Mobile Stroke Unit News

News magazine of the PRE-hospital Stroke Treatment Organization

Volume 3, No. 2

Turning Point for Efficacy in Prehospital Stroke Care

BEST-MSU Results Reported at International Stroke Conference

By Jim Grotta, MD
President

For me, the past few months have been momentous. From the global perspective, the rollout of COVID vaccination has allowed us to turn the corner on this pandemic and look forward to a return to life as we knew it where in-person human interaction can once again occur outside the home or hospital. Personally, as a 75 yo "first-responder", I was fortunate to be one of the first to be vaccinated at my hospital. I am hopeful that by summer we can put the COVID pandemic in the rear-view mirror of our

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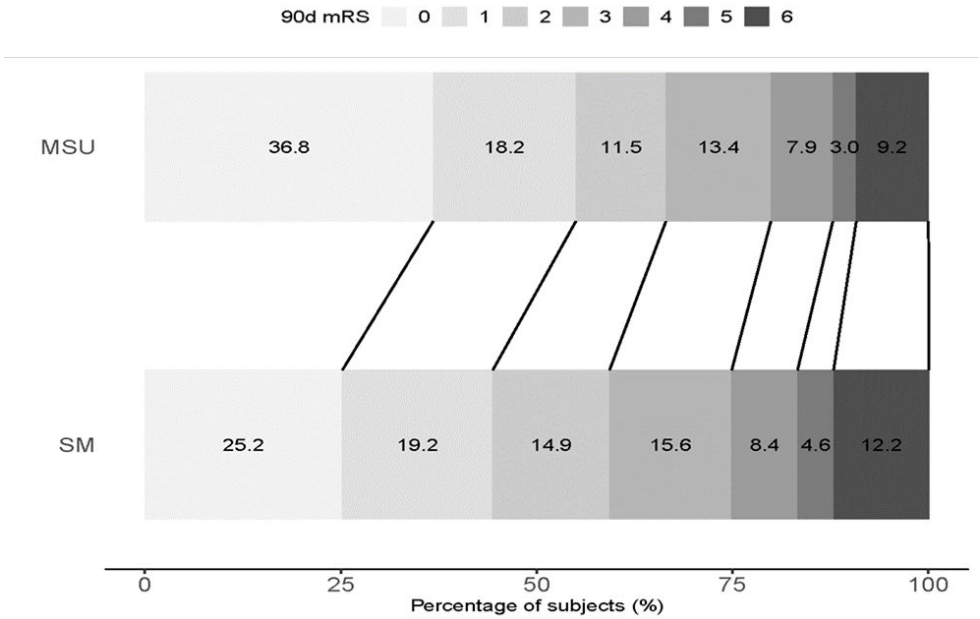
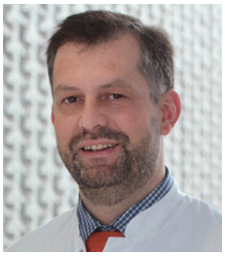


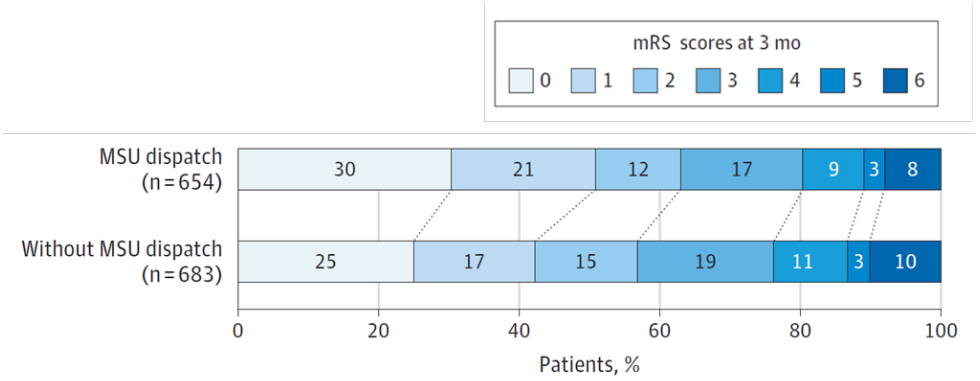
BEST-MSU results reported at ISC: Modified Rankin Scale score distribution at 90 days

