

ARIZONA DEPARTMENT OF HEALTH SERVICES

PREPAREDNESS

Emergency Medical Services Council

Date: May 23, 2019 - Time: 10:30 hrs

Location: ADHS, 150 N. 18th Ave, 2nd Floor, 215 A&B, Phoenix, AZ 85007

Via computer with call back: azgov.webex.com, meeting code 804 368 048, password EMS2019

Via telephone: dial 240-454-0879, meeting code 804 368 048 (#)

AGENDA

- I. <u>Call to Order</u> Glenn Kasprzyk, Vice Chair
- II. <u>Roll Call</u> Shelley Bissell (31 members, 16 required for quorum)
- III. <u>Chairman's Report</u> Glenn Kasprzyk
 - a. Attendance report (Attachment III.a.)
 - b. New Members: Todd Jaramillo, MHA; Deborah Gorombei, DNP; Assistant Chief Mike Garcia; Melanie Mitros, PhD; Garth Gemar, MD; Vivienne Gellert; Assistant Chief Mike Duran; and Heather Miller, BSN, RN
 - c. Vacancy report
- IV. <u>Bureau Report</u> Chief Terry Mullins and Staff
 - a. Regulatory Section Update Ithan Yanofsky
 - a. Rule Writing
 - b. Certificate of Necessity (CON)
 - c. Trauma and Base Hospitals
 - d. Certification
 - e. Education
 - b. Services Section Update Ben Fisher, MPA, NRP
 - a. Linkage Projects
 - b. Data Completeness Measurement update
 - c. Motor Vehicle Traffic-Related Trauma Report
 - d. Dataset Revision Methodology a Refresher
 - e. EMS Registry
 - f. Trauma Registry
 - g. Recognition Programs
 - h. EMS Resiliency, Wellness & Safety
- V. <u>Standing Committee/Regional Council Reports</u>
 - a. Education Standing Committee Brian Smith, CEP
 - b. Protocols, Medications and Devices Standing Committee Brian Smith, CEP
 - c. Trauma and EMS Performance Improvement Standing Cmte. Rebecca Haro, NREMT-P

- d. Regional Emergency Medical Services Councils
 - i. AEMS Joe Gibson (Attachment V.d.i.)
 - ii. SAEMS Sara Perotti, ANCP-BC (Attachment V.d.ii.)
 - iii. NAEMS Paul Coe
 - iv. WACEMS Rod Reed
- e. Pediatric Advisory Council for Emergency Services (PACES) Dale Woolridge, MD

VI. <u>Discussion and Action Items</u>

- a. Discuss, amend, and approve EMS Meeting Minutes from September 27, 2018 (Attachment VI. a.)
- VII. <u>Presentation</u> Dan Spaite, MD, UA's Arizona Emergency Medicine Research Center
 - a. Report on the conclusions of the Excellence in Prehospital Injury Care Traumatic Brain Injury Project (EPIC-TBI) (Attachment VII.a.)
- VIII. Agenda Items to be considered for the next meeting
- IX. <u>Call to the Public</u>

A public body may make an open call to the public during a public meeting, subject to reasonable time, place and manner restrictions, to allow individuals to address the public body on any issue within the jurisdiction of the public body. The Council may ask staff to review a matter or may ask that a matter be put on a future agenda. Members of the public body shall not discuss or take legal action on matters raised during an open call to the public unless the matters are properly noticed for discussion and legal action. A.R.S. § 38-431.01(G)

Persons with disabilities may request reasonable accommodations such as a sign language interpreter, by Angie McNamara, angie.mcnamara@azdhs.gov, 602-364-3156; State TDD Number 1-800-367-8939; or Voice Relay Number 711. Request should be made as early as possible to allow time to arrange accommodations.

X. <u>Summary of Current Events</u>

- June 12 PEDS Aplenty An EMS Odyssey Pre-Conference Pediatric Education Event -Phoenix
- June 13 14 19th Annual EMS Odyssey Conference Phoenix
- June 27 -28 Southwest Regional Trauma Conference Tucson
- July 12 EMS Resiliency, Wellness & Safety Summit Kingman
- July 17 19 Western Pediatric Trauma Conference Telluride, Colorado

Visit the Bureau's News & Conferences page for upcoming events: <u>http://azdhs.gov/preparedness/emergency-medical-services-trauma-system/index.php#news-conference-home</u>

Visit the Bureau's Training Programs page for upcoming CE opportunities: <u>http://azdhs.gov/documents/preparedness/emergency-medical-services-trauma-</u> <u>system/training/continuing-education.pdf</u>

XI. <u>Next Meeting</u>

September 19, 2019 @ 10:30 hrs at ADHS, 150 N 18th Ave., Conference Rooms 215 A&B, Phoenix, AZ 85007

XII. <u>Adjournment</u>

Committee Attendance Report

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Attachment III.a.

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EMS Council

EMS Council

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EMS Council Report Central Arizona Region January - May 2019 Prepared by Arizona Emergency Medical Systems, Inc. (AEMS)

• The AEMS Functional Group meetings were held January 16, March 20, and May 15.

Topical Focus and Lunch & Learn presentations included:

Evolving Care of Stroke

Timothy Ingall, MD, Mayo Clinic Hospital; Jeremy Payne, MD, Banner-University Medical Center Phoenix; Mohamed Teleb, MD, Banner Desert Medical Center

Evolution of Neurosurgery Marco Marsella, MD, Neurosurgeon, Abrazo Central Campus and Abrazo West Campus

Stress, Grief and Suicide in First Responders Dara N. Rampersad, Ph.D., LPC, NCC, BluePaz, LLC, First Responder Psychologist

Central Region Agency/Hospital Profiles have included:

Banner Emergency Stroke Treatment Unit (BESTU) Gabe Gabriel, RN, CEN, Dignity Health St. Joseph's Hospital & Medical Center

Maryvale Hospital Barb Bovee, RN

Florence Hospital - A Campus of Mountain Vista Medical Center - Steward Nathan Windatt, RN

Abrazo Mesa Hospital Martin Murphy

The next AEMS Functional Group meeting will be held on July 17, 10:00 am, at Phoenix College.

• AEMS Board meetings were held on February 20 and April 17.

The next AEMS Board of Governors meeting will be held June 19, Noon, at Phoenix College

Several Board transitions have occurred. We recently installed two new and one returning Board members:

Steve Maher, MD

Mayo Clinic Hospital Physician, Active in the Practice of Emergency Medicine and/or Pre-Hospital Administrative Medical Direction, Employed, or Contracted, as an Administrative Medical Director for a Pre-Hospital EMS Agency.

