

Trial Overview



RAnimized Cluster Evaluation of Cardiac ARrest Systems

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RACE-CARS Trial
12/13/2023

Objectives



- Discuss the RACE-CARS Trial
- Review the trial interventions
- Discuss future cardiac arrest work

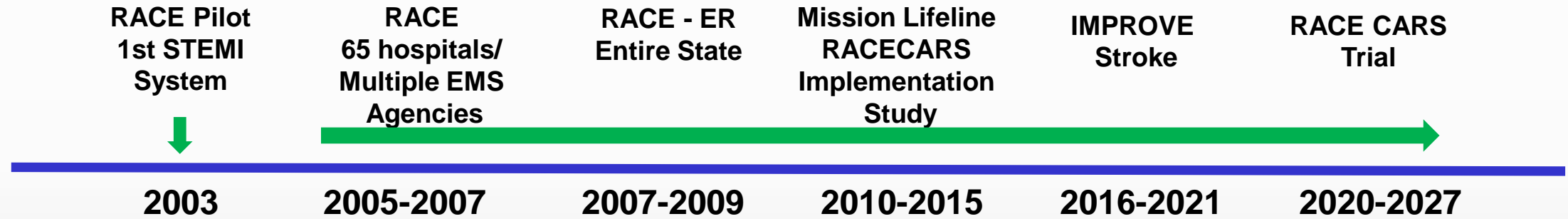
History on North Carolina RACE



“AHA’s Mission: Lifeline – A Call to Arms for Emergency Medicine” ACEP News Jan 2009

“RACE: A Herculean attempt to improve STEMI care” Nov 12, 2007 Lisa Nainggolan

“AHA’s Mission: Lifeline – A Call to Arms for Emergency Medicine” ACEP News Jan 2009



“RACE moved beyond the cath lab and PCI hospitals to focus on EDs, EMS, hospital networks, and associated communication and transport systems.” Heart.org

“Racing Against the Clock: A North Carolina-based project becomes a model for discovery-to-balloon” Richard R. Rogoski 2008



“North Carolina’s RACE program cuts door-in door-out times for STEMI patients” Jun 28, 2011 Reed Miller

[Association of Bystander and First-Responder Intervention With Survival After Out-of-Hospital Cardiac Arrest in North Carolina, 2010-2013. JAMA. 2015 Jul 21; 314\(3\):255-64. doi: 10.1001/jama.2015.7938](#)

RACE observed:
 25% increase in bystander CPR and first responder defibrillation
 37% increase in survival with good neurologic function

NC statewide data continue to demonstrate substantial variability for OHCA.

The Why



- 350,000 cardiac arrests/year
- < 10% survive
- < 40% receive bystander CPR
- In the last 30 years, survival rates have not changed
- There is a lot of regional variation in survival (7-40%)
- Only 1% of the cardiac arrest guidelines are supported by trial evidence

- EMS Response times 8-10 mins
- Fire Response times shorter 6-8 mins

Levels of evidence

Only 12% based upon randomized trials



American
Heart
Association®

Level A

- High-quality from more than 1 randomized trial (RCT)
- Meta-analyses of high-quality RCTs

LOE A
1%

“The fact that only 6 of these 491 recommendations (1.2%) are based on Level A evidence testifies to the ongoing challenges in performing high-quality resuscitation research. A concerted national and international effort is needed to fund and otherwise support resuscitation research.”