Berlin B_PROUD Mobile Stroke Outcome Findings Published



By Heinrich J. Audebert, MD

Mobile Stroke Units (MSU; in Berlin: STEMO for Stroke Emergency Mobiles) have been serving Berlin for ten years. The specialized stroke emergency response vehicles allow physicians to start treating stroke patients before they reach hospital. For the first time, it has been shown that the dispatch of mobile stroke units is linked to improved clinical outcomes. These findings, which show that patients to whom STEMO were sent were more likely to survive without long-term disability, have been published in JAMA[1].



B_Proud: Modified Rankin Scale score distribution at 3 months, unadjusted only for patients[1]

Ten years ago, a team led by Heinrich Audebert and Martin Ebinger (Center for Stroke Research Berlin and Charité's Department of Neurology) set itself the

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Overcoming the Tyranny of Distance in Australia – The "Stroke Golden Hour"

Major government support for air ambulance. Story, p. 4

Reimbursement a Significant Persisting Hurdle for Mobile Stroke Care Paradigm

U.S. National MSU Reimbursement Survey. Story, p. 3

Mobile Stroke Unit News

Semi-Annual Newsletter of the PRE-hospital Stroke Treatment Organization (PRESTO)

April 2021
Volume 3 – Number 2

Note From the Editor

By Robert G. Kowalski, MD, MS

This issue of the PRESTO newsletter comes at a critical and arguably historic juncture for the organization, for Mobile Stroke, for pre-hospital stroke care, and for stroke in general. On the first page, we are privileged to reproduce eponymous "Grotta bars" with new results from two large studies of outcomes in mobile stroke, the BEST-MSU study in the U.S., and the B_PROUD study in Germany.

These studies represent years of concerted research involving one of the most important new approaches in stroke care since the advent of tPA and endovascular therapy for ischemic stroke – mobile stroke. The BEST-MSU results were presented last month at the International Stroke Conference by PRESTO President Jim Grotta, MD (after whom the modified Rankin Scale results graphic display is named), and the B_PROUD results were published by Prof. Heinrich J. Audebert and colleagues in JAMA in February of this year. Although the term is used cautiously, it is fair to say both are landmark studies in the field of stroke.

In his column, Dr. Grotta describes the culmination of the BEST-MSU study and does so in the context of his long and storied career and the recent COVID pandemic. With this, Dr. Grotta's tenure as PRESTO President comes to a close, but certainly not his work in the mobile stroke world. Compilation and analysis of additional results of the BEST-MSU study, including economic aspects of this paradigm, is underway.

Dr. Audebert, Professor of Neurology at Charité University, in Berlin, Germany, describes the published results of the B_PROUD study, which compared stroke care in a conventional ambulance with care in an MSU (in Berlin called STEMO, or Emergency Mobiles). Prof. Audebert was Principal Investigator on the B_PROUD trial and is the incoming PRESTO President.

The newsletter also features an update on a major commitment by the Australian government to support pre-hospital stroke care, including delivery to far-flung reaches of the continent via aircraft. Stephen Davis, MD and Geoffrey Donnan, AO, MBBS, MD, of the University of Melbourne and Co-Chairs of the Australian Stroke Alliance, describe the initiative. The effort includes development of light-weight CT scanning technology for use on helicopters and airplanes.

