Mobile Stroke Unit

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- MSU Program Update
- BEST-MSU Trial Results
- FASTEST Trial - Upcoming

Mobile Stroke Unit

- Novel and innovative
- Leverages pre-hospital systems of care
- Parallel processes

Fully operational 911 ambulance

- EMT and Paramedic

But that's not all…

- CT Scanner
- CT Technologist
- Stroke Nurse
- Vascular Neurologist
- Pharmacy
  - IV thrombolytics, anticoagulant reversal agents, anti-hypertensives

Sutter Health

San Mateo County MSU

Sutter Health | Mills-Peninsula Medical Center

1st MSU in Northern CA

ONLY community hospital in the country to pursue a Mobile Stroke Unit and participate in the BEST-MSU Clinical Trial

In operation since December 2018

Support:

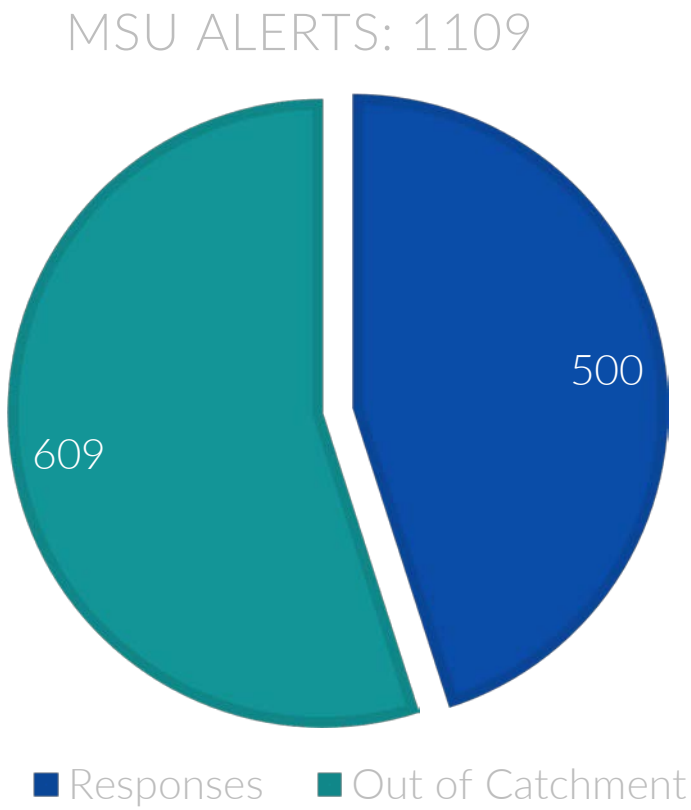
- Funded by philanthropic donations from the community and Sutter/Mills Peninsula hospital
- San Mateo County EMS
- San Mateo AMR
- Public Safety Communications
- San Mateo County
- MPMC and Sutter
- Other hospitals in SMC