Mike Grant

Maricopa Fire Department Representative from a Rural EMS Provider Agency

Mike Naehrbass (returning) Surprise Fire-Medical Department Emergency Medical Care Technician (EMCT), Serving their Employers in a Predominantly Non-Administrative Capacity

Special **THANK YOU** to: **Mark Nichols**, Daisy Mountain Fire & Medical Mark recently departed from the Board. We appreciated his service!

EMS Council Report - Central Arizona Region - January - May 2019 - Prepared by AEMS Continued

- AEMS 2019 membership dues campaign is ongoing through June. Our goal for the 2019 campaign is \$55,000. Membership dues remain an important part of AEMS base funding and underwrite many of our operational expenses.
- AEMS is in the process of coordinating and will soon be hosting 19th Annual EMS Odyssey Conference. The conference is June 13-14, 2019 at the Desert Willow Conference Center in Phoenix. This year, the Arizona Emergency Nurses Association (AZENA) has partnered with helps to help coordinate several sessions and to help promote the conference.

Our annual event commences on June 12 with **PEDS APLENTY**, an all-day Pediatric education pre-conference. The morning session will focus on presentations of topics including: TBI, special considerations, toxicology, and airway. The afternoon session will focus on interactive training stations, including airway, trauma, medical and OB. AEMS will be awarding 15 scholarships to attend the conference. **CONFERENCE REGISTRATIONS ACCEPTED THRU May 31 – visit** <u>aems.org/odyssey</u> **AND our event page** <u>eventzilla.net/user/aems</u>

 The EMS Odyssey Conference presentations include: weapons of mass destruction for medical professionals, traumatic amputations, legal and ethical issues facing EMS, stroke VAN assessment, first responder resilience, ventilators, opioids and EMS occupational exposure, basic x-ray interpretation, human trafficking, disaster search dogs, pediatric seizures, injury prevention, active shooter panel, and bullets and ballistics.

During the EMS Odyssey Conference, a special luncheon ceremony will be held to recognize our 2019 Aces of Hearts Award and Heart to Heart recipients. The Aces of Hearts awards are presented annually to recognize the outstanding contributions of EMS and trauma care colleagues. This year's recipients include:

2019 Aces of Hearts Recipients					
Warren Bahle	Heather Gonzalez	Mike Ocampo			
Chandler Fire Department	Banner Goldfield Medical Center	AMR – Pinal			
Andrew Bergeson	Brandon Hestand	Dan Oscislawski			
Banner Ironwood Medical Center	Chandler Regional Medical Center	Tempe St. Luke's Hospital			
Jason Erbes	Rob Johnsson	Barbara Schaffer			
Surprise Fire-Medical Department	Glendale Fire Department	Banner Casa Grande Medical Center			
Tammy Eydeler	Jeffrey McCarley	John Shufeldt			
Banner Del E. Webb Medical Center	Pinal County Sheriff's Office	San Carlos Apache Healthcare			
Bradley Fulton	PJ McCullough	Ryan Spilsbury			
Coolidge Police Department	Coolidge Fire Department	Maricopa Ambulance			
Rob Gibbons	Heather McKinnon	Beth Yancey			
Scottsdale Fire Department	Gilbert Fire & Rescue	AMR-Maricopa			

Additionally, four recipients will be receiving the **AEMS' Heart to Heart Award**, which is presented to citizens or off duty healthcare professionals, who have been involved with an extraordinary and recent life-saving event. **Chance Buddecke and Sara Wise** will be receiving the award for saving the life of Jim Wise (Chance's boss and Sara's husband) while working their jobs at Baskin-Robbins. **Marcos Lopez** will be receiving the award for saving the life of his neighbor – a 10 month old baby – whom was choking and went into cardiac arrest. **The Fetch Foundation**, a 501(c)(3) non-profit organization, will be receiving the award for their work that provides first responders with the tools and resources, including the FIDO Bag, to save the lives of pets and other animals.

- On behalf of AEMS, the Valley Medical Directors, with input and involvement from other regional constituents, continue to manage and update the RED Book.
- Over the next several months, AEMS will be updating our categorization questionnaire and requesting that all hospitals complete it so that we have current information about their services and resources.



SOUTHEAST ARIZONA EMERGENCY MEDICAL SERVICES COUNCIL DAN SPAITE, MD; CHAIR VICE CHAIR CHIEF TOM BRANDHUBER SARA PEROTTI, ACNP-BC, MSN, APRN, NREMT-P; EXECUTIVE DIRECTOR

SAEMS REPORT TO EMS COUNCIL – May 23rd, 2019

SAEMS Regional Council New Representatives:

- Chair PDR Committee: Dr. Amber Rice
- Regional Council Vice-Chair: Chief Tom Brandhuber *Re-elected for additional term

Committees:

-Medical Directors

Approved:

New updates and revisions from PDR committee:

- Scene Transfer of Patient Care-Approved
- CPAP Protocol-Approved

-PDR:

- Self Learning Packets (SLP's): Removed from website.
- Documents under development:
 - Standing Orders:
 - Narrow complex tachycardia
 - Wide Complex tachycardia
 - Pain Management SO
 - Sexual Assault SO
 - Protocols:
 - Air Medical Services, Emergency Use Assessment
 - Critical Pediatric Triage
 - Disaster Medical Management Protocol
 - Documentation Criteria
 - Infection Control for EMS Personnel
 - HazMat Incident, General Mgmnt
 - HazMat Incident Drug Antidote Therapy
 - Prehospital Medical Care Directive
 - Refusal/Cognitive Screening Procedure
 - Restraint Protocol
 - Treat and Release Protocol
 - Trauma Triage Decsion Scheme
 - LVAD Protocol

-Regional Trauma Committee:

- Dr. Tang: Presentation: Quarterly activity summaries provided to each agency/hospital-Utilization Review
- Revision of Trauma Triage Guideline/Protocol-Approved

-Regional Council

- EPIC-TBI Study: results release
- Extensive bylaw review and revision underway for all committees as well as the general council.

Scholarships:

• Chuck Kramer Fund Scholarship: Submissions to be reviewed/approved in upcoming meeting

Funding requests:

• Pediatric funding granted for Pediatric focused topics at the SWRTC.

