ACCESS Praxis: Should All VF Cases Go to the Cath Lab?

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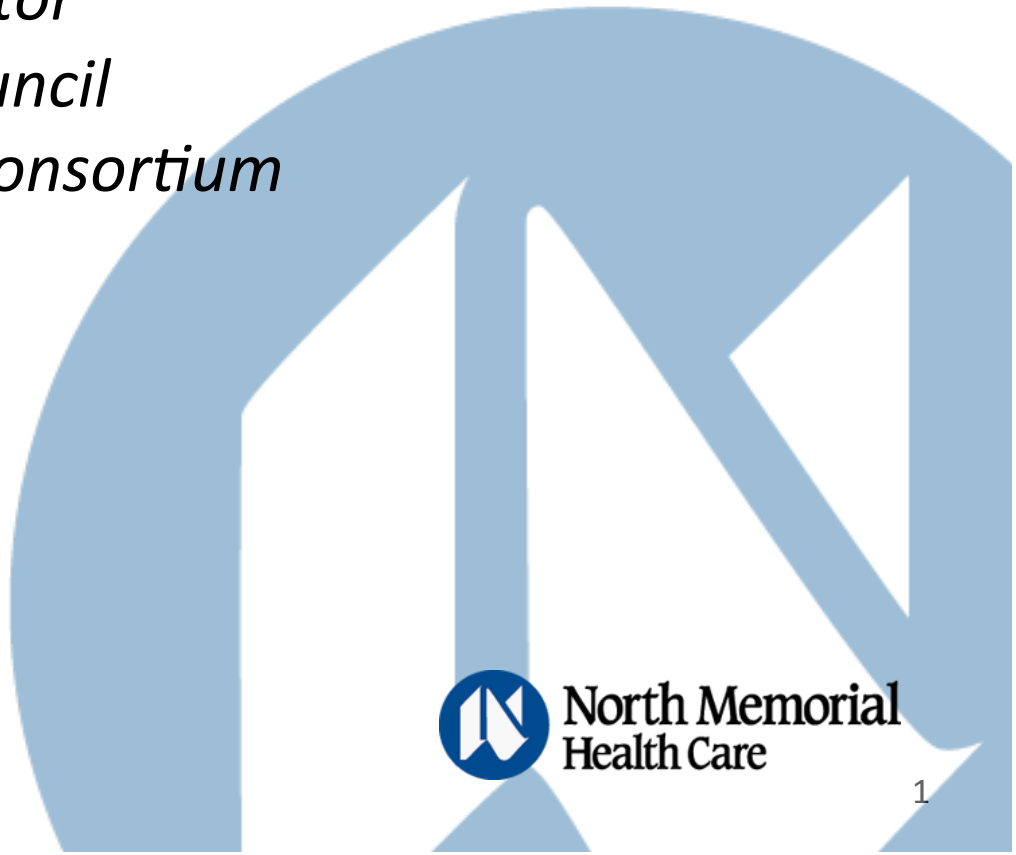

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DISCLOSURE STATEMENT

- CME Speaker for ZOLL Circulation/Alsius Corp
- Specializing in Resuscitative Hypothermia and Emergency Medicine related issues
- Board Member, MN Resuscitation Consortium

MN Resuscitation Consortium
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ACCESS Praxis

The Twin Cities
Experience in resuscitated VF/VT patients going early to the CCL

MRC data

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Early angiography and survival

