Journal of Neurology (2024) 271:188–197
https://doi.org/10.1007/s00415-023-12028-y

REVIEW

Informed consent practices for acute stroke therapy: principles, challenges and emerging opportunities

Amir Mbonde[1,2] · Michael J. Young[1] · Adam A. Dmytriw[3,4] · Quentin J. Moyer[3,4] · Joshua A. Hirsch[4] · Thabele M. Leslie-Mazwi[5] · Natalia S. Rost[1] · Aman B. Patel[3] · Robert W. Regenhardt[1,3]

Received: 18 August 2023 / Revised: 24 September 2023 / Accepted: 25 September 2023 / Published online: 10 October 2023

Abstract

Importance Informed consent (IC) plays a crucial yet underexplored role in acute stroke treatment, particularly in the context of intravenous thrombolysis (IVT) and endovascular thrombectomy (EVT). This narrative review examines data on current IC practices in acute ischemic stroke management, specifically for patients treated with IVT or EVT, with the aim of identifying areas for improvement and strategies to enhance the IC process.

Observations IC practices for IVT vary significantly among hospitals and physicians with the frequency of *always* requiring consent ranging from 21 to 37%. Factors influencing IC for IVT include patient decision-making capacity, standard of care, time sensitive nature of treatments, legal and moral obligations, risk of complications, physician age and speciality, treatment delays, and hospital size. Consent requirements tend to be stricter for patients presenting within the 3–4.5-h window. The content and style of information shared as part of the IC process revealed discrepancies in the disclosure of stroke diagnosis, IVT mechanism, benefits, and risks. Research on IC practices for EVT is scarce, highlighting a concerning gap in the available evidence base.

Conclusions and relevance This review underscores the significant variability and knowledge gaps in IC for EVT and IVT. Challenges related to decision-making capacity assessment and the absence of standardised guidance substantially contributes to these gaps. Future initiatives should focus on simplifying information delivery to patients, developing formal tools for assessing capacity, standardising ethical frameworks to guide physicians when patients lack capacity and harmonizing IC standards across sites. The ultimate goal is to enhance IC practices and uphold patient autonomy, while ensuring timely treatment initiation.

Keywords Informed consent (IC) · Acute ischemic stroke · Intravenous thrombolysis (IVT) · Endovascular thrombectomy (EVT) · Decision-making capacity

Introduction

Informed consent (IC) is a cornerstone of patient autonomy, empowering patients, and their healthcare proxies to make informed medical decisions. [1] Optimal IC involves providing comprehensive and relevant clinical information, ensuring understanding of the diagnosis, prognosis, potential benefits, and risks associated with recommended treatment options, and importantly, incorporating patient preferences, values, and goals in the treatment decision making process. [1] However, in the context of acute ischemic stroke, achieving these goals can be uniquely challenging due to the urgency and time-sensitivity of decision-making, often compounded by acute patient incapacity due to stroke-related

Amir Mbonde and Michael J. Young have contributed equally to this work.

✉ Amir Mbonde
Mbonde.amir@mayo.edu

1 Harvard Medical School, Boston, MA, USA

2 Mayo Clinic Arizona, 13400 E Shea Blvd, Scottsdale, AZ 85259, USA

3 Harvard Medical School, Boston, MA, USA

4 Harvard Medical School, Boston, MA, USA

5 University of Washington, Seattle, WA, USA

neurological deficits such as aphasia, neglect, and reduced awareness. [2–5]

Acute ischemic stroke, affecting an estimated 800,000 people annually in the United States alone, is associated with high rates of death and disability [6]. Acute treatments, specifically, intravenous thrombolysis (IVT) and endovascular thrombectomy (EVT), play a critical role in improving patient outcomes after stroke but carry significant inherent risks [7, 8]. Ensuring that patients or their proxies have a comprehensive understanding of the condition and treatment options is essential. However, many stroke patients lack the mental capacity to comprehend clinical information and provide consent. Further, the availability or willingness of healthcare proxies to provide consent can be uncertain [9]. These challenges can result in delays, underscoring the need to understand current practices and identify gaps related to IC in IVT and EVT.

This narrative review examines current IC practices and gaps related to IC for IVT and EVT. Notably, this review does not include data on IC practices for clinical trial or research study enrolment. We sought to identify areas for IC improvement, explore emerging opportunities for streamlining and strengthening the process, and ultimately ensure excellent patient-centred care, effective ethical delivery of acute stroke therapy, and improved neurological outcomes.

Acute ischemic stroke and treatments

Acute ischemic stroke occurs when blood flow to a specific area of the brain is disrupted, resulting in neurological symptoms [10–12]. The primary objective of acute stroke treatment is to promptly restore blood flow to the affected brain region [11, 13, 14]. Two main acute treatment approaches are used for individuals experiencing ischemic stroke: IVT and EVT. [10]

IVT involves the intravenous administration of clot-dissolving medications to restore blood flow [3, 15]. Recombinant tissue plasminogen activator is commonly used in two forms, Alteplase and Tenecteplase [7, 16]. These work by converting plasminogen to plasmin, a potent lytic enzyme that leads to thrombus dissolution. IVT is recommended by the American Stroke Association for eligible patients presenting within 4.5 h from stroke onset or their last known normal state [7]. Clinical trials have demonstrated the effectiveness of these medications, with up to 33% of patients treated within 3 h experiencing no disability at 90 days [17, 18]. However, IVT also carries potential life-threatening adverse events, such as bleeding, including intracranial haemorrhage [18].

