours. A brain scan will be repeated in the next day or two.

What are your options?

You may choose to decline treatment with alteplase. If you decline, you will be admitted to the Neurology ward, managed by a team of healthcare professional and receive standard stroke therapy. This includes close monitoring and treatment for complications, medications to reduce stroke recurrence, assessment and management of risk factors and rehabilitation.