- Physiological or mechanistic studies in humans

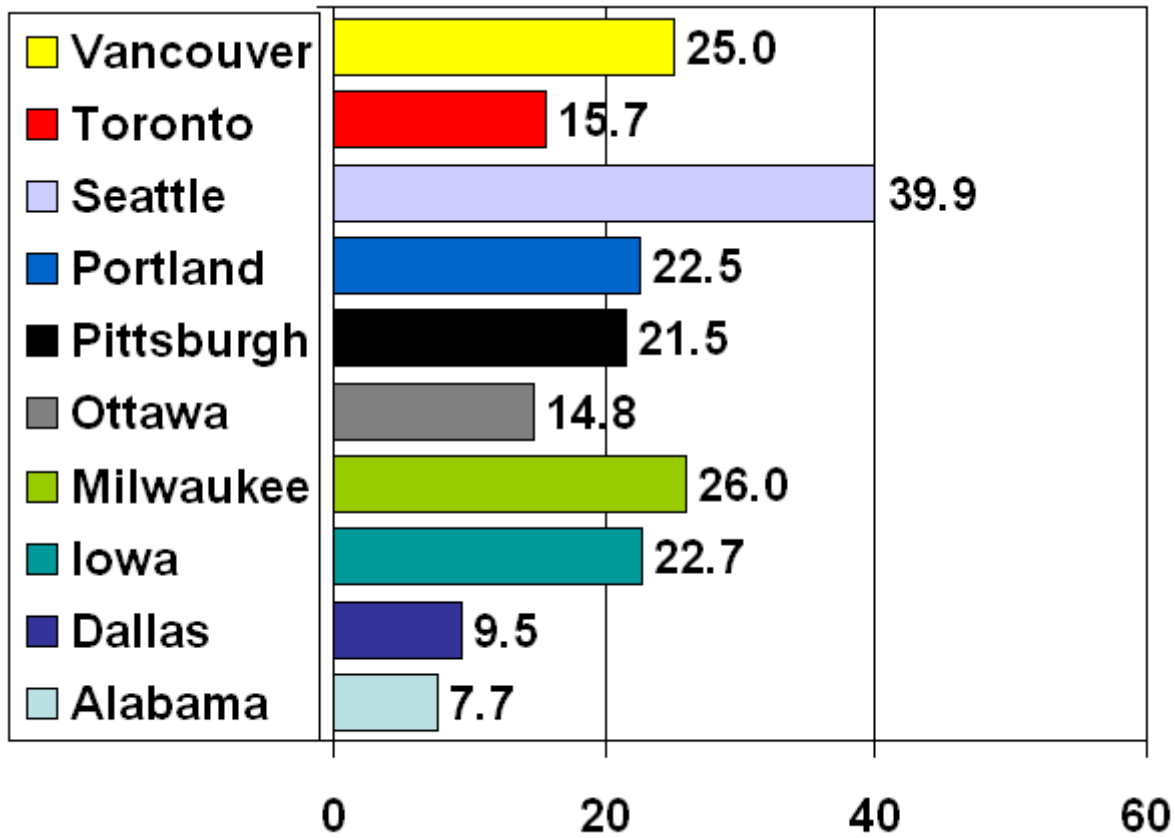
Level C-EO (Expert opinion)

- Consensus of expert opinion based on clinical experience

Variation in survival VF arrest Resuscitations Outcomes Consortium



Survival to discharge



*“Where you live
should not determine
whether you live”*

RACE CARS Rationale



- Main barrier preventing progress is not the lack of knowledge but the **effective systematic implementation** of what works.
- The greatest opportunity for improving cardiac arrest outcomes is an intensified strategic focus on:
 - improved 911 recognition of OHCA and delivery of telephone CPR
 - improved use of bystander CPR
 - more rapid deployment of first responder defibrillation
 - improved AED use

RACE-CARS Cluster Randomized Trial



Out-of-hospital cardiac arrest, presumed cardiac etiology,
resuscitation attempted by 911 responder

Cluster randomize 62 (57 clusters) counties
~ 20,000 patients



Intervention

Community and EMS care
improvement with data feedback

Control

Usual care, continuing standard
quality improvement efforts

Data collection through CARES registry and quality of life surveys

Primary endpoint: hospital survival with good neurologic outcome
Secondary outcomes: rates of bystander CPR, defibrillation prior to EMS
arrival

Other outcomes: 911-dispatcher recognition of cardiac arrest, overall hospital
survival, functional status and quality of life at 6 and 12 months