Education/Events:

- Upcoming: 30^h Annual Southwest Regional Trauma Conference: June 27th-28th, Location: JW Marriott Starr Pass, Tucson, AZ.
- Youth Mental Health First Aid Trainer Certification Course Where: Sierra Vista Police Department, 911 N. Coronado Drive, Sierra Vista AZ. 85364. Date: June 4th to June 7th from 9:00 am to 5:00 pm
- Opioid Epidemic and our Community Webinar: Southeast Arizona Health Education Center-Arizona Telemedicine. Date: Friday May 31, 2019 12:00 pm PDT

Meetings:

- Next Regional Council Meeting: June 18th, 2019: Location-Northern Trust Bank, Tucson
- *<u>2019</u> calendar for Regional Council meetings, as well as sub councils/subcommittees updated and posted to website

Absent



ARIZONA DEPARTMENT OF HEALTH SERVICES

PREPAREDNESS

Bureau Of Emergency Medical Services & Trauma System 150 N. 18th Avenue, Suite 540 Phoenix, Arizona 85007-3248 602-364-3150

Emergency Medical Services Council

Date: September 27, 2018 - Time: 10:30 hrs Location: 150 N. 18th Ave., Conference Room 540A, Phoenix, AZ, 85007 Via computer with call back: azgov.webex.com, meeting code 807 962 417, password EMS2018 Via telephone: dial 240-454-0879, meeting code 807 962 417 (#)

Draft Minutes

- I. <u>Call to Order</u> Ben Bobrow, MD
 - The meeting was called to order at 10:32 hrs.
- II. <u>Roll Call</u> Shelley Bissell (31 members, 16 required for quorum)
 - Quorum was present.

Present

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Ben Bobrow, MD	Rebecca Haro	Alberto Gutier
Bob Ramsey	Rodney Reed*	Tyler Mathews, CEP
Brian Smith, CEP	Sara Perotti, ACNP-BC	Howard Reed, RN
Joe Gibson	Dan Spaite, MD	Jon Maitem, DO
James Hayden	Glenn Kasprzyk	Paul Coe
Dale Woodridge, MD	Nathan Lewis, RN	Rianne Page, MD
Dan Millon	Robert Costello	James Dearing, DO
Patricia Coryea-Hafkey, RN*	Chris Salvino, MD*	
* Indicates teleconference	Michele Preston, DO*	

III. <u>Chairman's Report</u> – Ben Bobrow, MD

- a. Attendance report
 - As presented.
- b. Vacancy report
 - Dr. Bobrow announced the seven vacancies: Pre-hospital Training Program; Non-governmental Employer of Intermediate EMTs; Hospital Administrator for population less than 500,000; Volunteer Medical Rescue Program; Three Largest Employers of EMCTs – AMR, Phoenix Fire, and Tucson Fire.

Chief Mullins encouraged persistence with the appointment process via the Governor's office. Dr. Bobrow announced the inclusion of the 2019 meeting schedule in the packets.

- c. "LifeLinks" NHTSA EMS High Performance CPR and 911 Telephone CPR Training and Performance Improvement Program
 - Dr. Bobrow reported on the ongoing work for national CPR standards for training for EMTs and 911 dispatchers.

Dr. Bobrow reported that the first EMT Suicide research paper has been recently published in a peer-reviewed journal. The findings show the significant increased rate dying by suicide for EMTs over the general population.

Mr. Hayden reported updates on EMSHelp.org's progress. Dr. Spaite reported the findings for the EPIC TBI Project are in review with a major journal. Dr. David Harden reported on the Blue Campaign with the Department of Homeland Security: <u>www.dhs.gov/blue-campaign</u>.

Due to Dr. Gross taking a new job out of state, Dr. Gemar lauded her for the wide-ranging contributions she has made during her years on the Medical Direction Commission and the Protocols, Medications, and Devices Committee to improve EMS care in Arizona. Dr. Gross thanked those in attendance for the opportunities available to her during her time in Arizona.

- IV. <u>Bureau Report</u> Terry Mullins, Bureau Chief
 - a. New Bureau Staff: Ben Fisher, MPA, Services Section Chief
 - Chief Mullins introduced Jessica Rigler, MPH, CHES, as the new Assistant Director for the Preparedness Division at DHS. Also introduced: Mary Acosta for the role of Bureau Finance Manager and Ben Fisher for the role of Services Section Chief.
 - b. AZ-PIERS and HIE update
 - Chief Mullins reported the Bureau is still taking steps to link AZ-PIERS and HIE. For those agencies interested in participating, it will allow for fields to populate regarding pre-hospital data and outcome data. More updates to come.
 - c. Rules update
 - i. Base Hospital/Administrative Medical Direction
 - Two workgroup meetings have occurred to draft language to be published. After posting the draft, and after taking comments, it will move to a formal rulemaking process, with an anticipated conclusion around the first of the new year.
 - ii. Required Agents (Drug Box)
 - Chief Mullins reported on moving the Medication Tables 5.2, 5.3, and 5.4 from rule and instead have MDC recommend changes that are then approved by the Director. This change allows MDC to modify the medications to meet changes in clinical practice or shortages. He reminded the group that the tables are still in effect until updated to reflect the changes approved by MDC during the last 18 months during a special MDC meeting in November.
 - d. CON updates Aaron Sams
 - Mr. Sams gave a brief update on the ground ambulance applications and air ambulance applications for Certificates of Necessity.
 - e. ADOT Highway Mortality Goal Council
 - i. PHTLS Training David Harden
 - In a joint effort with ADOT to lower highway mortality, Dr. Harden reported that the Bureau has hired a vendor to provide free PHTLS training classes to rural-based providers.
 - ii. Highway Mortality Mapping Ben Fisher
 - Mr. Fisher indicated the Services Section is in the early stages of planning to produce a report outlining highway crash mortality using the state data.

- f. Annual STAB Report
- The STAB members recently approved their 2018 Annual Report and it will be posted to the website. <u>https://azdhs.gov/documents/preparedness/emergency-medical-services-trauma-system/reports/2018-stab-annual-report.pdf</u>
- g. Drug Shortage update
 - (Discussed earlier)
- h. EMS Resiliency, Wellness & Safety Workgroup update Alyson Welch
 - Ms. Welch reported progress on the posted resources, curriculum, and summit planning. Initial timing for the summit is now the spring of 2019. Mr. Hayden requested reaching out to the crisis line to see if there was a report available showing the volume of calls from Arizona.