Study or Subgroup	Acute angiography Events	Total	No acute Angiography Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Aurore 2011	31	133	30	312	8.2%	2.86 [1.65, 4.96]
Bro-Jeppesen 2012	129	198	87	162	9.3%	1.61 [1.05, 2.47]
Bulut 1999	4	10	10	27	2.9%	1.13 [0.26, 5.01]
Cronier 2011	54	91	6	20	4.7%	3.41 [1.20, 9.67]
Grasner 2011	80	154	57	430	9.3%	7.07 [4.64, 10.78]
Hollenbeck 2013	80	122	71	147	8.7%	2.04 [1.24, 3.34]
Mooney 2011	63	101	15	39	6.5%	2.65 [1.24, 5.67]
Nanjayya 2012	18	35	12	35	5.2%	2.03 [0.78, 5.31]
Nielsen 2009	303	479	187	507	10.6%	2.95 [2.27, 3.82]
Reynolds 2009	40	63	22	33	5.6%	0.87 [0.36, 2.11]
Strote 2012	44	61	88	179	7.5%	2.68 [1.42, 5.03]
Tomte 2011	76	145	9	29	5.9%	2.45 [1.04, 5.74]
Waldo 2013	57	84	7	26	5.1%	5.73 [2.15, 15.27]
Werling 2007	19	28	10	57	4.7%	9.92 [3.48, 28.25]
Zanuttini 2012	33	48	21	45	5.9%	2.51 [1.08, 5.86]
Total (95% CI)		**1752**		**2048**	**100.0%**	**2.77 [2.06, 3.72]**
Total events	1031		632			

Heterogeneity: $Tau^2 = 0.20$; $Chi^2 = 43.27$, df = 14 ($P < 0.0001$); $I^2 = 68\%$

Test for overall effect: $Z = 6.79$ ($P < 0.00001$)

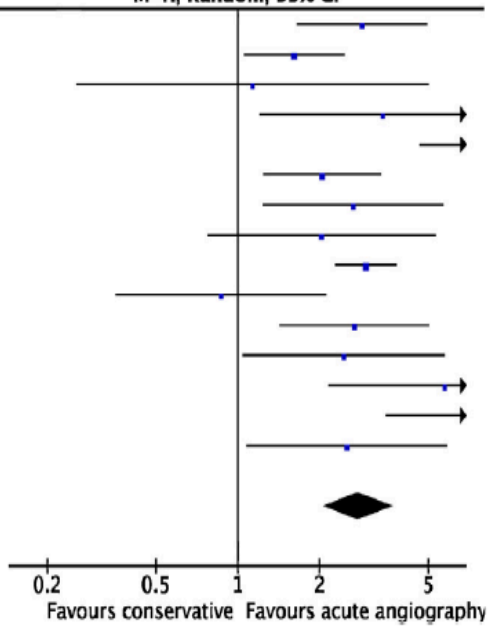

Fig. 2. Weighted hazard effects model of the relationship between acute coronary angiography and survival after OHCA.

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Early angiography and neurological outcomes

Study or Subgroup	Acute angiography Events	Total	No acute Angiography Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Bro-Jeppesen 2012	126	198	79	162	13.1%	1.84 [1.20, 2.81]
Grasner 2011	80	154	57	430	13.1%	7.07 [4.64, 10.78]
Hollenbeck 2013	74	122	65	147	12.5%	1.94 [1.19, 3.17]
Mooney 2011	61	101	12	39	9.8%	3.43 [1.56, 7.55]
Nanjayya 2012	14	35	11	35	8.1%	1.45 [0.54, 3.89]
Nielsen 2009	278	479	169	507	14.4%	2.77 [2.14, 3.58]
Reynolds 2009	33	63	19	33	9.2%	0.81 [0.35, 1.89]
Strote 2012	48	61	138	179	10.5%	1.10 [0.54, 2.22]
Tomte 2011	75	145	9	29	9.2%	2.38 [1.02, 5.58]
Total (95% CI)		**1358**		**1561**	**100.0%**	**2.20 [1.46, 3.32]**
Total events	789		559			

Heterogeneity: $Tau^2 = 0.29$; $Chi^2 = 40.71$, df = 8 ($P < 0.00001$); $I^2 = 80\%$

Test for overall effect: $Z = 3.75$ ($P = 0.0002$)