EVT involves mechanically removing the clot causing the blood flow disruption in the brain. EVT is offered to individuals based on specific criteria, including the demonstration of an occlusion of a large intracranial blood vessel, presentation within 24 h from symptom onset, and presence of salvageable brain tissue [7, 19–21]. The procedure is performed by navigating a catheter, usually inserted at the radial or femoral artery, through the body, neck, and into the cerebral vasculature to remove the clot using fluoroscopic guidance [22–24]. EVT has been shown to lead to significant clinical improvements in eligible patients, with a number needed to treat of 3–6 to prevent stroke disability at 90 days [19]. However, like IVT, EVT carries risks ranging from minor complications, such as discomfort, access site hematoma, infection, kidney injury, and allergic reactions, to more serious complications with significant morbidity and mortality, such as vessel dissection, stroke in a new territory, arterial perforation, and intracranial haemorrhage [19].

Given the potential benefits and risks associated with IVT and EVT (Table 1), it is essential to ensure that patients and surrogates have adequate information to make informed decisions about these treatments. Understanding the benefits, risks, and expected outcomes associated with IVT and EVT is crucial to enable appropriate provision of IC. By providing comprehensive information, healthcare providers can empower patients to make educated decisions that align with their preferences and goals of care, but how to achieve this expeditiously and responsibly given the time-sensitivity of treatment decisions in acute stroke has been underexplored.

Principles of ethics and informed consent practices

The core principles of biomedical ethics, comprising beneficence, non-maleficence, autonomy, and justice, are particularly relevant to the IC process for IVT and EVT [25]. These principles guide physicians in prescribing treatments that aim to reduce the risk of death or disability while avoiding harm (Fig. 1). IC, rooted in the principle of autonomy, emphasizes that patients have the right to make independent decisions about whether to receive a prescribed therapy. The principle of justice mandates the equitable treatment of all eligible patients without discrimination, and emphasizes the need for proactive measures to enhance treatment accessibility (Fig. 1).

There are five key principles of IC which apply to all stroke treatments [1]. First, patients or their surrogate decision makers must have the capacity to understand the information being shared and make a decision. Assessing patient capacity to understand information is extremely important and requires clinical evaluation. Second, they should receive full disclosure of all relevant clinical information including their diagnosis, prognosis, and the benefits and risks of treatment, in an individualized manner. Third, they should be able to comprehend the disclosed information effectively.

Table 1 Summary of risks and benefits of Intravenous thrombolysis and Endovascular thrombectomy

	Quantitative information on Treatment Benefits	Quantitative information on Adverse events
Intravenous thrombolysis (IVT)	About 33–35% of patients treated with alteplase will have a significantly higher likelihood of excellent recovery as compared to only 23–31% of patients not receiving this medication. [43] Individuals treated with IV alteplase are 1.75 times more likely to experience an excellent outcome compared to those who do not receive this treatment. [43] There is no mortality benefit associated with treatment compared to those who do not receive treatment TPA treatment is time dependent; Those treated within 60 min of stroke onset are 1.72 times more likely to be free of disability at discharge as compared to those are treated within 61–270 min[44]	The proportion of individuals who experience symptomatic intracranial hemorrhage from alteplase is estimated at 3–6.7%[43] The proportion of individuals who experience fatal intracranial hemorrhage from alteplase is estimated at 2.7% [43]
Endovascular Thrombectomy (EVT)	Approximately 27% of patients treated with EVT will have no disability, and 45% will have mild disability at 90 days. [19, 45] There is no mortality benefit with EVT [19, 45]	The rate of symptomatic intracerebral hemorrhage is estimated at 4–5% [19, 45]

