Understanding the Lived Experiences of Primary and Recurrent Stroke Survivors in the United States, with a Focus on Women: the ELEVATE Qualitative Study

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Introduction and Background

- 795,000 people in the United States (US) have a stroke every year, nearly one quarter of whom have previously had a stroke.[1] Transient ischemic attack (TIA) affects 240,000 people in the US annually and is a strong warning sign of subsequent stroke.[2]
- Previous qualitative research that examined the specific needs and experiences of survivors of recurrent stroke or TIA is limited.[3–5] There is a dearth of research exploring these topics that specifically focuses on Black or Hispanic populations, women, or US healthcare settings.
- The ELEVATE (Evidence-based Lived Experience of stroke to Voice the burden of disease And humanize the True Effects of stroke) study aims to address this gap by describing women survivors' experiences and exploring how inter-racial/ethnic factors influence their patient journey.

ELEVATE Study Objectives

- ELEVATE is a US-based, non-interventional, qualitative study.
- Women (Black, Hispanic, and non-Hispanic White) who have experienced one stroke/TIA or two or more stroke events are included. A sample of men who have experienced two or more stroke events is included for benchmarking.

Primary objective

The primary objective of ELEVATE is to describe women survivors' experiences of stroke, residual problems, care, and perceptions of recurrence risk, in total and by subgroups.

Secondary objectives

To describe and understand patient journeys of women survivors who have experienced one stroke/TIA or multiple stroke events.

To explore inter-racial/ethnic factors in women's patient journeys.

To describe the patient journeys of subgroups of women and men who have experienced multiple stroke events.

References

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Research Methods

- A steering committee (SC) of stroke survivors, care partners, patient advocacy group (PAG) leaders, and healthcare providers was formed to ensure patient needs and priorities are reflected in the study design, recruitment, and communications.
- Participants are recruited from SC-associated PAGs and may also be identified through other stroke networks and snowball sampling. Eligibility criteria are summarized in **Table 1**.

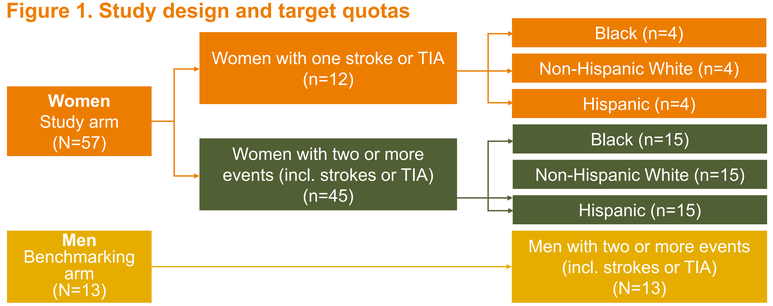
Table 1. Eligibility criteria

Major inclusion criteria	Major exclusion criteria
• Adult women ≥18 years of age with a self-confirmed diagnosis of either one stroke or one TIA or two or more strokes or a combination of one TIA and one or more stroke(s) **OR** • Adult men ≥18 years of age with a self-confirmed diagnosis of two or more strokes or a combination of one TIA and one or more stroke(s) • Non-Hispanic White or Black race, or Hispanic ethnicity • Understand, read, and speak English	• Self-confirmed diagnosis of stroke specifying bleeding on the brain (hemorrhagic stroke) • Self-confirmed diagnosis of atrial fibrillation • Live in a long-term care facility • Unable to communicate in their own words in an interview without assistance or interpretation from someone else

TIA, transient ischemic attack.

- Up to 70 participants will be interviewed. Participants are recruited until the target quotas for each subgroup are reached (**Figure 1**). An online survey is deployed to collect demographic and functional data, using a simplified modified Rankin Scale questionnaire to approximate respondents' level of physical functioning post-stroke.[6]

Figure 1. Study design and target quotas



TIA, transient ischemic attack.

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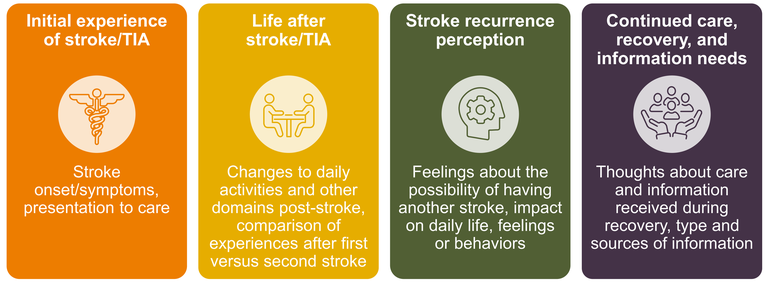
- One-time semi-structured interviews approximately 60 min in length are conducted with eligible participants who have provided their informed consent. Two versions of the interview discussion guide were developed: one for individuals who had one stroke/TIA and one for those with multiple stroke events (**Figure 2**). Participants receive an incentive payment after the interview.

Figure 2. Interview topics



TIA, transient ischemic attack.

- Interview concepts and themes will be continuously and iteratively reviewed until meaning saturation is achieved (ie, no further insights are found).[7] Additional interviews will be conducted to confirm saturation.
- Interview data will be analyzed using thematic analysis. Initial coding will identify key concepts, followed by iterative development and refinement of broader themes across interviews, aligned with the study objectives. Analyses will be conducted in Dovetail and all findings reported in aggregate.
- Recruitment is ongoing.

Conclusion

- ELEVATE aims to deepen our understanding of the experiences, unmet needs, and stroke-related education needs of US stroke/TIA survivors, particularly for women and racial/ethnic minorities who have experienced multiple stroke events.
- The study seeks to address a current gap in the knowledge about the lived experiences of stroke survivors. Its findings may guide the development of strategies and interventions to reduce stroke burden and better meet the specific needs of these populations.

Conflicts of Interest/Disclosures

CZ is a paid advisor of Sökerdata Ltd. SC and AW are employees of Bayer HealthCare Pharmaceuticals Inc. EM is an employee of Bayer AG. TM is an employee of Euroservices Bayer S.L. All employees of Bayer may own shares in the company. CC-G is a consultant for Bayer. LM is an advisor for Bayer. FR and CB have nothing to disclose.

To learn more about the study, contact the ELEVATE study team at ELEVATE@soker-data.com

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