Dr. Bobrow thanked Kim and Brian and Noreen for the work they did hosting an EMS Base Hospital full-day conference recently. He suggested trying to schedule the next conference closer to a medical director meeting and/or EMS agency meeting.

V. <u>Standing Committee/Regional Council Reports</u>

- a. Education Standing Committee Gail Bradley, MD
 - Mr. Fisher relayed the report from Dr. Bradley and shared that the PowerPoint trainings are completed for EMT ETCO2 and EMT IM/EPI for Anaphylaxis, and they are working on a training for BRUE/ALTE.
- b. Protocols, Medications and Devices Standing Committee-Brian Smith, CEP
 - Mr. Smith reported updates to TTTGs were approved to go to MDC, nitroglycerine updates were approved to go to MDC, and verapamil removal was discussed.
- c. Trauma and EMS Performance Improvement Standing Committee Rebecca Haro, NREMT-P
 - Ms. Haro reported that TEPI added a new member, Corbin King, they reviewed updated EMS data governance from the Bureau, discussed that AZ-PIERS agencies will need to re-verify data sharing entities, the Cactus data set was reviewed and approved to move forward to EMS Council, and the EMSRUG members indicated they would like to collaborate on data element issues moving forward.
- d. Regional Emergency Medical Services Councils
 - i. AEMS Joe Gibson
 - As presented. Next meeting is December 19.
 - ii. SAEMS Sara Perotti
 - As presented. Next meeting is October 16.
 - iii. NAEMS Paul Coe
 - As presented. Next meeting is November 2.
 - iv. WACEMS Rod Reed
 - As presented. Next meeting is November 8.
- e. PACES (Pediatric Advisory Committee for Emergency Services) Dale Woolridge, MD
 - Dr. Woolridge reported updates for PACES. Their next meeting is October 23.
- VI. <u>Discussion and Action Items</u>
 - a. Discuss, amend, and approve EMS Meeting Minutes from May 24, 2018

- Motion to approve by Mr. Smith, second by Mr. Ramsey. With no corrections, the **minutes** were approved.
- b. Discuss, amend, approve Premiere EMS Agency Standards
 - Chief Mullins reviewed this voluntary EMS program and the steps leading up to the revision of standards. The handout has words in red that reflect the updates being requested to approve. He requested that year one, if approved, be used to make a benchmark only.

Motion to approve the proposed updated standards with a friendly amendment to achieve a minimum benchmark after review of year one data made by Mr. Ramsey, seconded by Mr. Gibson. Members discussed benchmarks and pediatric resuscitation. Additional friendly amendment made to pediatric resuscitation element to indicate benchmark to be set after review of year one data made by Mr. Smith, seconded by Dr. Spaite. Members discussed the Medical Director Program component. Ms. Perotti requested a definition for pediatric resuscitation.

The Chair restated the motion to approve the proposed PEAP standards with the two friendly amendments about benchmarks after year one data and pediatric resuscitation with a reasonable definition and benchmarks after year one data. With no members opposed, **the motion passed.**

Chief Mullins and Dr. Bobrow thanked the stakeholders involved with the project.

- c. Discuss, amend, approve AZ-PIERS/Cactus Data Set
 - Chief Mullins explained the documents presented. Dr. Bradley thanked everyone who participated in the workgroup from all parts of the state. She explained the workgroup's process when reviewing the Cactus Data Set's data elements for each time-sensitive illness and injury, with the overall intent to improve the quality of the data entered. Some of the outliers may simply need a corrective educational component at the agency level or some may need a mapping adjustment from the agency's ePCR vendor.

There was also a request for annual maintenance on the Cactus Data Set, with the proposed process of revisiting data elements starting in May 2019 via TEPI workgroup, moving those updates to TEPI for approval in July 2019, moving those updates to EMS Council for approval in September 2019, to go into effect at the beginning of the new year (2020).

Members discussed the recently passed standards and how they interact with the Cactus Data Set. Motion to approve the AZ-PIERS/Cactus Data Set by Mr. Ramsey, second by Mr. Gibson. With no nay votes, **the motion passed**.

- d. Discuss, amend, approve Data Completeness Standard
 - Dr. Bradley explained the workgroup's process at looking at the outliers that had less than 90% completion rates. The workgroup found value in finding data point opportunities to educate users with how to better utilize their software in addition to questioning if the data points had value in their capture. Ms. Chikani explained the methodology and logic for the completeness measures; this excludes the specific number goals at this time. Dr. Bobrow clarified that the vote was to agree on the methodology to use to create the benchmark. In the future, the targets could be set.

Motion to approve by Mr. Gibson, second by Mr. Smith. The ayes have it, and the **motion passed.**

- VII. <u>Agenda Items to be considered for the next meeting</u>
 None presented.
- VIII. <u>Call to the Public</u>
 - No response.
 - IX. <u>Summary of Current Events</u>
 - As presented on the agenda.

X. <u>Next Meeting</u>

- January 24, 2019 @ 10:30 hrs at ADHS, 150 N 18th Ave., Conference Rooms 215 A&B, Phoenix, AZ 85007
- XI. Adjournment
 - The meeting adjourned at 12:09 hrs.

Minutes approved by _____on____.

JAMA Surgery | Original Investigation

Association of Statewide Implementation of the Prehospital Traumatic Brain Injury Treatment Guidelines With Patient Survival Following Traumatic Brain Injury The Excellence in Prehospital Injury Care (EPIC) Study

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IMPORTANCE Traumatic brain injury (TBI) is a massive public health problem. While evidence-based guidelines directing the prehospital treatment of TBI have been promulgated, to our knowledge, no studies have assessed their association with survival.

OBJECTIVE To evaluate the association of implementing the nationally vetted, evidence-based, prehospital treatment guidelines with outcomes in moderate, severe, and critical TBI.

DESIGN, SETTING, AND PARTICIPANTS The Excellence in Prehospital Injury Care (EPIC) Study included more than 130 emergency medical services systems/agencies throughout Arizona. This was a statewide, multisystem, intention-to-treat study using a before/after controlled design with patients with moderate to critically severe TBI (US Centers for Disease Control and Prevention Barell Matrix-Type 1 and/or Abbreviated Injury Scale Head region severity \geq 3) transported to trauma centers between January 1, 2007, and June 30, 2015. Data were analyzed between October 25, 2017, and February 22, 2019.

INTERVENTIONS Implementation of the prehospital TBI guidelines emphasizing avoidance/treatment of hypoxia, prevention/correction of hyperventilation, and avoidance/treatment of hypotension.