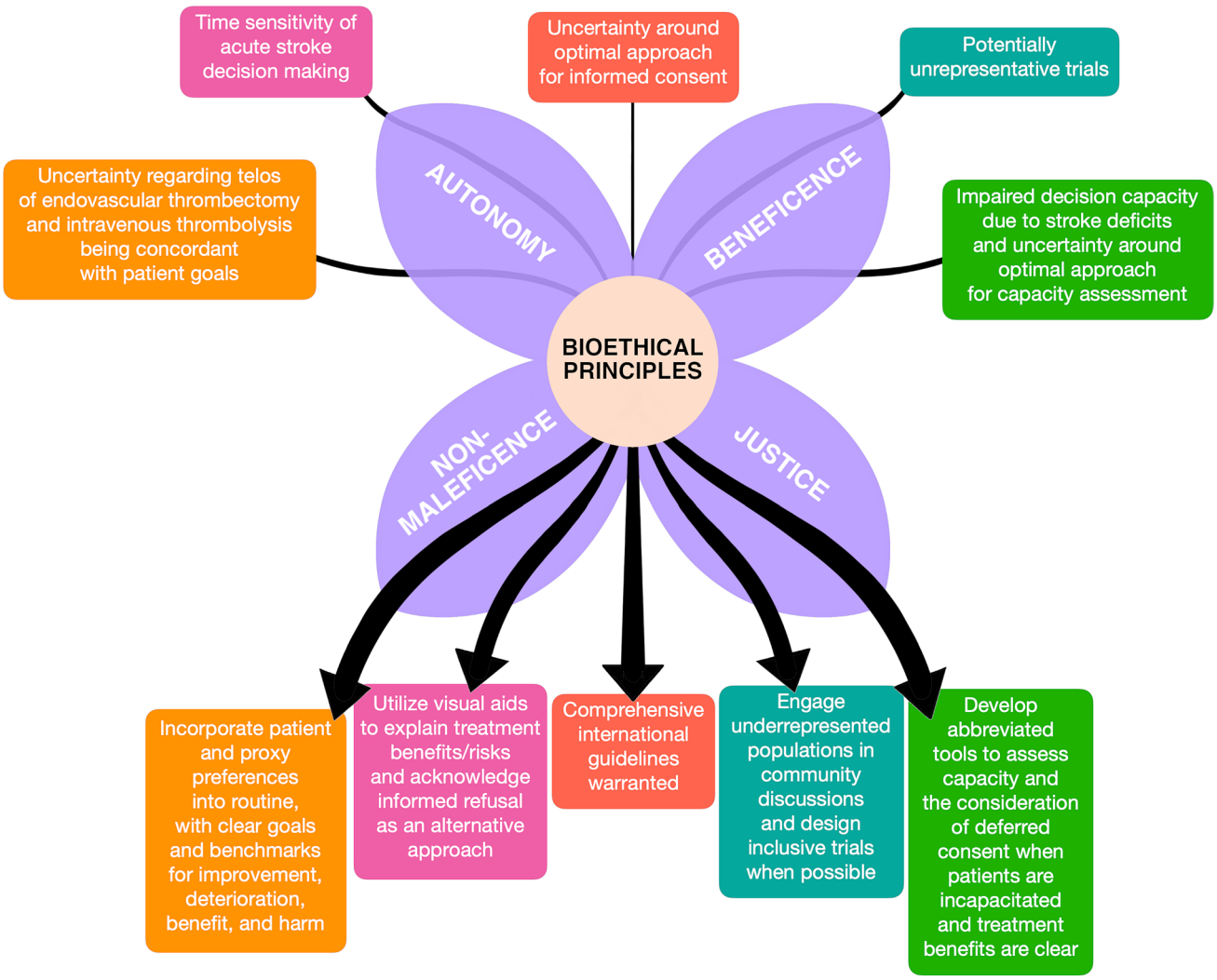

Fig. 1 Flower Diagram Showing the Biomedical ethical Principles alongside challenges to obtaining Informed Consent for acute stroke Therapies, including proposed solutions to the challenges

Fourth, their decision should be voluntary without coercion, and lastly, be able to communicate a treatment choice [1].

Assessing decision-making capacity in patients with stroke

Assessing patient capacity to understand information and make decisions is a critical aspect of providing ethical and patient-centred care in acute stroke management. However, the unique challenges posed by acute stroke, such as cognitive impairments, comprehension deficits and communication deficits, often complicate the assessment of capacity and decision-making ability (Fig. 1) [9]. In the context of acute stroke, a substantial proportion of patients experience deficits that impact their capacity to comprehend and retain information, analyse the risks and benefits of treatment options, and effectively communicate their preferences. Aphasia, neglect, and reduced level of alertness are common stroke-related deficits that can significantly affect the ability to participate in the IC process [26]. As a result, surrogate decision making becomes crucial in ensuring that patients receive appropriate treatment that is in line with their goals of care.

The process of assessing capacity in patients with acute stroke requires healthcare providers to navigate legal and ethical frameworks. The definition and selection of a surrogate decision maker may vary depending on local regulations and guidelines, thus requiring clinicians to be conversant with these regulations. When a patient preference regarding treatment options have not been previously expressed, surrogate decision makers must rely on substituted judgment or best interest standards [1]. Substituted judgment involves making decisions based on what the patient would have likely chosen if they were able to do so. The best interest standard requires selecting the treatment option that will yield the greatest expected overall benefit for the patient [1]. It is essential to recognize that even in instances where a patient has previously expressed general treatment preferences, these goals may not specifically clarify treatment preferences surrounding EVT or IVT, thus leaving the surrogate decision maker with the responsibility of making a treatment decision [27–29]. These challenges underscore the need for tailored approaches to IC and advance care planning specific to EVT and IVT, considering the unique nature of these treatments.

In cases where patients with acute stroke are unrepresented, meaning they lack capacity, advance directives, and available surrogate decision makers, clinicians may face considerable challenges in determining appropriate treatment strategies [30, 31]. The absence of clear guidelines regarding decision-making authority in such situations further complicates the process. Despite these challenges, healthcare professionals are ethically obligated to provide timely and appropriate treatment to these unrepresented patients. The concept of implied consent for emergency treatment with IVT, as recommended by the American Academy of Neurology (AAN) provides some guidance based on the assumption that most patients, if capable, would have consented to the treatment [32]. Similarly, the AAN guideline states that EVT may be considered in unrepresented patients if the indication for the procedure is clear and aligns with the principles of beneficence and non-maleficence [32].

Varieties of informed consent for EVT and IVT

Obtaining IC for both EVT and IVT can be achieved through different methods: written IC, verbal IC, and waived consent [1]. Written IC is typically obtained in person, where the healthcare provider explains the treatment options, risks, and benefits to the patient or surrogate decision maker. The patient or surrogate decision maker then signs the consent form to indicate their agreement with the chosen course of treatment. On the other hand, verbal IC can be obtained either in person or via telephone if the surrogate decision maker is not physically present. In the case of telephone consent, an additional healthcare professional may function as a witness and provide their signature.

In certain situations where the patient lacks the mental capacity to provide consent and no surrogate decision maker is available, waived consent, also known as deferred consent, may be employed. This approach is widely acknowledged and accepted by different professional bodies such as the AAN, particularly in instances related to the treatment of acute ischemic stroke [32]. Deferred consent recognizes the urgency of initiating immediate treatment to prevent severe complications or death. It is based on the presumption that, under similar circumstances, the patient would have likely chosen to receive the specific therapy if they possessed the capacity to provide consent [32].