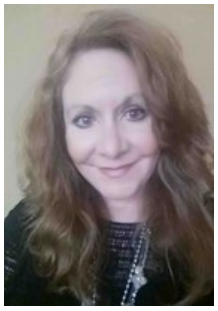
Despite the positive results of BEST-MSU and B_PROUD, the field of mobile stroke care is not without significant ongoing challenges. Foremost among these is cost reimbursement, which Anne Alexandrov, PhD, RN, explains in an article detailing results of the U.S. National MSU Reimbursement Survey, presented at ISC.

We now look forward to the 13th World Stroke Organization Congress, to be held virtually, Oct. 28-29, 2021. As the newsletter continues to chronicle developments and advances in the field of mobile stroke and pre-hospital stroke care, we welcome any ideas and contributions for future issues of the Mobile Stroke Unit News.

Robert G. Kowalski, MD, MS is Clinical Research Instructor at the University of Colorado School of Medicine, Departments of Neurology and Neurosurgery, and is leading research on the university's Mobile Stroke Unit.

Reimbursement a Continuing Challenge for Mobile Stroke

By Anne W. Alexandrov, PhD, RN



Patients treated on Mobile Stroke Units (MSU) are diagnosed significantly faster, and those treated with systemic thrombolytic agents achieve significantly better 3-month functional outcomes, with many more treated within the first 60-minutes of stroke onset. Despite delivery of high-quality care, MSUs struggle with suboptimal reimbursement that challenges their growth worldwide.

The PRESTO Reimbursement Committee recently presented the results of a U.S. National MSU Reimbursement Survey that was presented at the American Heart Association/American Stroke Association International Stroke Conference in March 2021. According to lead author, Ken Reichenbach, MSN, "We found that 100% of all U.S. MSUs are highly dependent on charitable donations or grants to cover operational expenses." Although the authors limited their study to programs in the USA, reports from MSU programs outside the USA show similar results. Operational costs for MSU programs consist of a number of items that drive expenses considerably beyond that of regular ambulances, yet billing a regular ambulance charge is the only billing option that can bring in revenue. "Our study found that on average USA MSUs have 4 providers on board. Most commonly, these include paramedics which are required by most States to maintain patient contact throughout the transport if the MSU is classified as an ambulance, emergency medical technicians who serve as drivers and assist with medical procedures, nurses that are either experienced with providing care for stroke or stroke nurse practitioners who can prescribe management, and CT technologists who manage all aspects of the CT scan, although we also found that some programs include vascular neurologists as the on-board expert. The daily personnel expenses alone for these practitioners exceeds the reimbursement that is provided." Additionally, because MSUs are not recognized as a place of service for neuroimaging by payers, the non-contrast CT scans along with the CTAs that most USA MSUs are now completing are not recognized as reimbursable despite not having to repeat most imaging at the hospital.

Kenneth W. Reichenbach Jr., CRNP, MSN, program director of the Mobile Stroke Unit at Lehigh Valley Health Network in Pennsylvania

Medications including alteplase, prothrombin complex concentrates, and continuous antihypertensive infusions are also not reimbursable since these are not recognized as drugs that should be given outside a hospital. "Presently, insurance payers are providing some reimbursement for use of telemedicine on an MSU, but these payments are minor and go only to the hospital-based physician, not the MSU," said Reichenbach.

Reimbursement limitations are significant deterrents to USA program development and challenge ongoing operations for existing programs. "Although we know MSUs are an important evidence-based tool to improve acute stroke outcomes, we found during distribution of our survey that one program had already ceased operations in large part because of negative financial performance," said Reichenbach. Only one program that responded to the survey stated that they were financially viable because they had been designated as an outpatient clinic, whereas all other respondents were forced to rely on grants, philanthropy, or institutional support for program sustainment. According to Reichenbach, "It's time that MSUs become recognized as appropriate places of services for acute stroke diagnosis and treatment, so that their important services can be appropriately reimbursed, and more programs can be developed in the USA."

Anne W. Alexandrov, PhD, RN is a Professor and Mobile Stroke Unit Chief Nurse Practitioner, University of Tennessee Health Science Center, Memphis, TN.