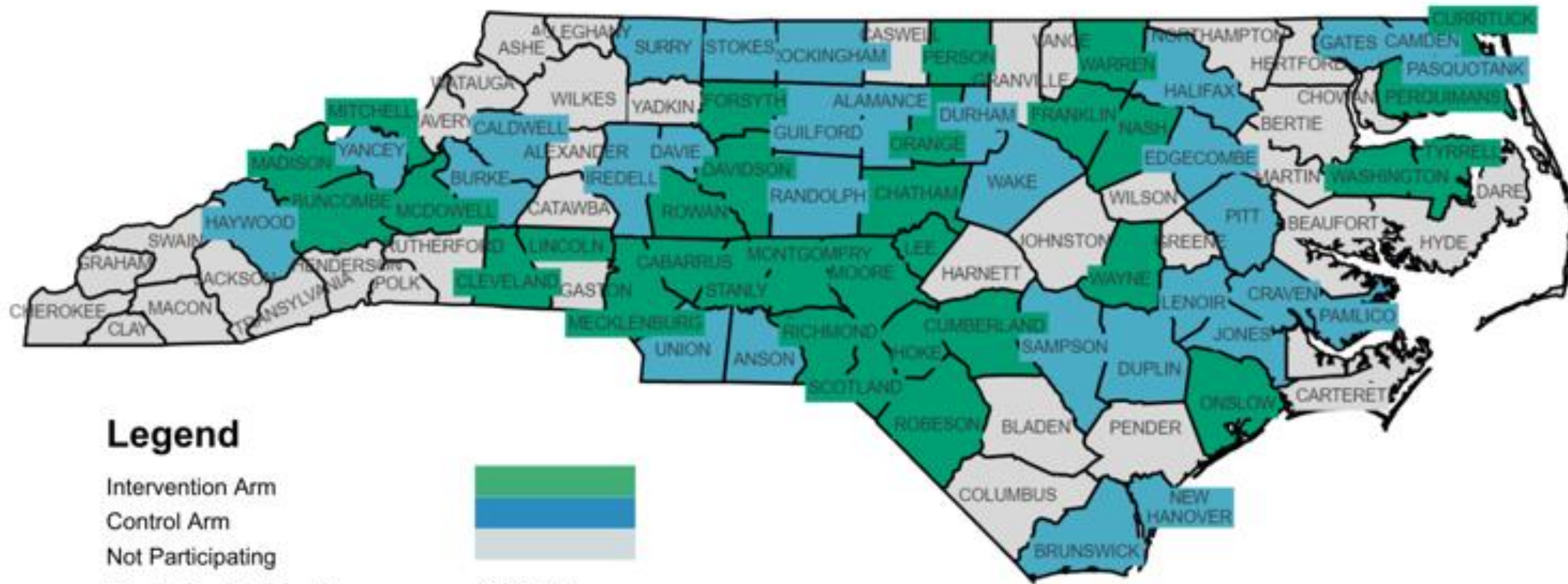


Intervention Elements

- Rapid cardiac arrest recognition protocols that trigger immediate priority EMS/first responder dispatch by 911 operators.
- Systematic bystander resuscitation instruction by 911 operators.
- Comprehensive community training of lay people in CPR and AED use.
- Optimized first responder performance including earlier use of AEDs.