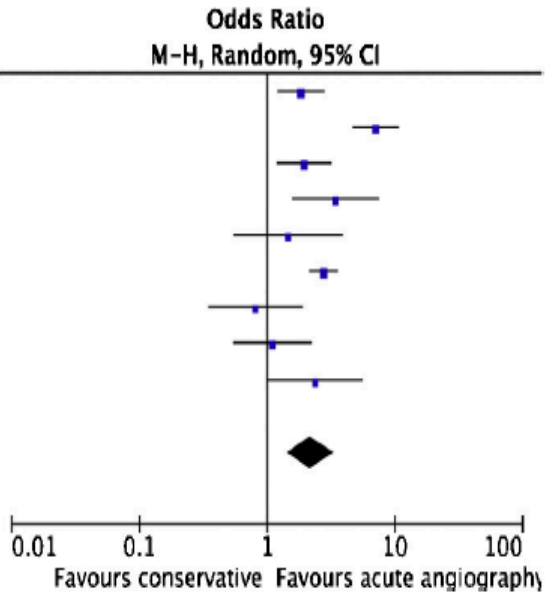

Fig. 3. Weighted hazard effects model of the relationship between acute coronary angiography and good neurological outcome after OHCA.

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ACCESS Trial Premise

- Patients who have a VF/VT arrest and have ROSC, even without a STEMI, have significant CAD that needs emergent remediation.
- That neurologic, cardiac function, AND patient long term outcomes would be better the sooner they went to the cath lab.
- The “shocky” patients that the Interventional Cardiologists feel are “too sick” to go to the cath lab (makes their numbers look bad!), actually need to go emergently!
- Interventional Cardiologists had two hours from EMS/ED notification to decide to take these patients to the cath lab, and total of six hours to get them there and work their magic.
- Exclusion Criteria: Age > 75 years < 18 years, DNR/DNI , Obvious Trauma, Known Terminal Disease, Active Hemorrhage (any cause)

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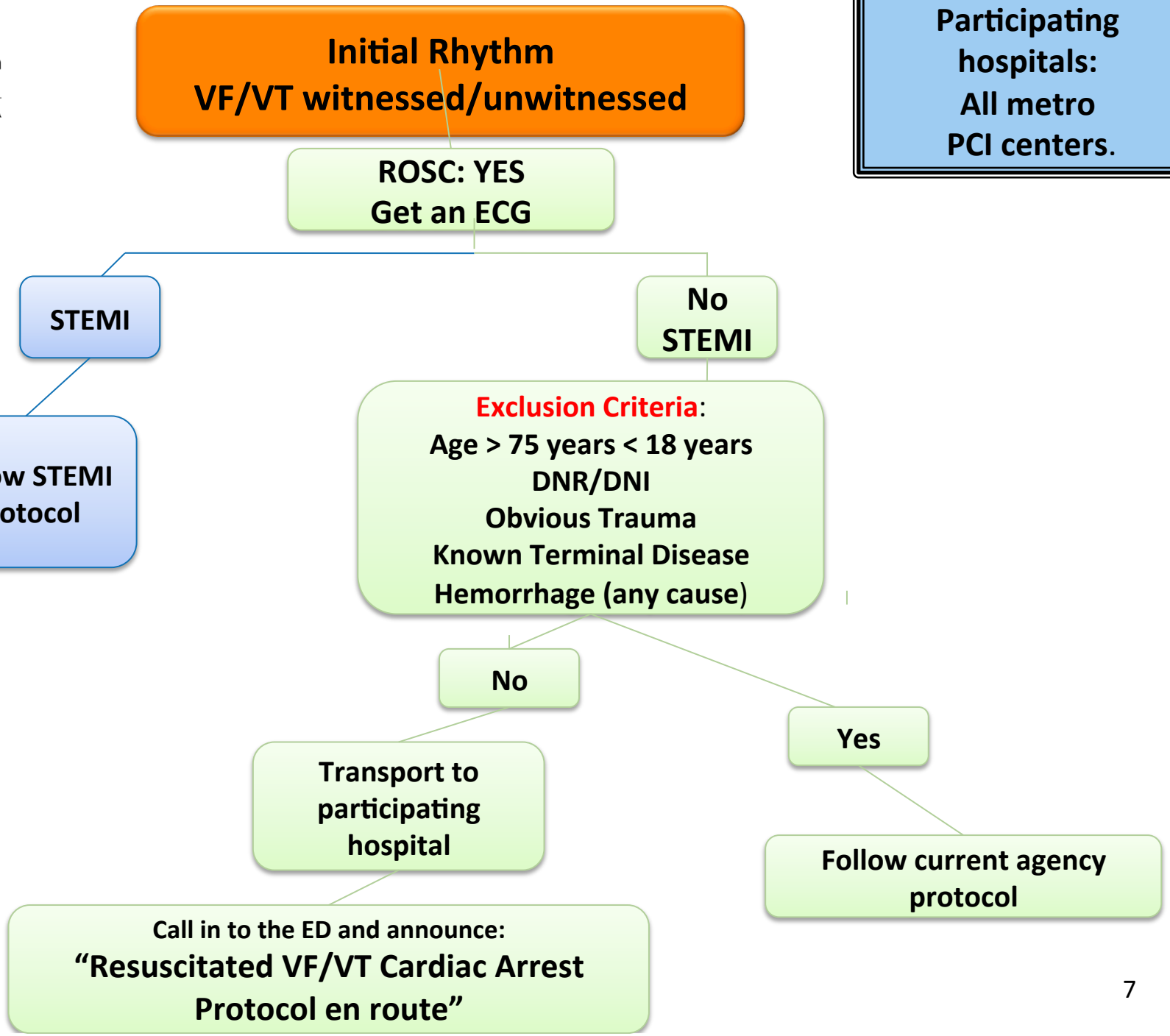