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Major Investment: Overcoming the Tyranny of Distance in Australia

The "Stroke Golden Hour" Program

By Stephen Davis, MD and Geoffrey Donnan, AO, MBBS, MD (Co-Chairs Australian Stroke Alliance); Damien Easton and Amanda Place, on behalf of the Australian Stroke Alliance

More Australians will have rapid access to time-critical stroke care following the funding of the Australian Stroke Alliance's "Stroke Golden Hour" program by the Australian Government's Frontier Health and Medical Research initiative. The funding by this program is designed to support researchers to push the boundaries, to develop big, new ideas to revolutionise health care and to create new industries. The Alliance brings together more than 30 national organisations committed to transforming stroke response times and treatment.

Our 5-year, $40 million program aims to reduce the risk of death and disability from stroke for many Australians, but particularly for the one third of our national population, who live in rural or remote locations. Stroke patients living outside of major metropolitan centres have little access to modern stroke care and have significantly worse clinical outcomes. This inequity is even greater for Indigenous Australians in remote communities who suffer stroke around a decade earlier with poorer outcomes.

Program co-chief investigators and PRESTO members, Profs Stephen Davis and Geoffrey Donnan, are building on the success of Australia's first mobile stroke ambulance which serves metropolitan Melbourne. The Melbourne Mobile Stroke Unit is the first MSU in Australia and only one of two in the Southern Hemisphere.

Stephen Davis, MD

Geoffrey Donnan, AO, MBBS, MD

Damien Easton

Amanda Place

As reported in the last edition of PRESTO's newsletter, Ambulance Victoria operates the vehicle within a 20km radius of the Royal Melbourne Hospital and has seen some impressive results.

It treats 10 times as many patients in the first 'Golden Hour' after stroke, enabling a rapid diagnosis and thrombolytic treatment to be delivered faster than a traditional transfer to hospital. An independent economic review showed that the MSU was cost effective, due to a combination of faster thrombolysis and facilitation of endovascular thrombectomy, with bypass of primary stroke centres to an endovascular-equipped comprehensive stroke centre.

The major research aim is to create innovative light, portable brain scanners to be embedded in road, helicopter and fixed-wing ambulances to access regional Australia. These scanners will be essential for the rapid diagnosis and appropriate treatment of stroke.

Conventional CT scanners, typically weighing three tons, are located in major city centres, providing little hope for many Australians who live in the "outback" of our country. The

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The Royal Flying Doctor Service treating a patient in the Australian outback. We aim to fit out aircraft with lightweight novel brain scanners to enable on-site stroke diagnosis and treatment.

BEST-MSU, and a PRESTO Motto: From "efficacy" to "effectiveness"

Continued from *Grotta*, p. 1

MSUs and write books, movies, and stories for our grandchildren about how we survived the great pandemic.

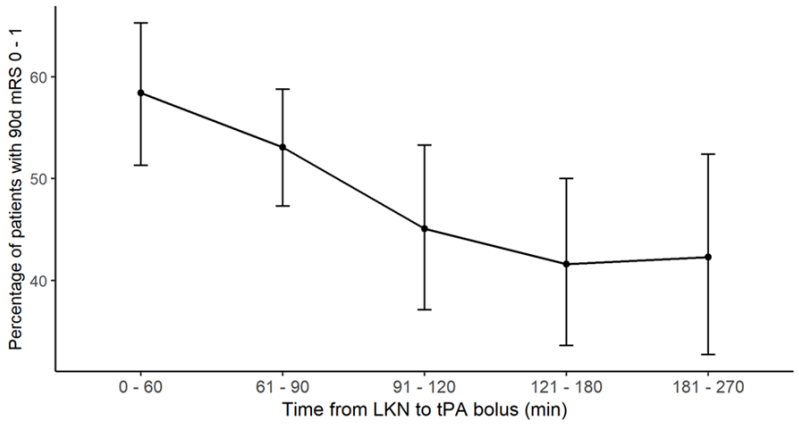
It has been a momentous time for the world of mobile stroke units as well. When Jose-Miguel Yamal, the PI of our Data Core revealed the unequivocally positive results of the BEST-MSU study in a "private showing" to our Project Manager Stephanie Parker and me, we were overwhelmed by emotion. I was transported back to Airlie Virginia in 1994 when Barbara Tilley, the PI of the NINDS tPA Trial Data Core, evoked the same gasps from the investigators when she flashed up the slide showing p< .01 for 90 day mRS 0,1. History repeats itself! Time is brain, time is clot, and MSUs provide a new definition of "time". It is not 6 hrs, or 3 hrs; it is 60 minutes or less.