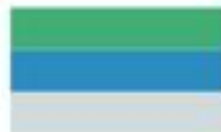


RACE CARS Trial Participation



Legend

- Intervention Arm
- Control Arm
- Not Participating



Population Participating 8,464,601
% NC Population Participating 79.1%

RACE CARS Trial Objectives



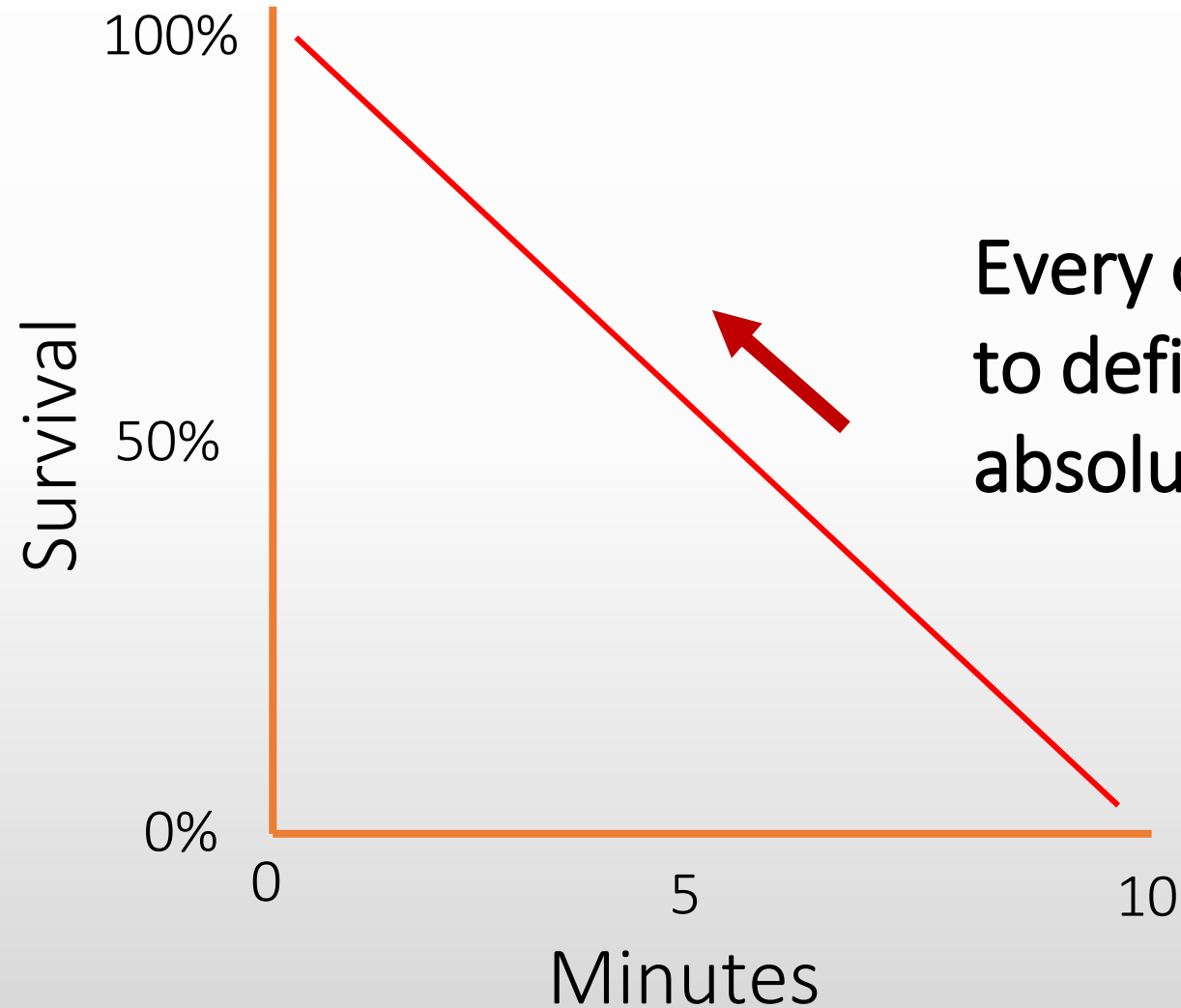
- **Primary Objective:**

- Improve survival to hospital discharge with good neurologic function by 33% from 9.0% to 12.0%