These different varieties of consent practices allow for flexibility in accommodating the unique circumstances and needs of patients receiving EVT and IVT. Whether through written or verbal consent, the goal remains to ensure that patients or their surrogate decision makers are adequately informed and involved in the decision-making process, while prioritizing prompt initiation of treatment for optimal outcomes.

Review of current IC practices for IVT

Content of information shared and decision-making capacity

Studies examining the content of information and the style of information sharing in relation to IVT have revealed significant variations across and within sites. A survey conducted among neurology residents and attendings at academic and non-academic institutions in the Netherlands found that the information disclosed to patients and their caregivers included stroke diagnosis, the mechanism of action of IVT, the benefits of IVT, and the risks of IVT [33]. The percentages of neurology residents disclosing this information were 87% for stroke diagnosis, 78% for the mechanism of action of IVT, 60% for the benefits of IVT, and 67% for the risks of IVT [33]. Furthermore, when adverse effects of IVT were discussed, the risk of intracranial haemorrhage was mentioned in 100% of cases. Other side effects such as angioedema were also frequently shared [33]. Comparatively, when attending physicians were surveyed, they reported that residents under their supervision, shared information on stroke diagnosis, IVT risks vs benefits, and mechanism of IVT 76%, 53%, and 55% of the time, respectively, thus indicating variation in the perceived importance of completing these tasks. Information on the time-dependent requirement for IVT was disclosed at a relatively high frequency, reported at approximately 76% [33]. Additionally, nearly 40% of respondents shared that the recommended treatment aligns with national guidelines. [33]

According to one retrospective review, decision making capacity was judged to be adequate in only 14% of patients (9/63) with the majority of patients considered to either have diminished or impaired capacity for IVT consent [34]. Not surprisingly, however, the same study found that medical records frequently lacked enough information to ascertain capacity in patients.

Frequency of obtaining informed consent for IVT

Several studies have examined the frequency of obtaining IC prior to administering IVT, revealing differences in practices among clinicians. These studies, as summarized in Fig. 2, have demonstrated that most clinicians do obtain some form of IC for IVT, but there is substantial variability. For example, a study from the Netherlands reported that the proportion of resident physicians who explicitly obtained consent was higher than that of neurology attendings. Among neurology residents, 99% obtained some form of consent prior to IVT (33% always, 40% often, and 21% sometimes), while only 65% of neurology attendings obtained consent (21% always, 26% often, and 18% sometimes) (Fig. 2). Interestingly, 6% of neurology residents compared to 18% of neurology attendings reported that seeking consent prior to IVT was not necessary [33]. The reasons cited for not obtaining consent included: proven and effective treatment; impaired decision-making capacity; and the need to act in the best interest of the patient in a timely manner [33]. The reasons cited for obtaining IC included legal and moral obligation, risk for adverse events, invasive treatment and no real cause for delay. [32]

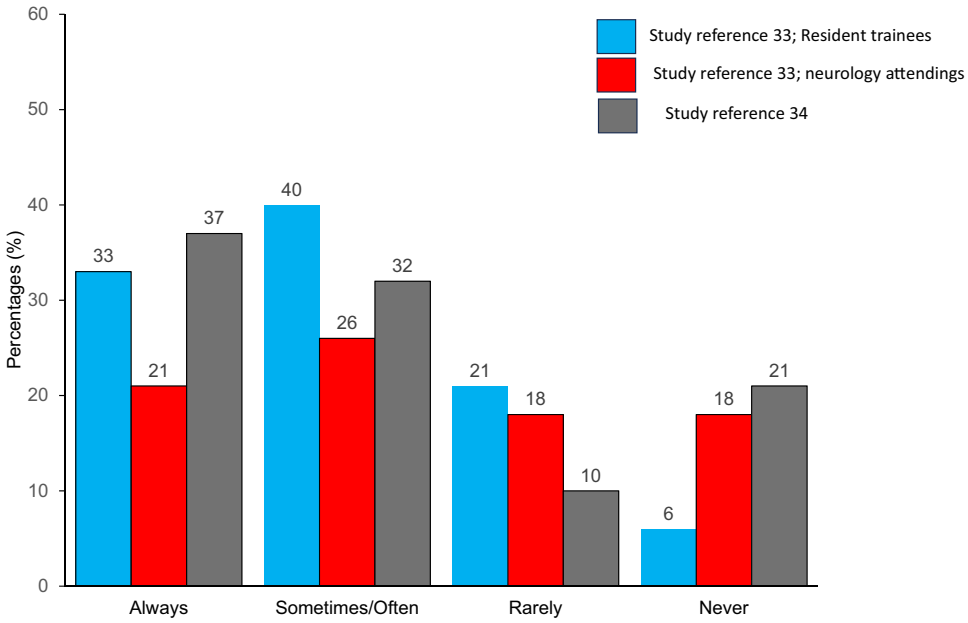

Fig. 2 Figure showing a summary of the frequency of obtaining informed consent prior to administering IVT as reported in two studies reviewed [33, 34]

Similarly, in a national online survey conducted in the United States involving neurology and emergency medicine attending physicians/residents, significant variation in IC practices for patients presenting within the 3-h time window was also noted. Among the respondents, 21% reported never seeking consent prior to administering IVT. Among those who obtained consent, only 37% reported always obtaining IC, while the remainder obtained it rarely (11%), sometimes (15%), and often (17%). [34]

A retrospective study of 63 patients who received IVT at 10 hospitals in Connecticut found that 84% had documentation of IC. Among these patients, 30% provided their own consent, while for the remaining 70%, surrogates provided consent on their behalf. Interestingly, surrogates frequently provided consent even when patients were considered to have capacity, and conversely, 18% of patients who lacked capacity provided their own consent [33].

