Informed Consent for IV t-PA in New York State Designated Stroke Centers: A Current Snapshot

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Introduction

The New York State Department of Health (NYS DOH) began designation of Stroke Centers in 2004. Investigators sought to ascertain current informed consent procedures in the IV t-PA treatment windows.

Hypothesis

There is an association between IV t-PA informed consent practices and hospital demographics among NYS DOH Stroke Centers across treatment windows.

Methods

- Hospitals were sent a 13-question online survey to determine whether written, verbal or no consent was required within the 0-3 hour and 3-4.5 hour treatment windows.
- Surveys were conducted in August and September of 2014. Hospital size, academic vs. non-academic and classification authorizers of consent were obtained.
- Chi-square tests were used to assess possible association between demographic measures and whether or not consent was required in either treatment window.

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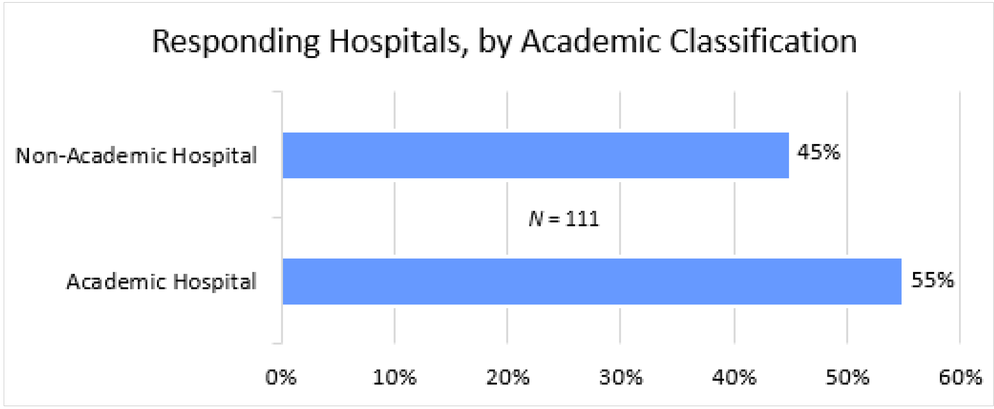

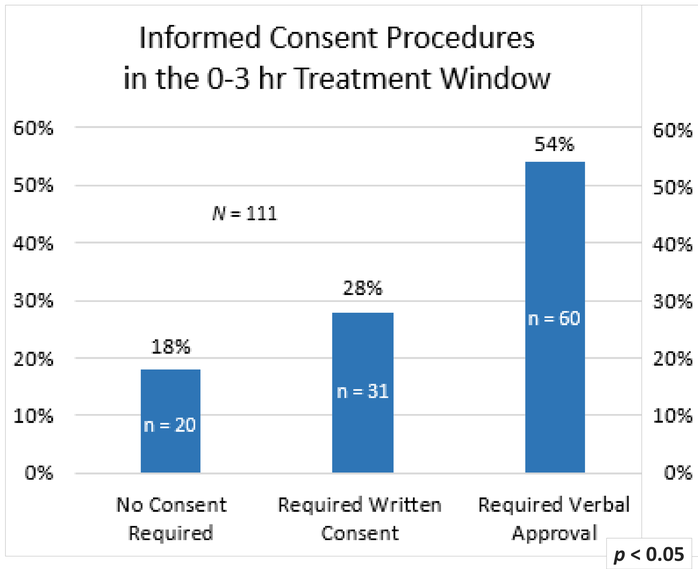

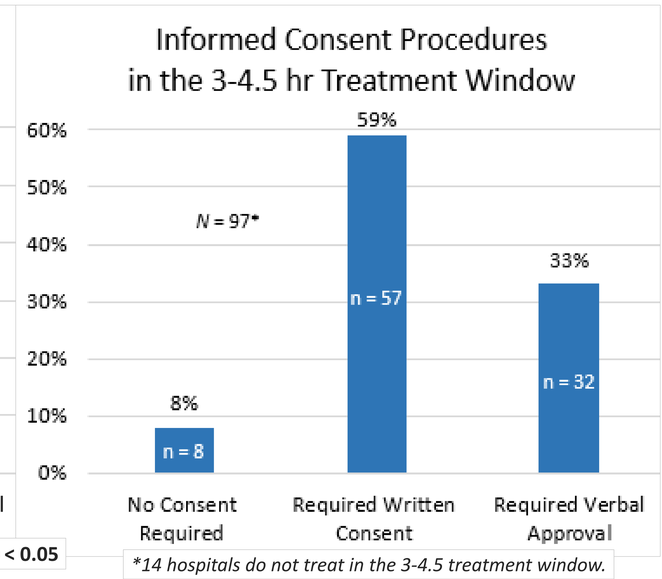

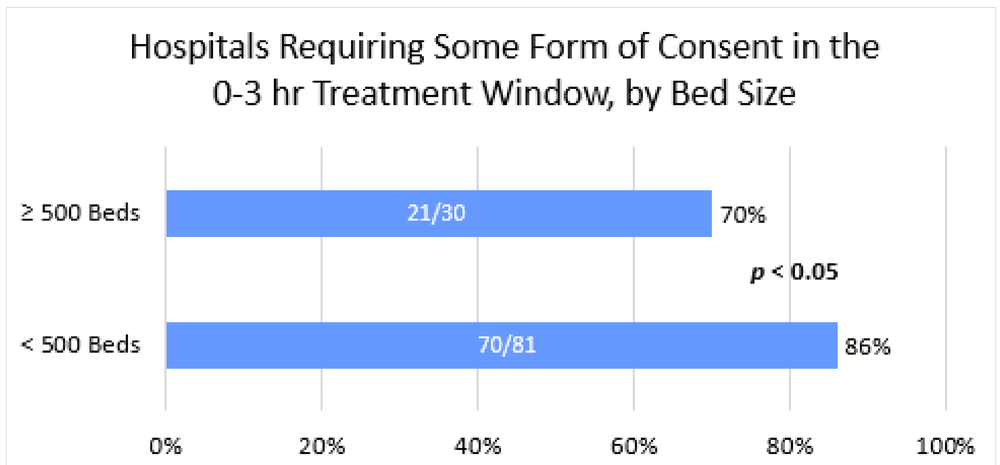

Results

One hundred and eleven of the 117 Stroke Centers responded (95%). Within the 3-hour treatment window, 28% required written consent compared to 54% that required verbal approval, and in the 3-4.5 hour treatment window, 97 (87%) used IV t-PA with 59% requiring written consent, compared to 33% requiring verbal discussion only ($p < 0.05$). Combining both treatment windows, 98% accepted a health care proxy or surrogate to give consent in lieu of the patient. Among hospitals with fewer than 500 beds, 86% (70/81) did require some form of written or verbal consent within the 3-hour treatment window, compared to only 70% (21/30) of hospitals with 500+ beds ($p < 0.05$). Beyond the 3-hour treatment window, there was no significant association between bed size and consent requirement. Fifty-five percent of hospitals were academic vs. 45% non-academic. Academic status was not related to form of consent during either time window.

Conclusions

The majority of hospitals did not require written consent within the 3-hour treatment window, but did require written consent for the 3-4.5 hour treatment window (2-fold increase in latter window). Smaller hospitals were significantly more likely than larger hospitals to require any form of consent in the 0-3 hour window. Further research should be conducted to determine whether this variability in consent for IV t-PA affects clinical outcomes, which may in turn impact health policy and practice.