- **Secondary Objectives:**

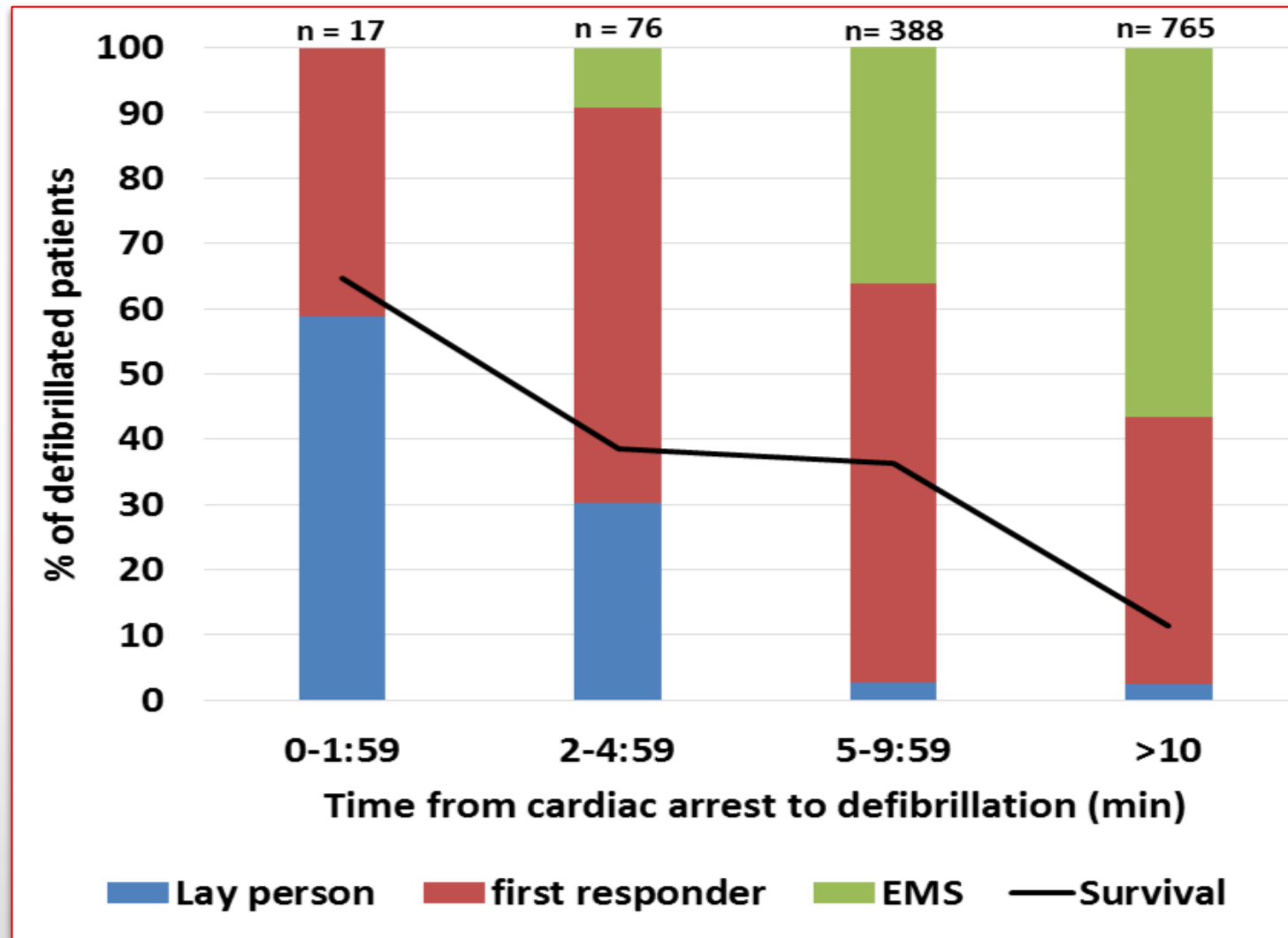
- Increase bystander rates of CPR in intervention counties by 33% compared with control counties
- Increase rates of bystander or first responder defibrillation prior to paramedic (emergency medical provider trained in advanced cardiac resuscitation) arrival in intervention counties by 50% compared to control counties.