Participating hospitals: All metro PCI centers.

ACCESS Praxis

ORIGINAL RESEARCH

American Heart Association | American Stroke Association.

Early Access to the Cardiac Catheterization Laboratory for Patients Resuscitated From Cardiac Arrest Due to a Shockable Rhythm: The Minnesota Resuscitation Consortium Twin Cities Unified Protocol

Santiago Garcia, MD; Todd Drexel, MD; Wobo Bekwelem, MD; Ganesh Raveendran, MD; Emily Caldwell, RN; Lucinda Hodgson, BA, EMT-P; Qi Wang, MS; Selcuk Adabag, MD; Brian Mahoney, MD; Ralph Frascone, MD; Gregory Helmer, MD; Charles Lick, MD; Marc Conterato, MD; Kenneth Baran, MD; Bradley Bart, MD; Fouad Bachour, MD; Steven Roh, MD; Carmelo Panetta, MD; Randall Stark, MD; Mark Haugland, MD; Michael Mooney, MD; Keith Wesley, MD; Demetris Yannopoulos, MD

***Background*—**In 2013 the Minnesota Resuscitation Consortium developed an organized approach for the management of patients resuscitated from shockable rhythms to gain early access to the cardiac catheterization laboratory (CCL) in the metro area of Minneapolis-St. Paul.

***Methods and Results*—**Eleven hospitals with 24/7 percutaneous coronary intervention capabilities agreed to provide early (within 6 hours of arrival at the Emergency Department) access to the CCL with the intention to perform coronary revascularization for outpatients who were successfully resuscitated from ventricular fibrillation/ventricular tachycardia arrest. Other inclusion criteria were age >18 and <76 and presumed cardiac etiology. Patients with other rhythms, known do not resuscitate/do not intubate, noncardiac etiology, significant bleeding, and terminal disease were excluded. The primary outcome was survival to hospital discharge with favorable neurological outcome. Patients (315 out of 331) who were resuscitated from VT/VF and transferred alive to the Emergency Department had complete medical records. Of those, 231 (73.3%) were taken to the CCL per the Minnesota Resuscitation Consortium protocol while 84 (26.6%) were not taken to the CCL (protocol deviations). Overall, 197 (63%) patients survived to hospital discharge with good neurological outcome (cerebral performance category of 1 or 2). Of the patients who followed the Minnesota Resuscitation Consortium protocol, 121 (52%) underwent percutaneous coronary intervention, and 15 (7%) underwent coronary artery bypass graft. In this group, 151 (65%) survived with good neurological outcome, whereas in the group that did not follow the Minnesota Resuscitation Consortium protocol, 46 (55%) survived with good neurological outcome (adjusted odds ratio: 1.99; [1.07–3.72], P=0.03).