MOBILE STROKE UNIT
CALL 911
TIME IS BRAIN

Sutter Health

Mobile Stroke Unit

- Alerts
- Transports
- Treatment Averages

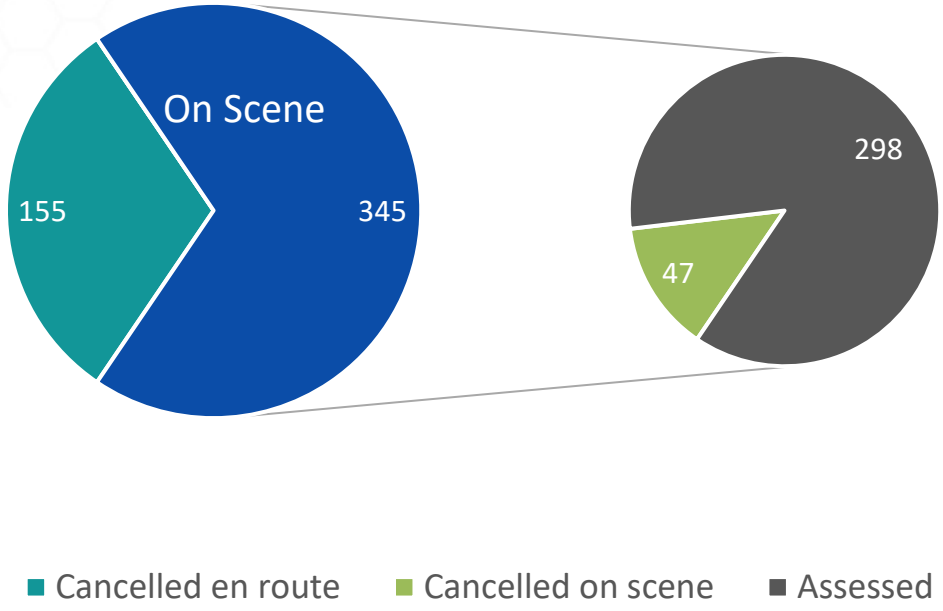


Data: Dec2018 - Dec 2021

Mobile Stroke Unit

- Alerts
- Transports
- Treatment Averages

MSU Responses: 500

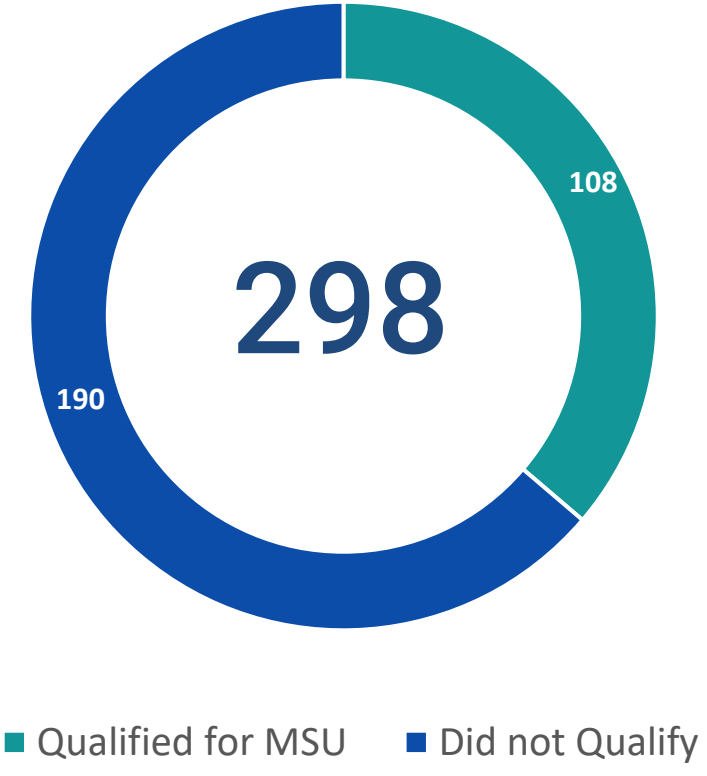


Data: Dec2018 - Dec 2021

Mobile Stroke Unit

- Alerts
- Transports
- Treatment Averages

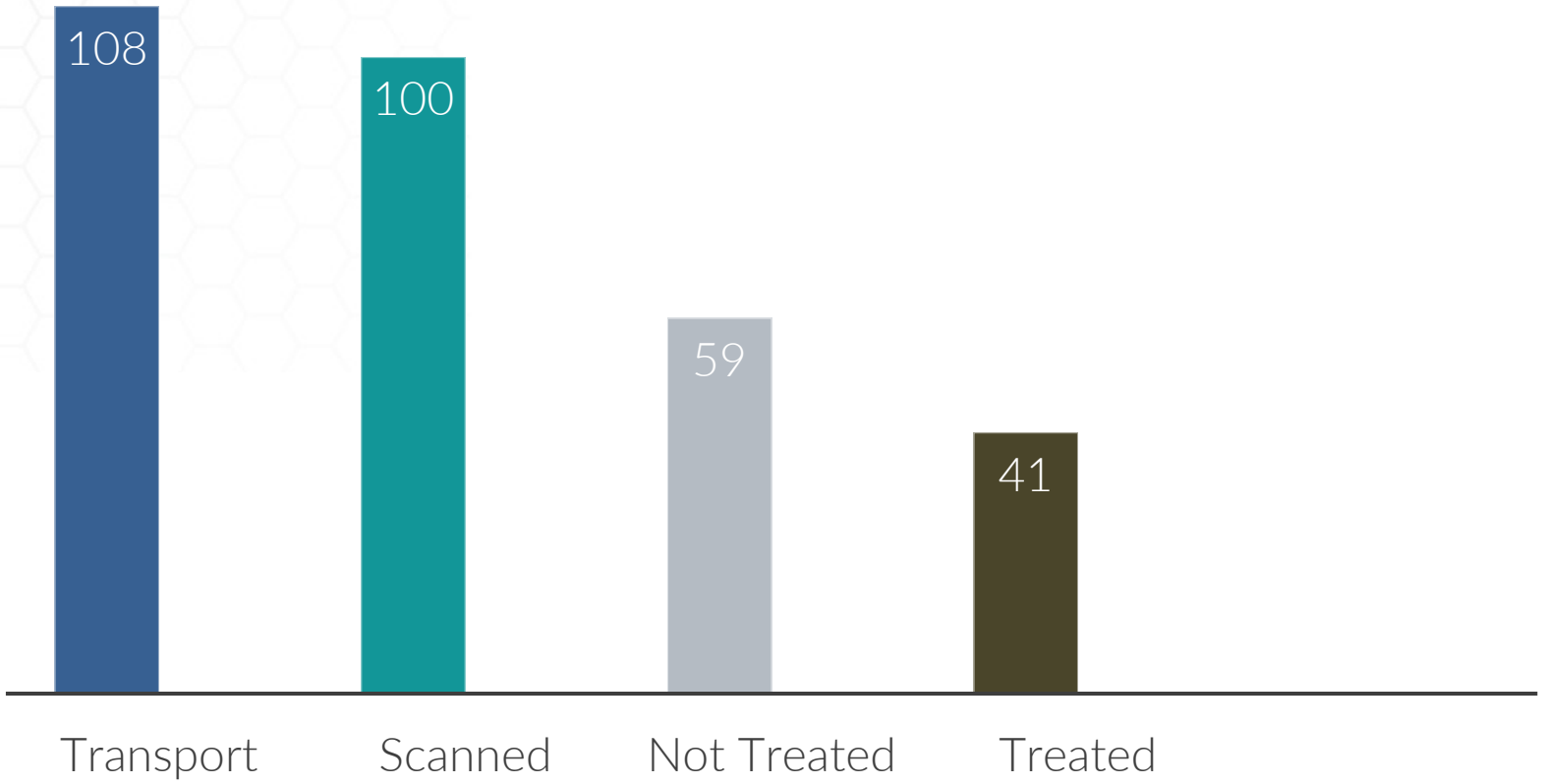
MSU Assessments



Data: Dec2018 - Dec 2021

Mobile Stroke Unit

- Alerts
- **Transports**
- Treatment Averages