In a multicentre study that included 38 Veterans Health Administration hospital locations, clinicians were surveyed on consent practices for IVT. The study found that a significant majority of stroke clinicians (38%) did not believe that any form of consent was necessary, while only 47% thought that some form of consent was necessary. Remarkably, 15% of stroke clinicians were unsure. Among clinicians who believed IC was necessary prior to IVT, there was a division on whether consent should be written (40%) or verbal (60%).

At an institutional level, a survey of hospitals in New York found that more than 80% of New York State Department-designated Stroke centres require some form of consent prior to IVT administration. Specifically, IC (written or verbal) was required by 82% of hospitals for patients presenting within the 3-h window and 92% of the time for those presenting in the 3–4.5-h IVT treatment window. Written consent was more commonly required for those presenting in the 3–4.5-h window compared to those presenting in the 3-h window (64% vs 34%). Conversely, IC was not required in 18% of cases within the 3-h window and 7.2% within the 4.5-h window. Furthermore, among hospitals that required IC, there was a 98% agreement in allowing for surrogate consent. [35]

Review of current IC practices for EVT

The current landscape of IC practices in EVT remains relatively understudied. However, due to the clinical distinctions between EVT and IVT and the unique circumstances in which these treatments are performed, it is crucial to explore and develop specific approaches to IC for each modality. While IVT involves the administration of medication through a peripheral vein at the bedside, EVT is considered a significantly more invasive procedure or surgery. This differentiation raises important considerations for obtaining IC.

Regulations outlined by the Centres for Medicare and Medicaid Services stipulate that hospitals conducting any surgical operation must acquire IC and document it in the patient's chart before the procedure takes place. [36] Consequently, most hospitals providing Medicare and Medicaid services in the United States have included IC as a mandatory requirement prior to EVT. Whether this is the case in countries outside of the United States is unknown. A survey conducted in the United States among healthcare providers revealed that IC was obtained in 92% of participants (139/159) who underwent EVT, while deferred consent was only employed in a minority of cases (8%, 20/159). [37] Among the situations in which IC was obtained, the majority (75%, 119/139) of patients received EVT based on in-person consent, while the remaining 25% (20/139) were consented through virtual means, such as telephone encounters [37]. In cases where deferred consent was utilized, the two-physician rule, which considers medical necessity, was applied. Despite a significant delay in imaging for patients who obtained in-person consent as compared to those consented virtually (117 min versus 101 min, $p=0.01$), there was no difference in short-term outcomes at discharge (28% versus 30%, $p=0.8$). [37]

These findings emphasize the need for further investigation of IC practices in EVT to gain a broader understanding of IC practices in other geographical regions. Additionally, it is important to note that the aforementioned study was conducted prior to the publication of the pivotal EVT trials in 2015, which have not only expanded the inclusion criteria for EVT but provided high level evidence strongly supporting EVT for all eligible patients. It remains unclear, how this data has influenced physician IC practices for eligible patients in the modern EVT era. Therefore, conducting studies that aim to enrich our understanding of current practices regarding IC for EVT, including any potential variability is warranted. These studies should ideally be diverse and comprehensive, in order to provide a representative depiction of the prevailing EVT IC landscape and allow for comparisons of global IC practices particularly after the publication of the 2015 EVT clinical trials. Studies should also address the alignment of current IC practices for EVT with ethical principles and regulatory requirements. Additionally, investigating the impact of different IC approaches on patient outcomes is essential for advancing our knowledge in this area [37].

Discussion

There is substantial variation in approaches to obtaining IC for acute stroke treatments. While there is a general acceptance for IC prior to IVT, practices vary widely among hospitals and physicians [32–35]. The consistency of requiring

consent ranges from 21 to 37%, influenced by factors such as age, specialty, and hospital size [32–35]. Interestingly, one of the studies reviewed, conducted in New York, demonstrated that the stringency of consent requirements is higher for patients presenting within the 3–4.5-h window compared to the 0–3-h window, [35] which may be attributed to FDA's approval for IVT being limited to use within the first 3 h only. However, it remains unclear whether this level of stringency is also prevalent in European countries, where the European Medicines Agency has extended the approval for IVT use up to 4.5 h following stroke onset. It is additionally unclear if this cautious approach has evolved over time with increasing experience with IVT use, and the growing evidence base and clinical guidelines supporting use of IVT after 3 h. Therefore, further research is needed to understand the reasons, sources, and scope of variation in consent practices including how clinical experiences, and regulatory approvals, shapes clinician perspectives on IC. This information is vital in achieving a standardized patient-centred approach to IC in acute stroke treatments by ensuring consistency among clinicians.

Importantly, we found that there is a striking lack of studies specifically assessing the content of information shared during IC for both IVT and EVT. A single study evaluating the content of information shared during IC for IVT reported significant variations in this domain. Whilst information on stroke diagnosis was commonly shared with patients and their healthcare proxies, details regarding the mechanism of IVT and the associated risks benefits were only shared in approximately one-half to two-thirds of cases. We did not find a single study evaluating content shared during IC for EVT. These finding highlight the necessity to develop streamlined IC guidelines that clearly specify the information required to be shared with all stroke patients. The aim of such a guideline would be to promote uniformity and enhance the IC process for both IVT and EVT. Furthermore, future studies should evaluate the ideal quantity and quality of information including the use of qualitative versus quantitative language, its impact on information comprehension and retention, and ultimately, the overall effectiveness of the IC process.

