Mobile Stroke Treatment Units: Myth or Reality?



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Disclosures – last 12 months

- Financial Interest:
 - Blockade Medical
 - Perflow Medical
- Scientific Advisory Boards
 - Blockade Medical
 - Medtronic Neurosurgery
 - Perflow Medical
 - Stryker Neurovascular
- Institutional/Group/Research and Educational Support:
 - ev3/Covidien
 - Penumbra Medical
 - Codman/J & J
 - Immediate Past President Society of Neurointerventional Surgery



Neurosurgeon's Role in Stroke

- Brain aneurysms
- Brain AVMs
- ICH medical and surgical and minimally invasive
- Carotid stenosis CEA and CAS
- Hemicraniectomy
- EC-IC Bypass
- Endovascular management of acute and chronic ischemia (ICAD)
- Programmatic leader in your hospital/health system/community

There are Effective Treatments for Acute Stroke



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What is the most effective treatment for ischemic stroke?

Treatment/Te	chnique	NNT
Rx'ment chronic	hypertension	29
Stroke L	Jnits	18
0 - 90 min		3.6
IV tPA	91 – 180	4.3
	181 – 270	5.9
CEA/CAS for Asx stenosis		19
Aspiri	in	100
CEA/CAS for S	Sx stenosis	6 - 15



Time=Brain and the IV tPA Time Window



Figure 3: Model estimating odds ratio for favourable outcome at 3 months in rt-PA-treated patients compared with controls by OTT

Adjusted for age, baseline glucose concentration, baseline NIHSS measurement, baseline diastolic blood pressure, previous hypertension, and interaction between age and baseline NIHSS measurement.

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Patient Outcome vs. Δ Time (Onset to Treatment)



Time is Brain!

11 10 10	Neurons Lost	Synapses Lost	Accelerated Aging
Per Stroke	1.2 billion	8.3 trillion	36 yrs
Per Hour	120 million	830 billion	3.6 yrs
Per Minute	1.9 million	14 billion	3.1 weeks
Per Second	32,000	230 million	8.7 hrs

(Total number of neurons in the average human brain is 130 billion)

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Stroke 2006;37:263-266



Target: Stroke Outcomes (15 min reduction in IV tPA DTN times)

Outcome	Pre-Target: Stroke (n=27,319)	Post-Target: Stroke (n=43,850)	Difference Pre and Post	P Value
In-Hospital Mortality	9.93%	8.25%	-1.68%	<0.0001
Discharge Home	37.6%	42.7%	+5.1%	<0.0001
Ambulatory Status Independent	42.2%	45.4%	+3.2%	<0.0001
Symptomatic ICH	5.68%	4.68%	-1.00%	<0.0001
Any tPA Complications	6.68%	5.50%	-1.18%	<0.0001





Stroke – Impact and CCF Overview 2013

Devastating Problem	Yearly Discharge Volume	Adult Prevalence	Yearly Mortality	Stroke Mortality Rank	5 Yr Projected IP Growth
Cuyahoga County	5,600	3.2%	730	3 rd	3%

CC Slow to Improve	MC	HC	FVW	MYMT	LKWD	SP	Medina	Euclid	Luth
IVtPA delivery rate	17%	10%	11%	4%	7%	6%	18%	10%	0%
Door to Drug in 60 min	56	67	109	107	74		78	88	

Global IVtPA Underuse

- Modeling indicates that 23% can be achieved with prealert, 4.5hrs, > 80 yrs UK, 24% achieved in Sweden
 - Monks et al. *Stroke* 2012; Bergland, *Stroke* 2012
 - Improved DTN crucial; Foranow Stroke 2011. Meratoja, Neurology 2012
- Estimated 4.5% to 5.2% USA (Boehringer Ingelheim; Adeoye *Stroke* 2011; Foranow *Stroke* 2011)
- Huge Variation in Europe
 - Finland 16% (Meratoja 2012), Germany 11.7% (Minnerup Stroke 2011), Sweden 6.6% (Eriksson Stroke 2010), UK 5.8%, France 3%, Italy 1.2% (T Fischer Pers com 2013 Boehringer Ingelheim)
- Much lower rates in developing world <1%

We cannot expect the patient's disease biology to match our systems. Because the time window to treatment for stroke with most is so short, we must match our systems to the biology.