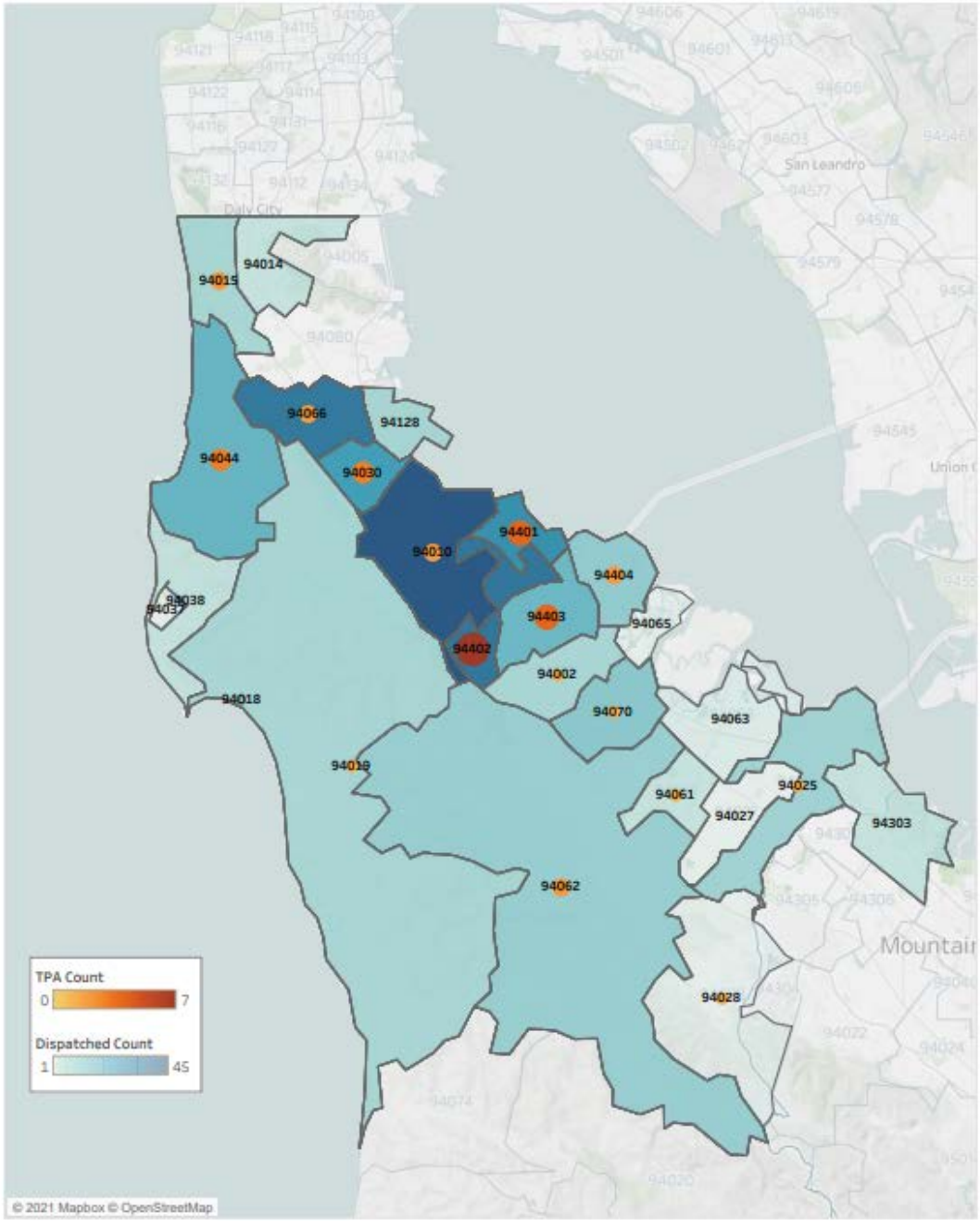


Data: Dec2018 - Dec 2021

Mobile Stroke Unit

- Alerts
- Transports
- Treatment Averages

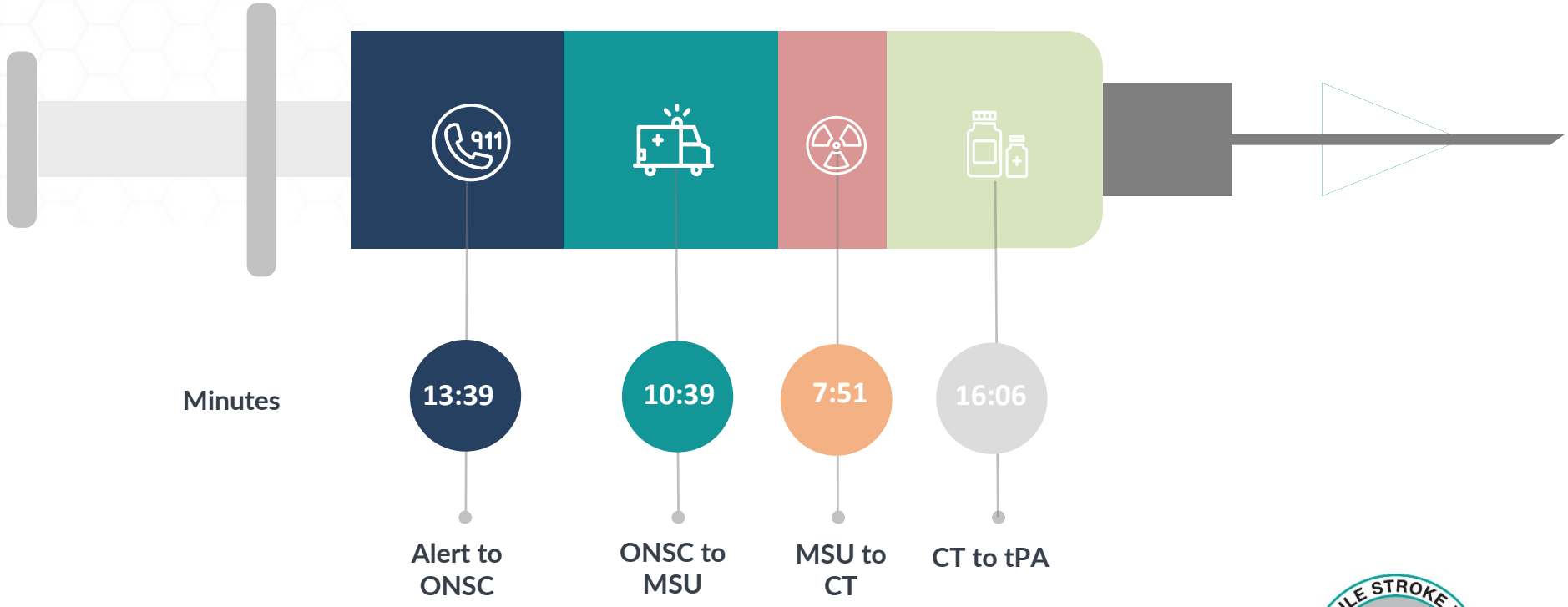
Mobile Stroke Unit (MSU): Number of Calls Dispatched & TPA Given



Data: Dec2018 - Dec 2021

Mobile Stroke Unit

- Alerts
- Transports
- **Treatment Averages**



Average MSU to tPA: 22:44 mins.

Data: Dec2018 - Dec 2021

BEST-MSU Clinical Trial

- Primary Outcomes:
  - 3 month functional outcomes (mRS) among tPA-eligible ischemic stroke patients
    - MSU vs. EMS + ED Standard Management
- Secondary Outcomes:
  - Cost effectiveness
  - Quality of Life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Prospective, Multicenter, Controlled Trial of Mobile Stroke Units

J.C. Grotta, J.-M. Yamal, S.A. Parker, S.S. Rajan, N.R. Gonzales, W.J. Jones, A.W. Alexandrov, B.B. Navi, M. Nour, I. Spokoyny, J. Mackey, D. Persse, A.P. Jacob, M. Wang, N. Singh, A.V. Alexandrov, M.E. Fink, J.L. Saver, J. English, N. Barazangi, P.L. Bratina, M. Gonzalez, B.D. Schimpf, K. Ackerson, C. Sherman, M. Lerario, S. Mir, J. Im, J.Z. Willey, D. Chiu, M. Eisshofer, J. Miller, D. Ornelas, J.P. Rhudy, K.M. Brown, B.M. Villareal, M. Gausche-Hill, N. Bosson, G. Gilbert, S.Q. Collins, K. Silnes, J. Volpi, V. Misra, J. McCarthy, T. Flanagan, C.P.V. Rao, J.S. Kass, L. Griffin, N. Rangel-Gutierrez, E. Lechuga, J. Stephenson, K. Phan, Y. Sanders, E.A. Noser, and R. Bowry

More Treatment.

Almost all eligible patients (97.1%) in the MSU group received the clot-busting medication tPA, compared to 79.5% of patients in the standard care group.

This represents nearly a quarter more patients (22.1% increase) who were able to receive timely treatment, compared to the standard care group.