***Conclusions*—**Early access to the CCL after cardiac arrest due to a shockable rhythm in a selected group of patients is feasible in a large metropolitan area in the United States and is associated with a 65% survival rate to hospital discharge with a good neurological outcome. **(*J Am Heart Assoc*. 2016;5:e002670 doi: 10.1161/JAHA.115.002670)**

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Protocol penetration in the Twin Cities:

313/370 (85%) patients got early access to the cath lab after resuscitated VF/VT

Of the patients with early access to the cath lab:

- 235/313 (75%) were discharged alive
- 222/235 (95%) had CPC 1 and 2
- 147/313 (46%) had PCI
- 5% had CABG and 38% had ICD placed

Patient that did not get access to the cath lab :

- 24/56 (42%) were discharged alive
- 19/24 (79%) had CPC 1 and 2

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outcome	Overall N=315	Access to Cath Lab within 6 hours N=237	All others (ref) N=78	Unadjusted OR (95% CI)	P value	Adjusted OR* (95% CI)	P value
EF > 40% vs. <=40%	150 (63%)	109 (62%)	41 (66%)	0.85 (0.46, 1.55)	0.59	0.69 (0.32, 1.48)	0.34
Alive vs. death	227 (72%)	170 (74%)	57 (68%)	1.31 (0.77, 2.27)	0.32	1.60 (0.83, 3.08)	0.16
CPC 1 or 2 vs. >=3 or death	197 (63%)	151 (65%)	46 (55%)	1.56 (0.94, 2.56)	0.09	1.99 (1.07, 3.72)	0.03

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outcome	All non-STEMI N=203	Access to Cath Lab within 6 hours N=130	All others (ref) N=73	Unadjusted OR (95% CI)	P value	Adjusted OR* (95% CI)	P value
EF > 40% vs. <=40%	99 (65%)	63 (64%)	36 (65%)	0.95 (0.48, 1.90)	0.88	0.80 (0.35, 1.86)	0.61
Alive vs. death	145 (71%)	95 (73%)	50 (68%)	1.25 (0.67, 2.34)	0.49	1.73 (0.80, 3.74)	0.16
CPC 1 or 2 vs. >=3 or death	125 (62%)	86 (66%)	39 (53%)	1.70 (0.95, 3.06)	0.07	2.77 (1.31, 5.85)	0.01

*adjusted for age, sex, race, PCI, CABG, MI, DM, HTN, CHF, HLD, tobacco Use, year, location of arrest, bystander CPR, Peak troponin

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outcome	Overall N=315	Access to Cath Lab within 24 hours N=237	All others (ref) N=78	Unadjusted OR (95% CI)	P value	Adjusted OR* (95% CI)	P value
EF > 40% vs. <=40%	150 (63%)	112 (62%)	38 (67%)	0.82 (0.44, 1.54)	0.54	0.66 (0.31, 1.44)	0.30
Alive vs. death	227 (72%)	175 (74%)	52 (67%)	1.41 (0.81, 2.45)	0.22	1.66 (0.86, 3.21)	0.13
CPC 1 or 2 vs. >=3 or death	197 (63%)	156 (66%)	41 (53%)	1.74 (1.03, 2.92)	0.04	2.16 (1.14, 4.07)	0.02