MAIN OUTCOMES AND MEASURES Primary: survival to hospital discharge; secondary: survival to hospital admission.

RESULTS Of the included patients, the median age was 45 years, 14 666 (67.1%) were men, 7181 (32.9%) were women; 16 408 (75.1%) were white, 1400 (6.4%) were Native American, 743 (3.4%) were Black, 237 (1.1%) were Asian, and 2791 (12.8%) were other race/ethnicity. Of the included patients, 21 852 met inclusion criteria for analysis (preimplementation phase [P1]: 15 228; postimplementation [P3]: 6624). The primary analysis (P3 vs P1) revealed an adjusted odds ratio (aOR) of 1.06 (95% CI, 0.93-1.21; P = .40) for survival to hospital discharge. The aOR was 1.70 (95% CI, 1.38-2.09; P < .001) for survival to hospital admission. Among the severe injury cohorts (but not moderate or critical), guideline implementation was significantly associated with survival to discharge (Regional Severity Score-Head 3-4: aOR, 2.03; 95% CI, 1.52-2.72; P < .001; Injury Severity Score 16-24: aOR, 1.61; 95% CI, 1.07-2.48; P = .02). This was also true for survival to discharge among the severe, intubated subgroups (Regional Severity Score-Head 3-4: aOR, 3.14; 95% CI, 1.65-5.98; P < .001; Injury Severity Score 16-24: aOR, 3.28; 95% CI, 1.19-11.34; P = .02).

CONCLUSIONS AND RELEVANCE Statewide implementation of the prehospital TBI guidelines was not associated with significant improvement in overall survival to hospital discharge (across the entire, combined moderate to critical injury spectrum). However, adjusted survival doubled among patients with severe TBI and tripled in the severe, intubated cohort. Furthermore, guideline implementation was significantly associated with survival to hospital admission. These findings support the widespread implementation of the prehospital TBI treatment guidelines.

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he burden of traumatic brain injury (TBI) on US society is enormous: annually it leads to 2.2 million emergency department visits, 280 000 hospitalizations, 52 000 deaths, and more than \$60 billion in economic costs.^{1,2} While improving outcomes has been difficult,³⁻⁹ early treatment may help mitigate secondary brain injury,¹⁰⁻¹⁵ and this has led to promulgation of official evidence-based TBI treatment guidelines.^{10-12,15} There is limited in-hospital evidence supporting the effectiveness of guideline-based treatment.¹⁶⁻²¹ However, to our knowledge, association of implementation by prehospital emergency medical services systems (EMS) with overall survival has not been evaluated.^{11,12} The objective of this study was to implement the nationally vetted TBI guidelines¹¹ among the EMS agencies of Arizona and to evaluate the association with outcomes in moderate, severe, and critical TBI.

Methods

Study Design, Setting, and Oversight

The Excellence in Prehospital Injury Care (EPIC) study was conducted throughout Arizona using a controlled, before-after, multisystem, intention-to-treat design.²²⁻²⁶ The methods have been reported in detail.²⁷⁻³⁰ The study phases were based on each EMS agency's training schedule: phase 1 (P1), preimplementation; phase 2, training (initiation to completion); and phase 3 (P3), postimplementation (eFigure in the Supplement).²⁷

Regulatory approvals were obtained from the state of Arizona. The University of Arizona institutional review board and Arizona Department of Health Services human subjects review board approved the project and the publication of deidentified data.²⁷⁻³⁰ The institutional review board exempted this project from informed consent, by virtue of being an official, state-vetted public health initiative. While not a clinical trial, EPIC is registered at ClinicalTrials.gov (NCT01339702).

Data Collection

The Arizona State Trauma Registry contains extensive data on patients taken to level I trauma centers (TCs). Information from included patients (January 1, 2007, to June 30, 2015) was linked to EMS data by accessing paper-based or electronic records from participating agencies, creating a comprehensive prehospital/TC database²⁷ (eTables 1 and 2 in the Supplement).

Participants

Inclusion criteria were adults/children with physical trauma who (1) were transported directly or transferred to a TC by participating agencies, (2) had hospital diagnoses consistent with TBI (isolated or multisystem), and (3) met at least 1 of the following definitions for major TBI: US Centers for Disease Control and Prevention Barell Matrix-Type 1 (eTable 3 in the Supplement)³¹⁻³³ and/or Abbreviated Injury Scale-Head of at least 3. To prevent selection bias, all patients meeting criteria were included regardless of whether EMS data were obtained.^{34,35}

Key Points

Question Is implementation of prehospital TBI treatment guidelines in demographically diverse emergency medical services systems associated with survival in patients with major traumatic brain injury (TBI)?

Findings In this cohort study, among 21 852 patients with moderate, severe, or critical TBI (15 228 preimplementation and 6624 postimplementation), guideline implementation was not associated with improved adjusted survival. However, it was associated with improved outcome in the severe and severe, intubated subgroups.

Meaning Statewide implementation of the prehospital TBI guidelines was independently associated with improvement in survival among patients with severe TBI and in the severe, intubated group; these findings support the widespread implementation of the prehospital TBI treatment guidelines.

Interventions

All Arizona EMS agencies were invited to participate. Program requirements included: EMS TBI guideline training (trainthe-trainer strategy²⁷); implementing systemwide, guidelinebased treatment (eTables 4-7 in the Supplement)²⁷; and providing prehospital data. Training emphasized guideline use in patients with physical trauma, reported/apparent loss of consciousness, and injury sufficient to warrant transport to a hospital.²⁷

The guideline-based clinical protocols and algorithms (eTables 4-7 in the Supplement)²⁷ focused on 4 interventions: (1) prevention/treatment of hypoxia through early oxygen administration; (2) airway interventions to optimize oxygenation/ventilation (bag-valve-mask [BVM] for airway/ ventilatory compromise and endotracheal intubation [ETI] and extraglottic/supraglottic airways reserved for patients with Glasgow Coma Scale score <9 when basic airway interventions were inadequate); (3) prevention of hyperventilation by using age-appropriate ventilation rates and ventilation adjuncts²⁷; and (4) avoidance and treatment of hypotension by infusing isotonic fluids.²⁷ Primary outcome was survival to hospital discharge (survival), and the secondary outcome was survival to hospital admission (SHA).

Statistical Analysis

Continuous variables were summarized by median and interquartile range (IQR) and were compared between 2 groups using the Wilcoxon rank sum test. Categorical variables were summarized by frequency and proportion (with 95% Clopper-Pearson confidence intervals) and were compared between 2 groups by χ^2 or Fisher exact test.