Faster Treatment.

A third of patients (32.9%) in the MSU group were treated within 60 minutes of stroke onset compared to very few patients (2.6%) in the standard care group.

The median time from stroke onset to initiation of treatment was 36 minutes shorter in the MSU group compared to the standard care group (72 minutes vs. 108 minutes).

This potentially saves seventy-two million brain cells, as approximately two million brain cells die each minute that blood is not freely flowing to the brain.

Independent Recovery.

Over half of patients (55%) in the MSU group were able to return to normal lives and activities within three months of their stroke.

This represents nearly a quarter more patients (23.8% increase) with little or no disability at 90 days post stroke, compared to the standard care group.

These results mean that, for every 100 patients treated on an MSU, 27 will experience less disability following their stroke than they would have if they had received standard care, and 11 will have no disability 90 days after their stroke.

What's Next?

- Cost Effectiveness analysis - ETA Feb 2022
  - Tracking health care services (hospitalization, rehabilitation, skilled nursing care, etc.) used by patients in the first year after their stroke.
  - With the mean lifetime cost of ischemic stroke at approximately $140,048 and care for the first year post-stroke approximately double the cost of the initial hospitalization, treatment in an MSU is hypothesized to result in a lower total cost of care compared to standard EMS care, by delivering better clinical outcomes that minimize the need for ongoing care.
- More MSUs in operation
- Innovative integration into systems of care
- Legislation to support reimbursement AB1254
- Ongoing clinical research in early time window

FVIIa for Acute hemorrhagic Stroke Administered at Earliest Time (FASTEST) Trial

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

ICH: Old or Damaged Blood Vessels Break Under Pressure

Background

- Brain Hemorrhage or intracerebral hemorrhage (ICH) is a type of stroke that accounts for more than 10% of the estimated 17 million strokes worldwide each year or about 1,700,000 cases per year.
- More than 40% of patients die and only 20% of survivors are functionally independent at 6 months.
- The size of blood in the brain is the most important determinant of outcome and most bleeding occurs within 2-3 hours.
- There is no scientifically proven effective treatment for ICH.