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outcome	Overall N=315	PCI and/or CABG N=139	All others N=176	Unadjusted OR (95% CI)	P value	Adjusted OR* (95% CI)	P value
EF > 40% vs. <=40%	150 (63%)	77 (67%)	73 (60%)	1.36 (0.80, 2.31)	0.26	1.86 (0.93, 3.70)	0.08
Alive vs. death	227 (72%)	112 (79%)	115 (66%)	1.88 (1.13, 3.14)	0.015	2.55 (1.32, 4.93)	0.005
CPC 1 or 2 vs. >=3 or death	197 (63%)	102 (72%)	95 (55%)	2.09 (1.31, 3.36)	0.002	3.04 (1.36, 5.66)	0.0005

*adjusted for age, sex, race, PCI, CABG, MI, DM, HTN, CHF, HLD, tobacco Use, year, location of arrest, bystander CPR, STEMI on ECG, Peak troponin

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Conclusions

- Early access to the cardiac catheterization for resuscitated patients from VF/VT is feasible, can be organized in a large metro area with close communication and collaboration of EMS directors and cath lab directors.

- Expected survival for this population is >75% and >95% are neurologically intact. Long term outcomes are stable as Sideris (et al) have shown.

- PCI is expected in about 50% of the patients and a smaller proportion will undergo CABG.

- Patients that do no get access to the cath lab have a poor outcome with expected survival of ~40%.

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ACCESS TRIAL

- Nationwide NIH funded trial based on the original MRC initiative.
- Aim is to evaluate on a large scale the results of the original trial.
- Scheduled to start in January 2018.

ACCESS

February 6, 2017

ACCESS Trial Investigators,

The purpose of this communication is to update you on progress with the ACCESS Trial start-up.

NIH has now established a DSMB. Their first meeting is scheduled for February 27, 2107. At that time, the DSMB will either accept the protocol as written or request revisions. If revisions are required, we will expedite completion of those revisions.

As soon as a DSMB-approved protocol is available, IRB submission can occur. We are expecting the EFIC process and IRB approval in its entirety to take approximately 9 months. Our goal is to enroll by January of 2018, we believe this is a very feasible timeline. We are planning a study investigator and research coordinator training in-service to occur in Minneapolis, MN (with Webinar participation for those who cannot attend in-person) sometime in the fall of 2017 and will provide more information as soon as it's available.

NIH has strongly recommended investigators use a central IRB process for the ACCESS Trial. The AAHRPP-approved Medical College of Wisconsin (MCW) IRB has been selected to lead this process. Participation in the ACCESS Trial central IRB process is voluntary. The MCW IRB is extremely flexible in accommodating the level of your IRB's interest and degree of participation (or partial participation), particularly with respect to the EFIC process. The MCW IRB is contacting ACCESS Trial IRBs now. If you have not done so, please forward the name of your IRB representative and complete contact information to: 1) Tom Aufderheide (taufderh@mcw.edu), and 2) Emily Caldwell (caldw076@umn.edu) so that the MCW IRB can initiate a discussion prior to your ACCESS Trial IRB submission.

We expect developments to occur rapidly as soon as the DSMB-approved protocol is available. Start-up packets will be sent out as soon as we have an approved protocol. If you have any questions or concerns, please contact us. We look forward to initiating the start-up process for the ACCESS Trial within the next few months!

Sincerely,

Dr. Demetris Yannopoulos
ACCESS Trial PI
Professor of Medicine
The Robert Eddy Endowed Chair in Cardiovascular Resuscitation
Medical Director | MN Resuscitation Consortium
Director of Research | Interventional Cardiology
Cardiovascular Division | University of MN

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ACCESS Trail PI
Professor of Emergency Medicine
Associate Chair of Research Affairs
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Director, Resuscitation Research Center
Medical College of Wisconsin
Department of Emergency Medicine

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Special Thanks to our Ringleader:

Demetris Yannopoulos M.D.

Professor of Medicine
Medical Director, Minnesota Resuscitation Consortium
Director of Research, Interventional Cardiology Section
Division of Cardiovascular Medicine
University of Minnesota

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