The primary analysis of risk-adjusted association between survival and intervention was examined by logistic regression, adjusting for important risk factors and potential confounders (see eTable 8 in the Supplement for rationale for choosing the covariates).²⁸⁻³⁰ Sensitivity analysis was performed incorporating the physiologic measures in the Trauma Injury and Injury Severity Score methodology. The effect of age (continuous variable) was fitted nonparametrically using penalized thin plate regression splines through the generalized additive model.³⁶ The same procedure used for survival was used to model SHA. Fitted models were assessed by deviance residual plots, and area under the receiver operating characteristic curve, with 95% confidence intervals, was obtained by the DeLong method.

In the secondary analyses (ie, moderate/severe/critical severity-based cohorts and intubated subgroup), standard logistic regression was used when there were at least 200 patients with the outcome and 200 without. Otherwise, the Firth penalized-likelihood logistic regression was used.^{37,38} Collinearity was checked using variance inflation factors for the parametric terms and concurvity for the nonparametric term. Mixed-effect models for survival/SHA were used to assess the effect of potential correlation of patients treated by the same EMS agency.

In a sensitivity analysis, a propensity score (the probability of being in P3 vs P1) was estimated by logistic regression using all covariates from the final models for outcomes. The propensity score was then included as either linear or smooth function predictors to evaluate the change in adjusted odds ratio (aOR) estimates of intervention for survival and SHA. In secondary analyses, the absolute change in event rates for the same patient at 2 different times (eg, prehospital vs emergency department hypoxia rates) was compared between P1 and P3 by fitting generalized estimating equation models for binary outcome with identity link and exchangeable working correlation matrix and testing an interaction term between time and study phase.

We evaluated secular trends in TBI outcomes in 2 groups of patients brought to the TCs that met study diagnostic criteria but were not eligible for study inclusion: those cared for solely by EMS agencies not participating in EPIC training and those brought to TCs by privately owned vehicle (ie, not affected by EMS care).

We used software environment R for the analysis³⁹ (The R Foundation; packages mgcv,³⁶ gamm4,⁴⁰ gee,⁴¹ and logistf⁴² for regression models). All tests were 2-sided, with a = .05, except for the primary analysis, which was .04 (1 interim analysis was conducted with a = .01).

Results

Enrollment

Phase 1 began for all agencies on January 1, 2007. Phase 2 began and ended at different times for each agency (the first agency began training on February 22, 2012, and the last agency completed training on January 23, 2015). Phase 3 ended for all agencies on June 30, 2015. Total enrollment was 26 873, and 5021 were excluded, leaving 21 852 (88% of estimated sample size) for analysis (15 228 patients in the preintervention phase [P1 control group] and 6624 patients in the postintervention phase [P3 intervention group]; Figure 1).

Treatment and Treatment-Related Physiologic Changes

Training was associated with changes in treatment and treatment-related physiology. The rate of patients having at least 1

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EMS indicates emergency medical services; EPIC, Excellence In Prehospital Injury Care study; P1, study phase 1 (preimplementation phase); P2, study phase 2 (training run-in phase; for each EMS agency, time from initiation to completion of training); P3, study phase 3 (postimplementation phase); TBI, traumatic brain injury.

EMS oxygen saturation value of 100% increased significantly after implementation (P1%, 4823 of 13 552 [35.6%]; P3%, 2513 of 6141 [40.9%]; *P* < .001; intubated cohort: P1%, 985 of 2226 [44.2%]; P3%, 482 of 885 [54.6%]; P < .001). Among intubated patients, hypoxia decreased after EMS care in both P1 and P3. However, the decrease was significantly greater after guideline implementation, and this association was seen at multiple levels of hypoxia (eTable 9 in the Supplement).

The rates of administering intravenous fluid boluses (eTable 10 in the Supplement) and the volume infused (eTable 11 in the Supplement) increased in P3. In addition, after implementation, patients with hypotension were more likely to arrive at the TC with a higher systolic blood pressure (SBP) compared with their prehospital SBP.

The intubation rate decreased significantly after implementation, and the BVM-only rate increased (eTable 12 in the Supplement). Among patients receiving positive-pressure ventilation (PPV), the rate of basic airway use only (BVM) increased (P1, 534 of 3531 [15.1%]; P3, 325 of 1491 [21.8%]; P < .001). Among intubated patients, the rate of hypocapnia (end-tidal carbon dioxide <35 mm Hg, reflecting hyperventilation) decreased significantly after implementation (P1, 899 of 1486 [60.5%]; P3, 372 of 712 [52.2%]; P < .001).

Analysis and Outcome

Table 1 shows patient demographics and clinical characteristics. Median age was higher in P3 (50.5 years; IQR, 27-70 years) than P1 (median, 43 years; IQR, 23-63.5 years; P < .001). The proportion of older patients (by multiple definitions) was much higher in P3 (eTable 13 in the Supplement).

Brain injury severity was greater in P3 (Regional Severity Score-Head [RSS-H] of 4: 2419 of 6624 [36.5%; P3] vs 4585 of 15 228 [30.1%; P1]; RSS-H of 5-6, 1492 of 6624 [22.5%; P3] vs 2952 of 15 228 [19.4%; P1]; *P* < .001). This was also true of overall injury severity (Injury Severity Score [ISS] of 16-24, 2411 of 6624 [36.4%; P3] vs 4863 of 15 228 [31.9%; P1]; *P* < .001; ISS ≥25, 2148 of 6624 [32.4%; P3] vs 4597 of 15 228 [30.2%; P1]; *P* < .001). Patients in P3 were also more likely to receive prehospital cardiopulmonary resuscitation (4.4%; 294 of 6624) than those in P1 (3.7%; 570 of 15 228; *P* = .02; Table 1).