I want to personally thank my co-investigators in the BEST-MSU study at our sites in Memphis, Colorado, New York, Indianapolis, Los Angeles and Burlingame who believed in carrying out a rigorous clinical trial, and after raising funds for their MSUs, were willing to allocate 50% of its time to Standard Management rather than having their MSU in operation full time. That required a sacrifice, and a commitment to research that I believe the results have validated. And of course I want to tip my hat to my colleagues in Germany, Drs. Fassbender and Audebert, who are the true fathers of the MSU concept and whose efforts we have built upon.

And congratulations to our Australian colleagues, Drs. Davis and Donnan who have received a transformative grant from their government to develop an air-MSU to serve the remote and indigenous communities of that continent.

Now we need to translate these positive trial results into clinical reality. From "efficacy" to "effectiveness". That should be the motto of PRESTO going forward,

BEST-MSU: Time from LKN to tPA bolus vs Percentage with 90d mRS 0-1; MSU + SM



and the reason that PRESTO as an organization was envisioned in the first place. Here is my "laundry list" of priorities from the immediate to the long range for what PRESTO as an organization should strive to achieve in the next decade:

1. How can we fine-tune our existing MSU systems to better identify and treat stroke patients at the first moments after symptom onset? This will require a focus on increasing stroke alerts, improved dispatch accuracy, and complete regional integration and coordination between MSU and EMS systems.

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International Stroke Conference Summary

BEST-MSU and Mobile Stroke Results for Clot Lysis in LVO

The Benefits of Stroke Treatment Delivered by a Mobile Stroke Unit Compared to Standard Management by Emergency Medical Services (BEST-MSU) Study (NCT 02190500) is a prospective, multicenter, alternating-week, cluster-controlled trial at 7 U.S. sites (Yamal YM, Rajan SS, Parker SA, et al. Benefits of stroke treatment delivered using a mobile stroke unit trial. Int J Stroke 2017 doi:10.1177/1747493017711950reference). Results were presented at the 2021 International Stroke Conference and have been submitted for publication. 1,047 tPA-eligible patients were analyzed; tPA treatment was significantly more frequent and faster on the MSU, with one-third treated within the first "golden hour". Outcomes measured at 90 days using a utility-weighted Rankin scale were significantly better in MSU patients and there were no safety concerns. Longer term follow up for cost-effectiveness is ongoing. At the same meeting, Alexandra Czap MD presented data on 69 MSU patients who had a LVO demonstrated either by CTA or a dense MCA on plain CT and who received tPA at a median of 68 minutes after stroke symptom onset. Twenty eight percent of these patients had LVO clot lysis on repeat imaging on average one hour later, and this was associated with substantial clinical improvement, providing biological proof of the powerful thrombolytic effect of tPA when given in the first hour.

Summary of the B_PROUD study results and 10 years MSU service

Continued from *Audebert*, p. 1

aim of further reducing time to treatment by bringing the necessary diagnostic and treatment procedures to the patient rather than the other way around. Berlin's first purpose-built mobile stroke unit was launched in February 2011. Following years of research, the team was able to confirm that STEMO-based stroke treatment is safe[2] and, more importantly, reduces time to treatment[3]. Nowadays, the Berlin Fire Department operates three STEMO vehicles. As part of a collaboration with three participating hospital owners, these vehicles cover most of the Berlin area. Data from the recently published B_PROUD study[1] show that dispatch of mobile stroke units is associated with improved outcomes in patients with stroke.