> Michael Hill, MD Stroke Neurologist Univ of Calgary

Stroke Treatment Decisions Hinge on the CT Scan



BP control <180 IV tPA (clot buster) Transport to Primary Stroke Center





BP control <140 Warfarin reversal Mannitol Anti-epileptic medications Transport to Comprehensive Stroke Center





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Kostopoulous et al. Neurology 2012

- Decision made in ambulance
- ER Target: door to needle time = 60 minutes

Table Timing of prehospital diagr	ostic stroke	workup and d	ecision makin	g (minutes)
Key stroke management times	Patient 1	Patient 2	Patient 3	Patient 4
Call to MSU arrival	13	8	20	12
Call to end of laboratory examination	25	25	34	24
Call to end of CT time	38	41	41	27
Call to therapy decision times	38	41	41	27
Call to hospital admission time ^a	67	55	64	48
Symptom onset to call time	60	37	65	8

Abbreviation: MSU = mobile stroke unit.

^a Mean standard call to hospital admission times to the Department of Neurology of the University Clinic of the Saarland (n = 134) in a recent study⁹ were 49 ± 29 minutes.

Berlin: Call to Needle Times



Diagnosis and treatment of patients with stroke in a mobile $\rightarrow W$ stroke unit versus in hospital: a randomised controlled trial

Silke Walter, Panagiotis Kostopoulos, Anton Haass, Isabel Keller, Martin Lesmeister, Thomas Schlechtriemen, Christian Roth, Panagiotis Papanagiotou, Iris Grunwald, Helmut Schumacher, Stephan Helwig, Julio Viera, Heiko Körner, Maria Alexandrou, Umut Yilmaz, Karin Ziegler, Kathrin Schmidt, Rainer Dabew, Darius Kubulus, Yang Liu, Thomas Volk, Kai Kronfeld, Christian Ruckes, Thomas Bertsch, Wolfgang Reith, Klaus Fassbender

- Randomized, single center
- Week on, week off
- Primary endpoint alarm to therapy decision
- Secondary alarm to end of CT, alarm to lab analysis, # pts IV tPA, 7 day neurological outcome (NIHSS)

	MSU group (n=53)	Control group (n=47)	p value	Difference (95% CI)
Primary endpoint				
Alarm to therapy decision (min)	35 (31–39)	76 (63-94)	<0.0001	41 (36–48)
Secondary endpoints				
Symptom onset to therapy decision (min)	56 (43-103)	104 (80–156)	<0.0001	43 (30–58)
Number of patients with intravenous thrombolysis	12 (23%)	8 (17%)	0.30*	
Alarm to intravenous thrombolysis (min)	38 (34-42)	73 (60–93)	<0.0001	34 (23-54)
Symptom onset to intravenous thrombolysis (min)	72 (53-108)	153 (136–198)	0.0011	80 (40-115)
Number of patients with intravenous thrombolysis or intra-arterial recanalisation†	12 (23%)	11 (23%)	0·81*	
Alarm to intravenous thrombolysis or intra-arterial recanalisation† (min)	38 (34-42)	78 (61–110)	<0.0001	44 (27-73)
Symptom onset to intravenous thrombolysis or intra-arterial recanalisation† (min)	72 (53–108)	152 (135–209)	<0.0001	80 (46-115)
Alarm to end of CT (min)	34 (30-38)	71 (62-87)	<0.0001	38 (33-43)
Symptom onset to end of CT (min)	56 (43-103)	97 (74–156)	<0.0001	39 (26–52)
Alarm to end of laboratory analysis (min)	28 (26–34)	69 (55–81)	<0.0001	38 (32-44)
Symptom onset to end of laboratory analysis (min)	51 (40-95)	99 (70–140)	<0.0001	39 (26–56)
NIHSS at day 1‡	3 (1-10)	4 (2–12)	0.48	1 (-1 to 3)
NIHSS at day 7‡	2 (1-8)	4 (0-8)	0.94	0 (-2 to 2)

Lancet Neurol 2012; 11: 397–404 **Original Investigation**

Effect of the Use of Ambulance-Based Thrombolysis on Time to Thrombolysis in Acute Ischemic Stroke A Randomized Clinical Trial

Martin Ebinger, MD; Benjamin Winter, MD; Matthias Wendt, MD; Joachim E. Weber, MD; Carolin Waldschmidt, MD; Michal Rozanski, MD; Alexander Kunz, MD; Peter Koch, MD; Philipp A. Kellner, MD; Daniel Gierhake, MD; Kersten Villringer, MD; Jochen B. Fiebach, MD; Ulrike Grittner, PhD; Andreas Hartmann, MD; Bruno-Marcel Mackert, MD; Matthias Endres, MD; Heinrich J. Audebert, MD; for the STEMO Consortium