Obtaining IC for acute stroke treatments is challenging, especially when patients lack decision-making capacity [38]. Common deficits like aphasia, neglect, and altered sensorium can hinder patients' ability to understand and make informed decisions [25]. However, a notable obstacle is the absence of a stroke-specific standardized tool to assess capacity in acute ischemic stroke patients. Existing tools, such as the Mini-Mental Status Test, are not well-suited for this population and can be time-consuming [39, 40]. This deficiency likely explains findings from one of the studies reviewed which reported that it is not uncommon for patients without capacity to provide their own consent, which is inappropriate [33]. To address this gap, future efforts should focus on developing simplified stroke specific assessment tools that incorporate relevant signs and symptoms from standardized scales such as the National Institutes of Health Stroke Scale (NIHSS). These tools should consider patients with low literacy levels and primarily focus on streamlining the capacity assessment to ensure strict fidelity of the process.

Patients who lack decision-making capacity pose another significant challenge in the IC process, often necessitating reliance on healthcare proxies [38]. However, the availability and familiarity or comfort of proxies can be unpredictable, leading to delays in obtaining consent [25]. Clear guidance on how to proceed in these situations is needed to streamline the process while preserving shared decision-making. The use of standardized decision aids and simplified materials, such as graphs, can enhance communication with healthcare proxies and facilitate understanding [41]. In cases where patients lack capacity and a healthcare proxy is unavailable, the American Academy of Neurology recommends initiating IVT based on presumed consent for emergency therapy [31]. Similarly, for unrepresented patients requiring EVT, presumed consent based on medical necessity is typically followed as recommended by regulatory bodies [31, 36]. Future research should focus on developing and implementing standardized protocols and guidelines tailored to the IC process for acute stroke treatments in patients lacking capacity and representation.

Finally, achieving true IC for acute stroke while upholding ethical principles is challenging due to the high-stress and time-sensitive nature of the disease [42]. Acute stroke usually occurs without warning, placing patients and their loved ones in an uncharted territory. It is, therefore, unsurprising that nearly half of patients with stroke, do not remember the content of information shared as part of IC [2]. In recognition of this challenge, alternative ethical frameworks, such as implied or waived consent and informed refusal, have been proposed for IVT and EVT-eligible patients [42]. These frameworks emphasize the reality that acute stroke is a life threatening condition requiring prompt treatment, and that both IVT and EVT are most effective when administered early to appropriate candidates [7]. Further, most professional society guidelines for acute stroke care underscore the need to initiate stroke treatment without delay. The alternative framework of implied consent proposes that acute stroke patients with a clear indication for IVT or EVT should receive immediate treatment without the explicit requirement for a lengthy IC process in order to maximise the benefits of early intervention. While patients and their caregivers are still informed about treatment, albeit in an abbreviated fashion, this approach could potentially compromise patient autonomy and potentially lead to mistrust if complications were to arise or if treatment is discordant with patient goals.

Alternatively, the framework of informed refusal proposes that instead of seeking explicit consent, clinicians present a comprehensive treatment plan that includes diagnosis, prognosis, treatment risks and benefits and treatment alternatives and allow for informed refusal (i.e., assent or dissent) of treatment. This approach may offer a more patient-centred decision-making process while reducing the burden on healthcare proxies, within the complex environment of acute stroke care. However, how to operationalize these frameworks in clinical practice and expediently determine patient capacity to assent or dissent requires further study.

This review provides valuable insights into IC practices for acute stroke treatments, but several limitations should be acknowledged. Firstly, the generalizability of the findings may be limited due to the geographic focus of the included studies as most studies reviewed were from two countries: the United States and the Netherlands. It is important to consider that consent practices may vary across different healthcare settings and cultural contexts. Secondly, the reliance on self-reported data from healthcare providers introduces the possibility of response biases and inaccuracies. Clinician perceptions and practices may not always align with their reported behaviours. Lastly, the review does not address the perspectives and experiences of patients and their families. Yet, understanding their viewpoints can likely provide valuable insights into the IC process, including the impact of IC on patient outcomes and satisfaction. Future research should strive to include the perspectives of patients and their families to gain a more comprehensive understanding of the IC process in acute stroke treatments.

Conclusion

In conclusion, this review highlights the significant variability in IC practices for IVT in acute stroke therapy, emphasizing the need for improved standardization and training in clinical practice. The lack of data on IC practices for EVT underscores a critical knowledge gap. Challenges, related to capacity assessment, reliance on healthcare proxies, dealing with unrepresented patients, and lack of standardised guidance for the information to be shared, likely contribute to the variability in IC practices. Future directions should focus on developing standardized decision aids utilizing simplified information presentation and investigating the impact on the quality of IC for acute stroke treatments. The development of formal tools for assessing capacity and the harmonization of IC standards across different sites is crucial. Ultimately, the goal is to enhance IC practices by standardizing content, format, and delivery while upholding patient autonomy and ensuring timely treatment of acute stroke.

Funding None.

Declarations

Conflicts of interest AAM has no conflicts to report. MJH has no conflicts to report. AAD has no conflicts to report. QJM has no conflicts to report. JAH serves as a consultant for Medtronic on a DSMB for Rapid Medical. TLM serves on a DSMB for Rapid Medical. NSR has no conflicts to report. ABP serves as a consultant for Medtronic, Microvention, and Penumbra. RWR serves on a DSMB for Rapid Medical.