The study evaluated patients with acute cerebral ischemia between February 2017 and May 2019. Whether a MSU was dispatched or not was effectively decided by chance: if one was available within the relevant area, it was dispatched at the same time as the conventional ambulance, enabling the patient to receive treatment before their arrival in hospital. A mobile stroke unit was dispatched in 749 of a total of 1,543 cases analyzed as part of the study (49 percent). If no MSU was available at the time of the emergency call, only a conventional ambulance was dispatched to ensure transport to a specialist hospital. In 794 of these cases, patients were cared for within the conventional emergency medical system. Using a standardized protocol, the researchers then determined survival at three months post-stroke and the extent of any neurological impairment affecting the patients. Functional outcome was measured with the modified Rankin Scale (mRS) ranging from '0' (no neurological deficit) to '6' (death) and rated by blinded certified raters.

Berlin currently has three STEMOs, mobile stroke units which help reduce time to treatment. Photo: S. Haase / Berliner Feuerwehr

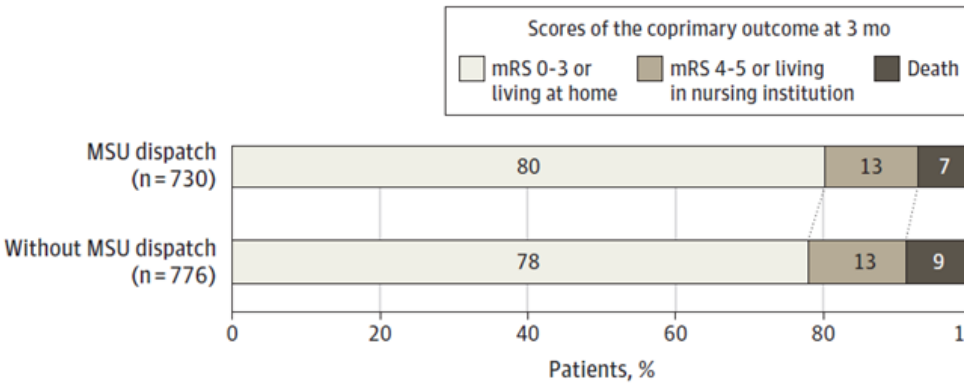
Not only did a greater number of MSU patients receive thrombolysis (60 percent vs 48 percent in the control group), they received this treatment on average 20 minutes earlier than controls. After 3 months, approximately 7 percent of patients in the MSU dispatch group died. This figure compared with 9 percent in the conventional ambulance group. Similarly, while approximately 51 percent of patients in the MSU group reported no stroke-related impairments in day-to-day functioning, the corresponding figure in the control group was only 42 percent.

The odds of patients with MSU dispatch for having significant disabilities 3 months after stroke was 29 percent lower compared to patients with conventional ambulance care. MSU dispatch therefore results in significantly more stroke patients returning to an independent life after stroke.

The health economic analysis looking at cost-effectiveness and cost-utility is currently underway.

Prof. Heinrich J. Audebert, M.D. is Professor of Neurology at Charité Universitätsmedizin, Berlin, Germany.

B_PROUD Co-Primary Outcome Results: Dichotomized mRS[1]



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1. Ebinger M, B. S, Kunz A, et al. Association between Dispatch of Mobile Stroke Units and Functional Outcomes among Patients with Acute Ischemic Stroke in Berlin. *JAMA.* 2021.
2. Weber JE, Ebinger M, Rozanski M, et al. Prehospital thrombolysis in acute stroke: results of the PHANTOM-S pilot study. *Neurology.* 2013;80(2):163-168.
3. Ebinger M, Winter B, Wendt M, et al. Effect of the use of ambulance-based thrombolysis on time to thrombolysis in acute ischemic stroke: a randomized clinical trial. *JAMA.* 2014;311(16):1622-1631.