Growth of bleeding in the Brain Leads to Bad Outcomes

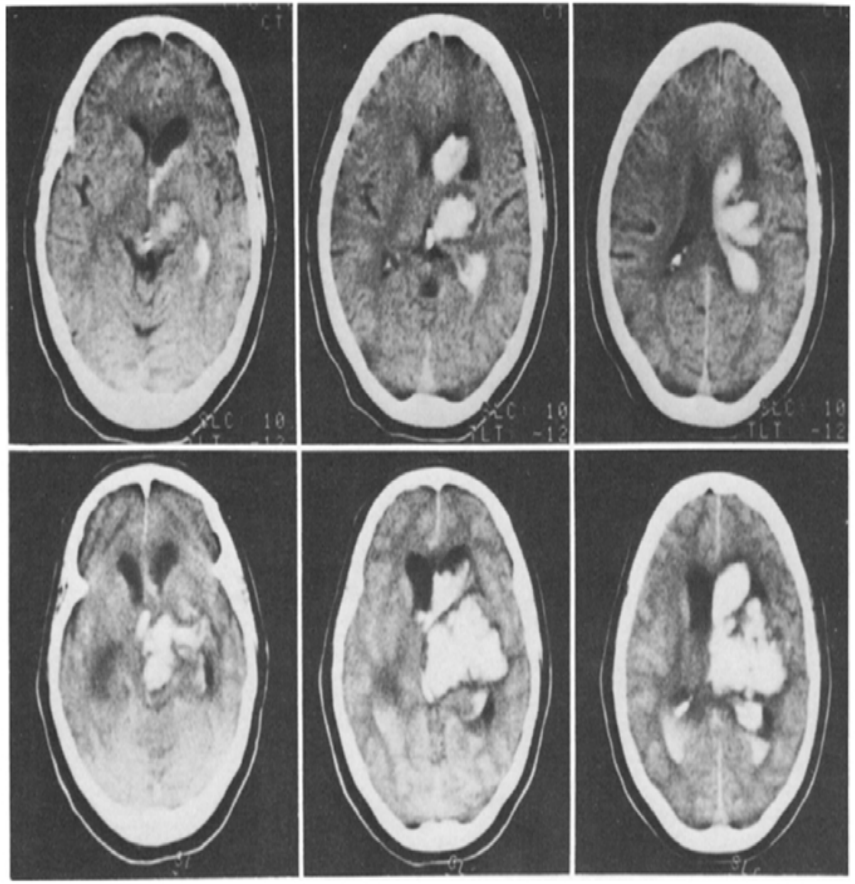

FIG. 2. Serial computerized tomography (CT) scans in Case 3. An increase in volume of hemorrhage from 8 to 35 cc was recorded between the first CT scans *(upper)*, obtained 50 minutes after onset of symptoms, and the second CT scans *(lower)*, obtained 210 minutes after onset.

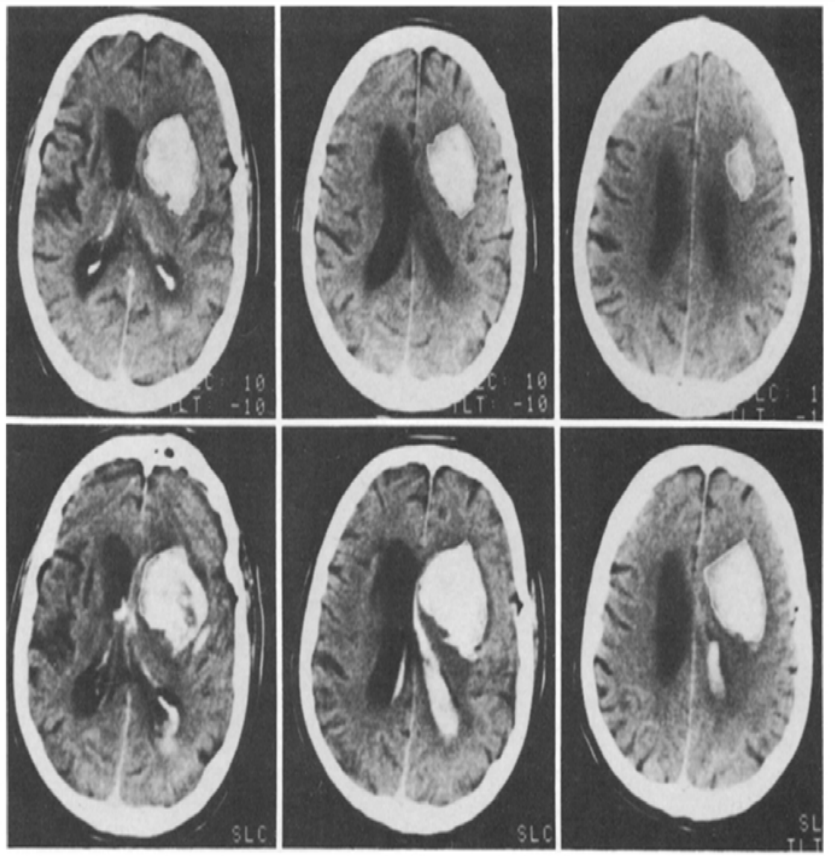

FIG. 1. Serial computerized tomography (CT) scans in Case 1. Measurement of the volume of hemorrhage revealed an increase from 25 to 44 cc between the first CT scans *(upper)*, obtained 35 minutes after onset of symptoms, and the second CT scans *(lower)*, obtained 105 minutes after onset.

J. Neurosurg: 72: 195-199, 1990

FASTEST

Treatment of Brain Hemorrhage

- Admission to intensive care unit.
- Treatment of blood pressure which is often very elevated.
- Often ventilator machine to help breathe.
- Treatments to help relieve pressure in the brain.
- Occasionally surgery to remove blood.
- THERE IS NO SCIENTIFICALLY PROVEN TREATMENT FOR BRAIN HEMORRHAGE.