The overall preimplementation/postimplementation analysis revealed an aOR of 1.06 (95% CI, 0.93-1.21; P = .40; Table 2) for survival and 1.70 (95% CI, 1.38-2.09; P < .001) for SHA (eTable 14 in the Supplement). Sensitivity analyses incorporating random EMS agency effects in the models for survival and SHA yielded only minimal changes in the estimated intervention effects (aOR, 1.04; 95% CI, 0.91-1.19 and aOR, 1.73; 95% CI, 1.40-2.13, respectively; eTables 15 and 16 in the Supplement). Sensitivity analyses incorporating the physiologic components of Trauma Injury and Injury Severity Score methodology in the models for survival and SHA also resulted in inconsequential changes (SBP: aOR, 1.06; 95% CI, 0.93-1.21 and aOR, 1.76; 95% CI, 1.39-2.21; GCS: aOR, 1.01; 95% CI, 0.87-1.16 and aOR, 1.63; 95% CI, 1.32-2.01; respiratory rate: aOR, 1.04 95% CI, 0.91-1.18 and aOR, 1.79; 95% CI, 1.43-2.22; eTables 17-22 in the Supplement). Sensitivity analyses that included the propensity score in the models yielded minimal changes (linear predictor: change in aOR survival, 0.47%; SHA, 0.42%; smooth function survival, 0.89%; SHA, 0.42%).

The results of the severity-based cohort analyses (moderate: RSS-H 1-2 or ISS 1-14; severe: RSS-H 3-4 or ISS 16-24; and critical: RSS-H 5-6 or ISS 25-75) are shown in **Figure 2**. The severe subgroups (both TBI-specific and overall injury) showed positive and significant improvement in survival after guideline implementation, while the moderate and critical groups did not. Increases in SHA were most pronounced in the severe TBI group but also occurred in the critical cohort (Figure 2).

The outcomes associated with airway interventions are shown in **Figure 3**. Patients with severe injury who received any method of PPV (BVM, supraglottic/extraglottic airway, or intubation) and the severe, intubated subgroup showed marked survival improvement after implementation. The criticalinjury subgroups yielded conflicting results, showing either no significant change (overall injury, ISS ≥25) or a small negative change in survival (brain injury, RSS-H 5/6).

Discussion

The EMS TBI guidelines emphasize prevention and treatment of hypoxia, hypotension, and hyperventilation.¹¹ These recommendations are based on observational studies demonstrating increased TBI mortality from these insults (hypoxia,^{14,43-50} hypotension,^{13,14,44,45,47,49-57} and hyperventilation^{11,14,46,58-66}). However, the supporting evidence remains weak because to our knowledge, no controlled prehospital studies have directly evaluated the association of guideline-based care with survival.^{11,12}

The EPIC study is a statewide public health initiative implementing the prehospital TBI guidelines^{10-12,15} among patients who experienced injury-associated loss of consciousness. This inclusive approach to guideline implementation at the individual patient level was taken because TBI can be difficult to identify in the field, and its severity may not be immediately apparent.^{10-12,15,67-72}

We used an intention-to-treat design because we expected participation from more than 100 EMS agencies and could not guarantee access to prehospital records.^{35,73} None-theless, we achieved a 98.7% linkage rate (ie, EMS data linked to TC data), and eTables 9 to 12 in the Supplement provide evidence that guideline-based treatment increased significantly. As expected in a large implementation effort, there was incomplete application of the guidelines at the individual patient/personnel level (eTables 9-12 in the Supplement). However, there is reason for optimism if future innovations in training and technology can improve guideline compliance (eg, real-time physiologic audiovisual feedback).

The primary analysis (across the entire moderate-tocritical severity spectrum) revealed an aOR of 1.70 (95% CI, 1.38-2.09; P < .001) for survival to admission. However, the overall aOR of 1.06 (95% CI, 0.93-1.21) for survival to discharge was nonsignificant (P = .40). The increase in SHA is important because this outcome is proximate to the intervention and likely reflects changes in EMS care. Early outcomes have been recognized to have value for evaluating the effect of prehospital interventions in other serious, time-sensitive conditions.⁷⁴⁻⁷⁸ In addition, improved early survival creates the potential for patients to benefit from subsequent specialized care.^{76,77,79-81}

We chose broad inclusion criteria because it is not known which severity subgroups benefit from treatment.^{3,4,6-11,67,71,72,82} This approach prevented unknowingly excluding patients who might benefit (if we made the criteria too narrow). However, it had the risk of diluting the treatment effect (by including nonresponding cohorts). Thus, we planned (a priori) to evaluate the moderate, severe, and critical cohorts separately to prevent some subgroups from potentially hiding the effectiveness of others. Indeed, this approach identified that implementation was strongly

	No. (%)				
Characteristic	All (N = 21852) ^b	P1 (n = 15 228) ^b	P3 (n = 6624) ^b	P Value	
Age, median (IQR), y	45 (24-66)	43 (23-63.5)	50.5 (27-70)	<.001	
Male					
No	7181 (32.9)	4940 (32.4)	2241 (33.8)		
Yes	14 666 (67.1)	10 283 (67.5)	4383 (66.2)	.048	
Unknown	5	5	0		
Race/ethnicity					
Black	743 (3.4)	506 (3.3)	237 (3.6)		
Asian	237 (1.1)	151 (1)	86 (1.3)		
American Indian/Alaska native	1400 (6.4)	973 (6.4)	427 (6.4)	.16	
White	16 408 (75.1)	11 454 (75.2)	4954 (74.8)		
Other	2791 (12.8)	1976 (13)	815 (12.3)		
Unknown	273 (1.2)	168 (1.1)	105 (1.6)		
Hispanic					
No	16 488 (75.5)	11 276 (74)	5212 (78.7)		
Yes	4719 (21.6)	3405 (22.4)	1314 (19.8)	<.001	
Unknown	645 (3)	547 (3.6)	98 (1.5)		
Payer					
Private	7109 (32.5)	5035 (33.1)	2074 (31.3)	<.001	
AHCCCS/Medicaid	5378 (24.6)	3920 (25.7)	1458 (22)		
Medicare	4901 (22.4)	3081 (20.2)	1820 (27.5)		
Self pay	3119 (14.3)	2144 (14.1)	975 (14.7)		
Other	910 (4.2)	648 (4.3)	262 (4)		
Unknown	435 (2)	400 (2.6)	35 (0.5)		
Trauma type					
Blunt	20 794 (95.2)	14 504 (95.2)	6290 (95)		
Penetrating	1053 (4.8)	723 (4.7)	330 (5)		
Burn	4 (0)	0	4 (0.1)	.01	
Unknown	1 (0)	1 (0)	0		
Regional Severity Score-Head (ICD-9)					
1 to 3	10233 (46.8)	7563 (49.7)	2670 (40.3)		
4	7004 (32.1)	4585 (30.1)	2419 (36.5)		
5 to 6	4444 (20.3)	2952 (19.4)	1492 (22.5)	<.001	
Unknown	171 (0.8)	128 (0.8)	43 (0.6)		
njury Severity score (ICD-9)					
1 to 14	7826 (35.8)	5765 (37.9)	2061 (31.1)		
16 to 24	7274 (33.3)	4863 (31.9)	2411 (36.4)		
≥25	6745 (30.9)	4597 (30.2)	2148 (32.4)	<.001	
Unknown	7 (0)	3 (0)	4 (0)		
Body region		. ,			
Isolated TBI	16 663 (76.3)	11602(76.2)	5061 (76.4)		
Multisystem TBI	5189 (23 7)	3626 (23.8)	1563 (23.6)	.74	
Fransfer		(-0.0)			
No	14671(671)	10310(677)	4361 (65.8)		
Yes	6646 (30.4)	4383 (28.8)	2263 (34.2)	< 001	
Unknown	535 (2.4)	535 (3 5)	0	.001	
°PR	555 (2.7)	555 (5.5)	5		
No	20.088 (06)	14658 (06 2)	6330 (05.6)		
Vec	20 900 (90)	14 030 (90.3)	204 (4 4)	.02	
105	004(4)	5/0(5./)	294(4.4)		