Major Government Commitment to Air Mobile Stroke in Australia

Continued from *Davis et al*, p. 4

Ceretom CT scanner in the current Melbourne Mobile Stroke Unit still weighs over half a ton. Our aim is to develop scanners weighing around 100kg or even lighter! The "Stroke Golden Hour" program brings together academic aeromedical and materials engineers, with commercial partners. The aim is to produce two scanners, weighing between 100kg and as little as 30kg.

One of these is using a microwave technique, which can detect changes in the electrical properties of brain tissue due to change in blood flow, water content and temperature with a high sensitivity. In early clinical tests, there is encouraging ability of microwaves to differentiate haemorrhagic stroke from ischaemic stroke. Another approach uses ultra- lightweight CT scanning using novel, non-thermionic nanotube technology. This allows miniaturization of the scanner and has no moving parts. The early prototypes have already provided images that show promise, although a huge amount of developmental work and clinical validation studies lie ahead in our 5-year program.

The aim is for paramedics to travel with one of the scanners, effectively taking the emergency department to the patient. The scanners would be embedded in standard road ambulances and aircraft. For those relying on the nation's ambulance helicopters or the Royal Flying Doctor Service's jets, the standard of care will be transformative. Treating clinicians at the remote location will be linked to stroke experts by a national tele-stroke system. The Royal Flying Doctor Service coordinates the world's largest fleet of air ambulances, with more than 80 aircraft.

"Fundamentally, we are taking the diagnosis and treatment to the scene of the patient's stroke. It's all about time and the need to administer thrombolysis within 4.5 hours of stroke onset – but ideally within stroke's 'Golden Hour'. And with new data showing a significant increase in younger Australians experiencing stroke, this will have enormous implications for the nation," says neurologist, Prof. Geoffrey Donnan.

A concept diagram for the Micro X ring device. This will be a lightweight CT scanner using novel nanotube technology. Developed by Micro X, Adelaide, Australia

Prof. Davis pointed out that patients in remote part of Australia are twice as likely as city stroke survivors to be left with a serious, lifelong disability. "And only 3% of rural and remote patients receive care in a specialist stroke unit, compared with 77 % of people in metro areas". Providing acute stroke care to remote indigenous communities will be a major aim. Indigenous Australians suffer stroke around 10 years younger with poorer outcomes. This program aims to help bridge that gap.

"One in four Australians will have a stroke sometime in their lives. While 1,000 Australians die from stroke every month, very few survive without some disability. "We are bringing together aeromedical and material engineers, stroke physicians, Indigenous medical professionals, specialist nurses and paramedics, as part of our team," he says.

The Golden Hour research program also includes a novel stroke patient app which will use a digital telehealth platform to transfer and receive real-time patient video and audio communication with a city-based stroke physician, 24-hours a day, transforming the support of health careers out in the field. It is underpinned by an educational program and an economic evaluation.

Stephen Davis, MD is *Professor of Translational Neuroscience at the University of Melbourne, Director of the Melbourne Brain Centre at the Royal Melbourne Hospital and Co-Chair of the Australian Stroke Alliance. Geoffrey Donnan, AO, MBBS, MD* is *Professor of Neurology, University of Melbourne, and Co-Chair of the Australian Stroke Alliance. Damien Easton is CEO of the Australian Stroke Alliance. Amanda Place is Director of Communications of the Australian Stroke Alliance.*

Vision for the Future of Mobile Stroke and PRESTO

Continued from *Grotta*, p. 5

2. How can we increase the number of MSUs so they transition from a "demonstration" project to a public health solution? This will require better reimbursement and a business model.

3. How can we speed and increase thrombectomy as well as tPA? This will require on-board CTA or other new technology to identify LVOs quickly and achieve the "direct to angio" paradigm.