References

1. Varkey B (2021) Principles of clinical ethics and their application to practice. Méd Princ Pract 30(1):17–28. https://doi.org/10.1159/000509119
2. Schuster L, Essig F, Daneshkhah N et al (2022) Ability of patients with acute ischemic stroke to recall given information on intravenous thrombolysis: results of a prospective multicenter study. Eur Stroke J 8(1):241–250. https://doi.org/10.1177/23969873221143856
3. Kraft AW, Awad A, Rosenthal JA et al (2022) In a hub-and-spoke network, spoke-administered thrombolysis reduces mechanical thrombectomy procedure time and number of passes. Interv Neuroradiol 29(3):315–320. https://doi.org/10.1177/15910199221087498
4. Meyer L, Bechstein M, Bester M et al (2021) Thrombectomy in extensive stroke may not be beneficial and is associated with increased risk for hemorrhage. Stroke 52(10):3109–3117. https://doi.org/10.1161/strokeaha.120.033101
5. Thomas L, Viswanathan A, Cochrane TI et al (2012) Variability in the perception of informed consent for IV-tPA during telestroke consultation. Front Neurol 3:128. https://doi.org/10.3389/fneur.2012.00128
6. Roger VL, Go AS, Lloyd-Jones DM et al (2011) Heart disease and stroke statistics—2011 update. Circulation 123(4):e18–e209. https://doi.org/10.1161/cir.0b013e3182009701
7. Powers WJ, Rabinstein AA, Ackerson T et al (2019) Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: a guideline for healthcare professionals from the American heart association/American stroke association. Stroke 50(12):e344–e418. https://doi.org/10.1161/str.0000000000000211
8. Regenhardt RW, Turner AC, Hirsch JA et al (2022) Sex-specific differences in presentations and determinants of outcomes after endovascular thrombectomy for large vessel occlusion stroke. J Neurol 269(1):307–315. https://doi.org/10.1007/s00415-021-10628-0
9. Janssen PM, Chalos V, van den Berg SA et al (2019) Neurological deficits in stroke patients that may impede the capacity to provide informed consent for endovascular treatment trials. J Stroke Cerebrovasc Dis 28(12):104447. https://doi.org/10.1016/j.jstrokecerebrovasdis.2019.104447
10. Regenhardt RW, Nolan NM, Rosenthal JA et al (2022) Understanding delays in MRI-based Selection of large vessel occlusion stroke patients for endovascular thrombectomy. Clin Neuroradiol 32(4):979–986. https://doi.org/10.1007/s00062-022-01165-y
11. Kuriakose D, Xiao Z (2020) Pathophysiology and treatment of stroke: present status and future perspectives. Int J Mol Sci 21(20):7609. https://doi.org/10.3390/ijms21207609
12. Takase H, Regenhardt RW (2020) Motor tract reorganization after acute central nervous system injury: a translational perspective. Neural Regen Res 16(6):1144–1149. https://doi.org/10.4103/1673-5374.300330