- Week on, week off randomization
- Compared STEMO deployment vs.STEMO weeks vs. control weeks
- tPA utilization improved to 33% (vs. 21% in control weeks)

	Patients With STEMO Deployment	P Value ^a	Patients During STEMO Weeks	P Value ^a	Patients During Control Weeks
Primary end point					
Alarm to treatment (1 missing), mean (95% CI), min	51.8 (49.0-54.6)	<.001	61.4 (58.7-64.0)	<.001	76.3 (73.2-79.3)
Median (IQR), min	48 (39-56)		55 (44-75)	<	72 (62-85)

Cleveland Clinic Stroke System

	МС	HC	FVW	MYMT	LKWD	SP	Medina	Euclid	Luth
IVtPA delivery rate	17%	10%	11%	4%	7%	6%	18%	10%	0%
Door to Drug in 60 min	56	67	109	107	74	-	78	88	-

US facing a health care crisis

- Costs too high
- Access too low
- Need to constantly innovate our care delivery model
- Need to increase revenues
- Need to decrease costs
 - Most cost of stroke patient is after acute hospitalization Need to reduce these costs
- Best way to reduce rehabilitation/disability costs is to reduce neurologic deficit
- Need to increase IV tPA delivery and access to endovascular therapy
- Need to bring highest possible level of care directly to the patient as soon as possible

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Mobile Stroke Treatment Unit



Collaboration with Local Government and Health Systems

- Requires collaboration with local government
- Go to the mayor
- Collaborative effort with the community
- Requires collaboration with local government
- Need to get out and "sell"
- Build excitement
- Change hearts and minds....







Mobile Stroke Treatment Unit: Diagnosis and Emergency Care

- Don't wait for the patient to get to the ED
- Bring the CT and stroke expertise to the patient
- Initiate treatment at the scene
- Dramatically cut time-to-treatment decisions
- •Triage patient to appropriate stroke resource











Portable CT Technology

- CereTom (Neurologica, Danvers, MA)
- 8 slice CT
 –CTA/CTP capable
- Able to scan head
- Used for a number of years in our NICU
 Reasonable quality



Telemedicine

- Inter-rater reliability reasonable to in person assessment
 - -Berlin kappa 0.69
 - Houston with mock patient 0.997 absolute agreement
 - -Well-proven in Telestroke networks
- Reliable Broadband has been limiting step in Germany
 - Berlin: only 18/30 technically successful connections

• Verizon 4GLTE

Distribution of 911 calls for Stroke by Hour of Day





Operations

- Stroke patient calls 911 activates Emergency Medical System
- Municipal ambulance dispatched simultaneously with MSTU (8a-8p)
- Local ambulance arrives first usual assessment, IV, O₂, draws blood samples
- MSTU arrives mutual care/hand off of care
- CT(A) head performed -> transmitted for neuroradiologist and neurologist review
- Point of Care Testing for CBC, INR, creatinine, glucose
- Telestroke System -> vascular neurologist "virtually" with the patient and team, Initiate IV tPA or other care as appropriate
- Triage to appropriate hospital (level of care) in stroke system









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Telemedicine

- Has been very reliable
- Review of 108 transports, 5 drop outs
 - -3 brief (< 30 seconds), did not affect clinical care
 - -2 longer (> 30 seconds), truck moved 10 feet and signal returned
 - -1 unable to restore connection
 - -Stroke neurologist communicated by telephone with critical care transport nurse, determined cause to be seizure, transported to closest ED.
- Relationship w Verizon
 Wireless VPN



Program Operations – Patient Transport Algorithm

Patient Condition identifies Hospital resources needed to effectuate subsequent care

- Patient Transport effectuated to nearest Hospital with clinical resources available to meet care needs
- Patient request will override the default mechanism (Care Continuity, Community Preference)



Treatment Paradigm of the Future?

- 43 y.o. with prior history of drug abuse, CHF
- Was with girlfriend who left briefly, came back 10 minutes later to find him with left hemiplegia
- Called 911
- EMS and MSTU dispatched
- MSTU arrived 40 minutes last known well

MSTU Telemedicine

- Stroke Neurologist signed in to see patient with dense left sided weakness and altered LOC, difficulty speaking
- NIHSS 20

Non contrast CT



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Treatment Initiated

- *IV tPA initiated at 11 minutes after* patient on board MSTU! (Door to needle)
- Transferred to Cleveland Clinic Main Campus for consideration of intraarterial stroke therapy (due to high NIHSS, hyperdense MCA sign)