4. How can we improve other aspects of stroke treatment using our MSU platform? This will require clinical trials of hemostatic agents for ICH such as FASTEST, TNK or other new thrombolytics, anti-thrombotic drugs to amplify the effect of tPA, revisiting cytoprotective therapies given within the first hour, etc.

5. How can we reach rural and underserved communities that are not amenable to a centrally based distribution? This will require air-MSUs such as soon-to-be implemented in Australia and Norway, and perhaps "roving" ground-based MSUs serving a defined underserved geographic area.

6. How can we leverage what we have learned with ischemic stroke management to other emergent conditions? MSU AIS management can be the "footprint on the moon" for other conditions; for instance ECMO for cardiac arrest, and enhanced resuscitation after head trauma.

From the organizational standpoint, PRESTO must have the mission to make these goals a reality. We will hopefully see an increase in membership as MSUs proliferate. We need to be prepared. What is our identity? What should we do as an organization? We have already begun by forming membership and research committees, but now we have to think bigger.

1. Do we want to sponsor our own congresses apart from AHA, ESOC, SVIN etc, or should we integrate with one of those to have a yearly satellite meeting?

2. How can we raise awareness, make ourselves known as an organization, increase membership, make membership more attractive?

3. How can PRESTO act as an organization to achieve each of the goals I have listed, and others that members may identify? I suggest we have working subcommittees to address each one.

We already have subcommittees addressing the first two—dispatch and reimbursement—but they need to be strengthened and broadened, and other subcommittees need to be formed.

4. Should we grow our "newsletter" into a regular publication? Something to think about.

Our positive results have created a new opportunity for PRESTO.

Carpe diem!

James C. Grotta, MD, is Director of Stroke Research and Director, Mobile Stroke Unit Consortium, Memorial Hermann-Texas Medical Center, Houston, TX.

Mobile Stroke Presentations at ISC 2021

Oral Presentations

Benefits of Stroke Treatment Delivered by a Mobile Stroke Unit Compared to Standard Management by Emergency Medical Services (BEST-MSU Study)
James C. Grotta, MD

Immediate Recanalization of Large Vessel Occlusions by tPA on the Mobile Stroke Unit
Alexandra Czap MD

Low Frequency Vibrations Enhance Thrombolytic Therapy and Improve Stroke Outcomes
Nirav Dhanesha, PhD

Going the Distance for Thrombectomy: The Ultra Long-Distance Transport
Carlos Garcia-Esperon, MD

The Mobile Interventional Team: Coming to a Hospital Near You
Johanna T. Fifi, MD

Virtual Care via Mobile Application Using a Patient Electronic Health Record Portal is Feasible and Increases Stroke Patient Engagement - A Pilot Study
Leslie Pope, RN

Propelling Prehospital Stroke Care: Stroke Care, Transport Trials, and Telestroke Helicopter
Enrique C. Leira, MD, MS

Poster Presentations

Mobile Interventional Stroke Teams Lead to Improved Outcomes in the Early Time Window for LVO Stroke
Jacob Morey, MBA

Association of Anemia with Functional Outcomes in Patients with Mechanical Thrombectomy
Taha Nisar, MD

Reimbursement of Mobile Stroke Units in the United States: A Survey by the Prehospital Stroke Treatment Organization (PRESTO)
Kenneth W. Reichenbach Jr., CRNP, MSN

Hemorrhage Enlargement in the First Two Hours: A Mobile Stroke Unit Study
Ritvij Bowry, MD

Successful Conduct of an Acute Stroke Clinical Trial During COVID
James C. Grotta, MD

Comparing Process, Performance Measures and Clinical Outcome Between Mobile Stroke Unit and Usual Care in Underserved Areas
Yongchai Nilanont, MD

Pitfalls of Mobile Stroke Treatment Unit - A Single Center Review
Mangala Gopal, DO