STROKE Perception Report©
Study Protocol

Study Aim: To analyze the psychometric properties of the STROKE Perception Report© as an instrument to measure patient/family perception of the quality of acute stroke care.

Protocol: To test the psychometric properties of the STROKE Perception Report©, a total national sample of 2500 instruments will be completed by acute stroke patients/families admitted to 25 U.S. hospitals. There is no limit on the volume of instruments collected by any one site, although each participating hospital is encouraged to submit as close to 100 completed instruments as possible. Informed consent is not necessary, as completion of the instrument implies consent to participate in the study.

Inclusion Criteria –
- Hospital admission for any of the following primary diagnoses:
  - Ischemic stroke
  - Transient ischemic attack
  - Intracerebral hemorrhage
- Patient age ≥ 18 years of age.
- For completion of the instrument’s “Patient Version” – requirements include:
  - NIH Stroke Scale items 1ABC and item 9 scores totaling zero.
- For completion of the instrument’s “Family Version” – requirements include:
  - Family member or significant other designated as patient’s spokesperson and/or legally authorized next of kin.
  - Patient with neurologic disabilities that interfere with completion of the “Patient Version” of the instrument.

Exclusion Criteria –
- Admission for a primary diagnosis other than stroke, even if the patient subsequently develops a stroke during their hospital stay.
- Inability to complete the instrument prior to hospital discharge.

Methods –
The supplies needed to conduct this study include:
- STROKE Perception Report©, Patient & Family Versions
- Unmarked legal size envelopes
- Instrument collection box (this can be a cardboard box decorated by the study team with a slot or lid, or any other box that can be used for patients/family members to deposit completed instruments inside).

Procedures: On the day of hospital discharge, the local Principal Investigator (PI) or his/her designee will provide the patient or designated family member with a copy of the instrument and an envelope. The PI will explain the study aims and ask the patient/family to provide truthful responses to the items listed on the instrument, emphasizing that no identifying information should be placed on the instrument itself. It should be clearly
explained to the patient/family member that findings from the instrument will also be used to improve the care that is provided to acute stroke patients at the study hospital. The PI or his/her designee should also emphasize that the instrument should be completed privately without the presence or input of any hospital personnel. Completion of the instrument takes on average no more than 15 minutes.

Once the instrument is complete, the patient/family should be instructed to place the instrument into the envelope and seal it. The sealed envelope should then be placed in the instrument collection box kept at the hospital unit’s Nursing Station (or other convenient location determined by study personnel) prior to the patient’s departure from the hospital. Instruments completed after leaving the hospital will not be accepted.

The PI or his/her designee should attempt to collect the sealed envelopes from the instrument collection box at least once every 2 days, and should store them UNOPENED in a safe, secure place. The PI is responsible for mailing completed/sealed instruments to the Health Outcomes Institute for data entry and analysis. The mailing address is:

Health Outcomes Institute, Inc.
16410 E. Emerald Dr.
Fountain Hills, Arizona 85268

It is recommended that instruments be mailed in bundles of 10 to 20 (depending on the volume of stroke admissions at the study site), so that data can be input in a timely manner by study personnel and a report generated for the facility quarterly.

Statistical Analyses: Methods used to analyze data will include descriptive statistics, factor analysis, and correlational methods. An interim analysis will be conducted after collection of the first 100 instruments to determine problems inherent in wording that may interfere with meaningful interpretation of findings. A second interim analysis will be conducted when a total of 500 instruments have been collected to provide a glimpse of the instrument’s factor layout.

No changes may be made to study instruments except by the national PI, Dr. Alexandrov. Changes made by Dr. Alexandrov may occur after interim analyses of instrument properties. Should a change be made, all participating centers will be provided with the rational supporting the change, and new study instruments will be issued.