Survival vs Time to Defibrillation for VF Arrest



Every one minute faster time to defibrillation results in 10% absolute increase in survival

Time to defibrillation, who did it, and survival



EMS

Establish a Regional System of Care



Step 1: Engage with 911, Fire, hospitals, and community organizations

Step 2: Organize community education and AED efforts

Step 3: Develop quality improvement process for OHCA in concert with hospital, first responders (fire and law), and 911

Step 4: Optimize Team Based CPR plan

Step 5: Organize Survivor Celebrations

Timeline



2020	2021			2022			2023			2024			2025			2026			2027											
Year 1			Year 2			Year 3			Year 4			Year 5			Year 6			Year 7												
Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4				
Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun				
Start-up (6 months)																														
			Randomization at 6 months																											
			Intervention Training (1 year, months 6-18)																											
			CARES Data Collection (4 years, ongoing)																											
			QOL Follow-up at 6 and 12 months post-discharge (start year 3, end year 6.5)																											
			Data Quality Checking (5 years, ongoing)																											
																									Analysis, Reporting, Papers (12 months)					

Implementation Science Analysis



- Hayden Bosworth, PhD
- Both implementation staff and RACE-CARES staff will work to carry out analyses
- Conduct an analysis of interventions, their implementation and impact
- Plan for both quantitative surveys and qualitative interviews at select time points throughout trial and intervention period. Assess small, medium, large size counties.
- Key Questions:
 - What county and community-based characteristics (EMS resources, culture, and context) are associated with adoption of interventions to improve CPR and early defibrillation?
 - What interventions are associated with increased reach, adoption, implementation, and maintenance of higher rates of CPR and early defibrillation?
 - Which approaches were more or less successful in key subgroups, for example African Americans or women?
- Engagement of Fire

Long-term follow-up with survivors



- Cardiac arrest survivors in the participating counties and/or their caregiver proxies will be asked to consent to 3 and 12 month telephone interviews
- All survivors are contacted for participation (CPC score 1-4)
- Vital status is collected for all survivors at 12-months regardless of participation
- Spanish language option was added in April
- **12-month interviews will start in July 2023**



4 Interventions

1. Rapid cardiac arrest recognition protocols that trigger immediate priority EMS/first responder dispatch by 911 tele-communicators.
2. Systematic bystander resuscitation instruction by 911 tele-communicators.
3. Comprehensive community training of lay people in CPR and AED use.
4. Optimized first responder performance including earlier use of AEDs.

Cardiac Arrest Registry for Enhanced Survival



<https://mycares.net>

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CARES
Cardiac Arrest Registry
to Enhance Survival

REGISTERED USERS LOGIN

>> [Click here to learn more about enrollment.](#)

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911



- First trained personnel to arrive at the scene
- Launched the dispatch module
- Working to improve recognition rates and hands on chest times
- Agreement of first responders to respond to all cardiac arrest calls
- Cardiac arrest training at the forefront
- Data feedback and monitoring
- Challenges
 - Staffing
 - Pay rates
 - Recognition as a profession
 - AED locations

Fire and Law Enforcement



- Includes both Fire and Law Enforcement
- Agree to respond to all calls
- Equip with AED's
- Challenges
 - Rural/volunteer agencies
 - Lack of volunteers
 - Pay scale
 - Lack equipment

Community Training



- Create a partner community group
 - 911, Fire, Law, hospitals, EMS, AHA/Red Cross, DEI groups, colleges/universities, etc
- Train an additional 10% of your county population
- TTT
- Organizational training
- Heart safe Business recognition
- Specialty training for underserved populations

Operations Manual

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THE RACE-CARS TRIAL Manual of Operations



REciprocal InnovationS TO ImpRovE Cardiovascular CARE in Rural America (RESTORE CARE)



- *The overall goal of this project is to design, develop, and pilot test an emergency healthcare drone delivery system suitable for rural communities that can deliver AEDs to OHCA locations more rapidly than can be achieved with current first responder and EMS systems.*
- *Our goal is to determine whether this method of AED delivery can be achieved rapidly enough to justify a future clinical trial directly testing its ability to improve OHCA survival.*
- 2023-2027
- Funded by the AHA

Forsyth County Sheriff's Office to test cardiac care drones in a first for the U.S.

Wes Young Oct 10, 2023 0