13. Regenhardt RW, Singhal AB, He J, Gonzalez RG, Lev MH (2023) Percent insular ribbon infarction for predicting infarct growth rate and 90-day outcomes in large-vessel occlusive stroke: secondary analysis of prospective clinical trial data. Am J Roentgenol 221(1):103–113. https://doi.org/10.2214/ajr.22.28852
14. Schneider AM, Regenhardt RW, Dmytriw AA, Patel AB, Hirsch JA, Buchan AM (2023) Cerebroprotection in the endovascular era: an update. J Neurol, Neurosurg Psychiatry 94(4):267–271. https://doi.org/10.1136/jnnp-2022-330379
15 Kraft AW, Regenhardt RW, Awad A et al (2023) Spoke-administered thrombolysis improves large-vessel occlusion early recanalization: the real-world experience of a large academic hub-and-spoke telestroke network. Stroke: Vasc Interv Neurol. https://doi.org/10.1161/svin.122.000427
16. Singh N, Menon BK, Dmytriw AA, Regenhardt RW, Hirsch JA, Ganesh A (2023) Replacing alteplase with tenecteplase: is the time ripe? J Stroke 25(1):72–80. https://doi.org/10.5853/jos.2022.02880
17 Group NI of ND and S rt PSS (1995) Tissue plasminogen activator for acute ischemic stroke. New Engl J Med 333(24):1581–1588. https://doi.org/10.1056/nejm199512143332401
18 Hacke W, Kaste M, Bluhmki E et al (2008) Thrombolysis with alteplase 3 to 4.5 hours after acute ischemic stroke. New Engl J Med 359(13):1317–1329. https://doi.org/10.1056/nejmoa0804656
19. Goyal M, Menon BK, van Zwam WH et al (2016) Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. Lancet 387(10029):1723–1731. https://doi.org/10.1016/s0140-6736(16)00163-x
20. Nolan NM, Regenhardt RW, Koch MJ et al (2021) Treatment approaches and outcomes for acute anterior circulation stroke patients with tandem lesions. J Stroke Cerebrovasc Dis 30(2):105478. https://doi.org/10.1016/j.jstrokecerebrovasdis.2020.105478
21 Regenhardt RW, Awad A, Kraft AW et al (2021) Characterizing reasons for stroke thrombectomy ineligibility among potential candidates transferred in a hub-and-spoke network. Stroke: Vasc Interv Neurol. https://doi.org/10.1161/svin.121.000282
22 Regenhardt RW, Rosenthal JA, Dmytriw AA et al (2021) Direct to angio-suite large vessel occlusion stroke transfers achieve faster arrival-to-puncture times and improved outcomes. Stroke: Vasc Interv Neurol. https://doi.org/10.1161/svin.121.000327
23 Ahmed RA, Dmytriw AA, Patel AB et al (2022) Basilar artery occlusion: A review of clinicoradiologic features, treatment selection, and endovascular techniques. Interv Neuroradiol. https://doi.org/10.1177/15910199221106049
24. Flite CA, Harman LB (2013) Code of ethics: principles for ethical leadership. Perspect Heal Inf Manag 10:1d
25. Demarquay G, Derex L, Nighoghossian N et al (2005) Ethical issues of informed consent in acute stroke. Cerebrovasc Dis 19(2):65–68. https://doi.org/10.1159/000083250
26. Sokol LL, Hauser JM, Lum HD et al (2021) Goal-concordant care in the era of advanced stroke therapies. J Palliat Med 24(2):297–301. https://doi.org/10.1089/jpm.2019.0667
27. Regenhardt RW, Young MJ, Etherton MR et al (2021) Toward a more inclusive paradigm: thrombectomy for stroke patients with pre-existing disabilities. J NeuroInterventional Surg 13(10):865–868. https://doi.org/10.1136/neurintsurg-2020-016783
28. Young MJ, Regenhardt RW, Sokol LL, Leslie-Mazwi TM (2021) When should neuroendovascular care for patients with acute stroke be palliative? AMA J Ethics 23(10):E783-793. https://doi.org/10.1001/amajethics.2021.783
29. Courtwright A, Rubin E (2016) Who should decide for the unrepresented? Bioethics 30(3):173–180. https://doi.org/10.1111/bioe.12185
30. Young MJ (2020) Compassionate care for the unconscious and incapacitated. Am J Bioeth 20(2):55–57. https://doi.org/10.1080/15265161.2019.1701734
31 Sattin JA, Chiong W, Bonnie RJ, Kirschen MP, Russell JA, Law and HC a joint committee of the AA of NANA and CNS on behalf of the E (2022) Consent Issues in the management of acute ischemic stroke. Neurology 98(2):73–79. https://doi.org/10.1212/wnl.0000000000013040
32. Zonjee VJ, Slenders JPL, de Beer F et al (2021) Practice variation in the informed consent procedure for thrombolysis in acute ischemic stroke: a survey among neurologists and neurology residents. BMC Méd Ethics 22(1):114. https://doi.org/10.1186/s12910-021-00684-6
33. Rosenbaum JR, Bravata DM, Concato J, Brass LM, Kim N, Fried TR (2004) Informed consent for thrombolytic therapy for patients with acute ischemic stroke treated in routine clinical practice. Stroke 35(9):e353–e355. https://doi.org/10.1161/01.str.0000136555.28503.55
34. Mendelson SJ, Courtney DM, Gordon EJ, Thomas LF, Holl JL, Prabhakaran S (2018) National practice patterns of obtaining informed consent for stroke thrombolysis. Stroke 49(3):765–767. https://doi.org/10.1161/strokeaha.117.020474
35. Weintraub MI, Colello AD, Johnson SA et al (2017) Informed consent for intravenous tissue plasminogen activator in New York State designated stroke centers. J Stroke Cerebrovasc Dis 26(6):1274–1279. https://doi.org/10.1016/j.jstrokecerebrovasdis.2017.01.021
36. § 482.51 Condition of participation: Surgical services. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-D/section-482.51
37. Qureshi AI, Gilani S, Adil MM et al (2014) Pattern of informed consent acquisition in patients undergoing emergent endovascular treatment for acute ischemic stroke. J Vasc Interv Neurol 7(2):21–25
38. Wade DT, Kitzinger C (2019) Making healthcare decisions in a person's best interests when they lack capacity: clinical guidance based on a review of evidence. Clin Rehabil 33(10):1571–1585. https://doi.org/10.1177/0269215519852987
39. Akinsanya J, Diggory P, Heitz E, Jones V (2009) Assessing capacity and obtaining consent for thrombolysis for acute stroke. Clin Med 9(3):239–241. https://doi.org/10.7861/clinmedicine.9-3-239
40. Etchells E, Darzins P, Silberfeld M et al (1999) Assessment of patient capacity to consent to treatment. J Gen Intern Med 14(1):27–34. https://doi.org/10.1046/j.1525-1497.1999.00277.x
41 Decker C, Chhatriwalla E, Gialde E et al (2015) Patient-centered decision support in acute ischemic stroke. Circ: Cardiovasc Qual Outcomes. 8(6 & lowbar;suppl_3):S109–S116. https://doi.org/10.1161/circoutcomes.115.002003
42 Schwamm LH (2018) Acute stroke. Circ: Cardiovasc Qual Outcomes 8(6 suppl 3):S69–S72. https://doi.org/10.1161/circoutcomes.115.002282
43. Emberson J, Lees KR, Lyden P et al (2014) Effect of treatment delay, age, and stroke severity on the effects of intravenous thrombolysis with alteplase for acute ischaemic stroke: a meta-analysis of individual patient data from randomised trials. Lancet 384(9958):1929–1935. https://doi.org/10.1016/s0140-6736(14)60584-5
44 Kim JT, Fonarow GC, Smith EE et al (2017) Treatment with tissue plasminogen activator in the golden hour and the shape of the 4.5-hour time-benefit curve in the national united states get with the guidelines-stroke population. Circulation

135(2):128–139. https://doi.org/10.1161/circulationaha.116.023336
45. Jovin TG, Nogueira RG, Lansberg MG et al (2022) Thrombectomy for anterior circulation stroke beyond 6 h from time last known well (AURORA): a systematic review and individual patient data meta-analysis. Lancet 399(10321):249–258. https://doi.org/10.1016/s0140-6736(21)01341-6