Initial runs – right M1 MCA occlusion







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One pass with aspiration cath – M1 recanalized, M3 thrombus (angular branch remaining)



Patient Course

- Improved next day with near resolution, only facial droop remained (NIHSS 1)
- Stroke due to underlying CHF (EF 10%)
- Discharged home on hospital day 4



Pre-hospital Stroke Treatments

	2014	2015
Dispatches	539	1247
Transports	156	312
IVtPA Tx	26	44
Hemorrhagic strokes	7	19

Advanced Therapy Treatment

	2014	2015	
Pre-hospital CTA Imaging		12	
Potential Endovascular Candidate	9	20	
Endovascular Tx	6	6 (7)	

Methods – Case Control Study

- MSTU quality data prospectively collected and maintained in a Redcap database
- Enterprise Stroke system data collected and maintained in separate Redcap database
- Comparison of MSTU patients with patients presenting to Cleveland Clinic Enterprise Hospitals within or adjacent to City of Cleveland border from January 1, 2014 to December 31, 2014
 - Must have had stroke alert called within 30 minutes of arrival to hospital.
 - Control patients presenting to hospital from 8am 8pm
- Statistical analysis: Comparison of medians by Wilcoxon Rank Sum, proportions by Pearson's Chi squared (JMP software)

Primary Stroke Metrics

	MSTU (100)	CONTROLS (53)	p-value
DOOR TO CT COMPLETED	13 (IQR 9-21)	18 (IQR 12-26)	0.0072
DOOR TO INR RESULT	13 (IQR 7-18)	44 (IQR 35-61)	<0.0001
DOOR TO IV TPA	31.5 (IQR 24-47)	58 (IQR 52-66)	0.0012

911 Alarm to

	MSTU (100) CONTROLS (53)		p-value
ALARM TO CT COMPLETED	33 (IQR 29-41)	56 (IQR 47-68)	<0.0001
ALARM TO CT READ	44 (IQR 39-52)	64 (IQR 54-76)	<0.0001
ALARM TO INR RESULT	25 (IQR 22-34)	79 (IQR 70-105)	<0.0001
ALARM TO IV tPA	55.5 (IQR 46-65)	94 (IQR 78-104)	<0.0001
LKW to IV tPA	97 (61-144)	122.5 (110-176)	0.0886

~45 min saved = 15% more patients d/c'd home \$12k v. \$40k cost for first 90 days of care.....

911 Alarm to Drug Administration



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MSTU Thrombolysis Rate

- Thrombolysis Rate:
- Based on MSTU encounter Dx (n=100 patients)
 –IV tPA given for 100 MSTU runs: 16%
 –Rate in probable stroke = 16/33 = 48.4%
- Based on Final Dx (known for 87 pts)

-Rate in AIS: 9/29 = 31.0%

-Rate in AIS + clinical TIA = 11/41 = 26.8%

Hospital Discharge Diagnosis MSTU Patients

FINAL Diagnosis of MSTU patients on discharge (n=87 pts)	
AIS	29 (33.3)
TIA	12 (13.7)
ICH	5 (5.7)
Noncerebrovascular	41 (47.1)
- Neurological	21 (51.2)
- Non-neurological	20 (48.8)

Transport Destinations: First 155 Patients

- Cleveland Clinic: 69
- Metro Hospital: 27
- University Hospital: 19
- Lakewood Hospital: 11
- Euclid Hospital: 7
- Marymount Hospital: 5
- Fairview Hospital: 5
- South Pointe Hospital: 4
- Parma Hospital: 3
- Southwest General Hosp
- St. Vincent Charity: 1
- Lutheran Hospital: 1
- Hillcrest Hospital: 1



Pre-hospital treatments

• Hemorrhagic strokes transported: 7

• 1 Kcentra-coumadin coagulopathy patient treated in the field

	July	August	September	October	November	December
Dispatch to Scene Arrival	13 mins	11	12	12	15	13
MSTU Door to Doctor	12	13	11	12	9	9
MSTU Door to CT complete	22	19	11	11	9	10
MSTU Door to CT Read	32	27	24	22	21	24
MSTU Door to Lab Results	15	10	14	14	13	14
MSTU Door to Drug	48	41	19	28	31	29
Total Time on Scene	52	46	39	40	43 Data	40 as of 12/31/2014

MSTU comparison to CCHS EDs

	MSTU	HC	MC	Fairview	Medina	MYMT	ACMC	LKWD	SP
# IV tPA Administration in ED	26	39	33	13	12	10	7	6	6
Door to Drug (Target <60 min)	33	75	64	71	60	88	57	56	67
6 month data 12 hrs/day				12 month data					



MSTU Programs Comparison Worldwide



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Figure 2. Thrombolysis Rates in 60-Minute Intervals



Pre-hospital ICH

- Hemorrhagic strokes transported: 7
- Can offer BP control, anticoagulation reversal
 - 1st patient ever treated with Kcentra (4 factor PCC) in the field
 - -INR 3.2 on POC in MSTU
 - -On arrival to NICU, INR normalized (1.1)
- Triage directly to neurosurgical center



Right Patient, Right Place, the First Time

Prior to MSTU



Thus far, no patients have required a second transfer



Concerns?