What is Recombinant Factor VIIa

- Factor VIIa is normal protein in our body that helps stop bleeding.
- Recombinant Factor VIIa (identical to Factor VIIa but given in much larger amounts) is the only medication that has been shown to substantially decrease bleeding in patients with hemorrhage in the brain.
- It is easily administered intravenously with rapid onset of action.
- It is approved for other medical indications that involve bleeding (hemophilia) but not for brain hemorrhage.
- Prior trials of rFVIIa showed that it slowed bleeding in the brain but that its benefits in improving outcomes are most likely when given within 2 hours of onset of symptoms.

FASTEST

Primary Specific Objective – FASTEST Trial

- The *objective* of the FVIIa for Acute hemorrhagic Stroke Administered at Earliest Time (FASTEST) Trial is to establish whether rFVIIa within two hours of the onset of brain hemorrhage in appropriately selected patients improves outcome at 180 days, as compared to placebo.

NIH Funded: 1U01NS110772-01

Enrollment of Study Population

- Subjects to be enrolled - 860.
- Anticipated number of trial sites – 100 hospitals including 15 mobile stroke units.
- Country(ies) participating. USA, Canada, Germany, Spain, UK, and Japan.

How to Minimize Time to Treatment

- Mobile stroke care units

Participants will be put into one of two groups.

- One group will receive rFVIIa in the intravenous line and the other group will receive placebo. This will be determined by chance (like flipping coin).

Intervention

- Participants will get another CT of the brain within the first 24 hours to measure if the hemorrhage has increased in size.
- They will receive treatment in the intensive care unit for as long as necessary.
- They will have follow-ups with the study team by phone at 30 and 90 days and in person at 180 days.

What are potential risks?

- Since rFVIIa helps stop bleeding by enhancing blood clots, there is a risk of heart attacks, stroke due to blockage of brain arteries, and clots in the lung.
- In prior studies, this occurred about 5 % more commonly in persons treated with rFVIIa as compared to placebo. In other words, if 100 persons were treated with rFVIIa as compared to 100 persons treated with placebo, 5 more patients would have heart attack, stroke due to blockage of brain arteries or clots in lungs.

FASTEST

What are potential benefits?

- If rFVIIa slows bleeding and improves outcome, participants may benefit from this study.
- Future patients with bleeding in the brain may benefit from what is learned in the study.

How are emergency studies different?

- In most studies, investigators describe what will happen, discuss potential risks and benefits, answer questions, and then eligible patients decide whether or not to participate. This process is called informed consent.
- In this study, eligible patients cannot communicate or decide if they want to participate in the study. Also, treatment is needed to be started often before family or patient legal representative are available to decide for the patient.

So how do we do emergency research?

- Specific federal regulations allow for **exception from informed consent for emergency research or EFIC**
- EFIC is only allowed when:
  - The condition under study is life threatening
  - Existing treatments are unproven or inadequate
  - There is potential benefit for patients
  - Informed consent cannot be obtained

Requirement for EFIC

- Community consultation (why we are here)
- Public disclosure before and after study
- Oversight during study

How does EFIC work in FASTEST

- If family member or representative is available within the 2 hour time window, they will decide for patient.
- If they are not available, eligible patients will be started in study without consent.
- Patients, family members and representatives are told about the study as soon as possible and asked if they want the patient (or themselves) to continue in the study.

What if I don’t want to be in FASTEST?

- Ask for an Opt-Out Card that says that you don’t want to be in the FASTEST Research Study and let your family members know your wishes.
- Call your local study team to have a card sent to you.
- Go to the Stroke Net website to print an Opt-out Card
  - https://nihstrokenet.org/fastest/home
- If you have bleeding in the brain, you will not be enrolled if you are carrying this Opt-Out Card when you arrive at the hospital.

FASTEST

Our Site

MPMC ED patients and MSU patients going to MPMC

Does NOT change patient destination per County EMS protocol

EFIC community engagement efforts over next several months

Anticipate enrollment Q2 2022

https://redcap.link/FASTEST

Sutter Health

Questions?

fastest@sutterhealth.org

Thank You!