- Cost
- Traffic
- Politics



- Never work in my market
- No one will work together...
- Excuses! Don't be pusillanimous!

Cost of a Mobile Stroke Treatment Unit

Portable CT scanner: ~\$400k Truck Chassis: \$60-110k Ambulance Box: ~\$150k Total Cost: -\$750k Personnel: ~\$500k/yr Cleveland Clinic One MSTU can Mobile Stroke Treatment Unit service ~1M citizens ~10-15 year life expectancy









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Specialized ambulances expedite stroke treatment

By Adam Rubenfire | January 4, 2016

Finance

Cleveland Clinic and the University of Texas Health Science Center at Houston have been leading clinical trials of mobile stroke unit vehicles, which enable hospitals to treat patients 40 minutes faster than traditional methods.

Armed with on-board imaging equipment, telemedicine equipment and lifesaving drugs, the ambulances provide faster treatment for stroke, which can cause brain damage with every passing moment. Experts say strokes often aren't treated quickly enough.

"It's about being responsible not only for the inpatient but what happens to that patient (before they arrive and) after they leave. When we thought about these topics we were thinking about that continuum," said Diane Robertson, director of health technology assessment information services at ECRI, ECRI, a membership organization that evaluates medical technologies.

The vehicles—which were pioneered in Germany—made ECRI Institute's Top 10 Hospital C-Suite Watch list for 2016. Many of the items help providers reduce costs and curb readmissions such as warm perfusion systems for donor organs, miniature leadless pacemakers and blue-violet LED light fixtures that kill bacteria.

MSUs are modified ambulances that include a mobile blood lab, a heads-only CT scanner and telemedicine equipment that can send diagnostic images and help first responders communicate with neurologists at the hospital. UT and Cleveland Clinic each launched a single vehicle in 2014 and exclusively used them for stroke cases. Care teams are dispatched by a 911 operator when it's believed a patient is having a stroke.

Workers on the units normally include a critical-care nurse, a CT technologist, a paramedic and a driver. Normally, the crew will perform CT scans and blood testing at the scene and begin transporting the patient while a diagnosis is

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Telestroke was initiated in Fairview and Medina Hospitals in 2014. Their specific cumulative IVtPA experience before and after initiation of Telestroke capabilities are represented by the Pre-Telestroke and Post-Telestroke labels above.

The MSTU began operations in 2014; the data represents its IVtPA administration rate during its first year of operations.



Cleveland Clinic With or without Telestroke...



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With Telestroke...



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Worldwide MSTU Programs



Denver and Toledo





Mobile Stroke Treatment Units: Popping Up All Over the Place!





Patients First

- the Rest will follow...



Summary - The "Right" Reasons to do this....

- No doubt about role of time in therapy... initiate treatment as fast as possible
- Low rates of IV tPA administration (and now IA therapy) despite stroke units and Joint Commission accreditation demand change to the System
- Brings highest level of expertise as soon as possible
- Intelligent triage decisions to maximize use of scarce resources
- Patients first: Will decrease neurologic deficit, disability and costs to society
- MSTUs are here to stay will be a part of US stroke systems broadly

The linked image cannot...

Acknowledgements

- City of Cleveland Mayor Jackson/Marty Sweeney
- Cerebrovascular Center and Critical Care Transport
 - Michael Modic and Robert Wyllie
- Matt Stanton/Brian Perse (CV Center Administrators)
- Stacey Winners (MSTU Program Manager)
- Cleveland Pre-Hospital Acute Stroke Treatment (PHAST) Study Group







2016 International Mobile Stroke Summit: Transforming Stroke Care Through Innovative Stroke Systems

May 20-21, 2016

InterContinental Hotel and Conference Center 9801 Carnegie Ave Cleveland, OH

For more information, including online registration, visit www.ccfcme.org/MobileStroke16



ETHED

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Every life deserves world class care.