(continued)

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	No. (%)				
Characteristic	All (N = 21852) ^b	P1 (n = 15 228) ^b	P3 (n = 6624) ^b	P Value ^c	
Airway management					
No PPV	16830(77)	11 697 (76.8)	5133 (77.5)		
BVM	859 (3.9)	534 (3.5)	325 (4.9)	-	
SGA	149 (0.7)	81 (0.5)	68 (1)	- <.001	
Intubation	4014 (18.4)	2916 (19.1)	1098 (16.6)		
Survival to discharge					
No	3036 (13.9)	2036 (13.4)	1000 (15.1)	. 001	
Yes	18816 (86.1)	13 192 (86.6)	5624 (84.9)	- <.001	
Survival to hospital admission					
No	1018 (4.7)	723 (4.7)	295 (4.5)	26	
Yes	20834 (95.3)	14 505 (95.3)	6329 (95.5)	36	

Abbreviations: AHCCCS, Arizona Health Care Cost Containment System; BVM, bag-valve mask (basic airway providing positive-pressure ventilation); CPR, cardiopulmonary resuscitation; *ICD-9, International Classification of Diseases, Ninth Revision*; IQR, interquartile range; isolated TBI, patients who met TBI inclusion criteria but had no injury with Regional Severity Score of at least 3 in any other (nonhead) body region; multisystem TBI, patients who met TBI inclusion criteria and also had at least 1 nonhead region injury with Regional Severity Score of at least 3; PPV, positive-pressure ventilation (patients received active ventilation regardless of basic or advanced airway type); P1, study phase 1 (preimplementation); P3, study phase 3 (postimplementation); SGA, supraglottic airway (eg, Laryngeal Mask Airway or King Airway); TBI. traumatic brain injury.

^a Treating trauma center was also highly significant. To protect the mandated anonymity of the participating hospitals, the numbers are not shown (preventing any possible identification or inference of facility-specific outcome differences).

^b Median (IQR) for numerical variables and count (percentage) for categorical variables.

^c Fisher exact test or χ^2 test, as appropriate, for categorical variables and Wilcoxon rank sum test for continuous variables; the unknown category, if present, is excluded from the testing procedure.

associated with improved survival in the severe subgroups (RSS-H 3-4: aOR, 2.03; 95% CI, 1.52-2.72; *P* < .001; ISS 16-24: aOR, 1.61; 95% CI, 1.07-2.48; *P* = .02; Figure 2).

These findings support a concept of an interventional sweet spot between the extremes of TBI severity. At the moderate end of the spectrum, detecting differences in mortality is unlikely owing to the low death rate. But in critical TBI, even optimal treatment may have little effect on survival. In contrast, the severe group may benefit far more from the prevention of secondary insults than patients who have devastating primary injury and whose mortality risk is high regardless of treatment. Indeed, the effect of hypoxia and hypotension on survival was significantly greater in patients with severe injury than those with critical injury. Both of these secondary insults were associated with lower odds of survival among the patients with RSS-H of 3 or 4 (hypoxia OR, 0.181; 95% CI, 0.137-0.243; hypotension OR, 0.193; 95% CI, 0.146-0.258) than in those with RSS-H of 5-6 (hypoxia OR, 0.262; 95% CI, 0.220-0.313; P = .03 for the difference; hypotension OR, 0.280; 95% CI, 0.229-0.342; P = .03). Hence, the relative association of primary vs secondary injury with survival may vary with severity, with primary injury being the main determiner of outcome in critical patients and secondary injury taking on more significance in patients with less severe injuries, where the initial insult leaves greater potential for improvement or deterioration. It is notable that other TBI studies have focused on the middleseverity cohort as well.^{3,9,72,83-85}

The lack of treatment effect in critical patients may not be solely owing to irreversible pathoanatomic injury. Rather, varia-

tions in severity-associated physiologic response may also play a role. For instance, while the rate of intubated patients with at least 1 oxygen saturation of 100% increased significantly after implementation (P1, 985 of 2226 [44.2%] vs P3%, 482 of 885 [54.6%]; P < .001). This increase varied dramatically with severity. In the severe group (RSS-H 3-4), the rate increased from 50.7% (491 of 968; P1) to 66.9% (216 of 323; P3) (16.2% absolute increase). However, in the critical cohort (RSS-H 5-6), the increase was only 7.1% (39.4% [463 of 1176] to 46.5% [252 of 542]; P = .02 for the difference between the severe and critical subgroups). Furthermore, the patients with hypotension and severe injury in P3 were less than half as likely to arrive at the TC with a further drop in SBP (2.0%) than those in P1 (5.1%, P = .048). In contrast, the hypotensive, critical cohorts in P3 and P1 had a similar likelihood of experiencing an additional SBP drop on arrival (P3 = 8.5%; P1 = 10.7%; P = .49). These findings support the concept that physiologic improvement may be more difficult to achieve in critical patients.

The lack of improvement in the highest-severity cohort is not surprising and may be due to the Stocchetti effect.^{83,86} Improvements in prehospital trauma care may lead to a paradoxical effect of improved prehospital survival but decreased hospital survival because critical patients who previously died in the field may survive to hospital admission but die in hospital from extremely severe injury.^{83,86} We believe that the postimplementation increases in SHA in the critical cohorts (RSS-H 5/6: 1.42; 95% CI, 1.15-1.76; ISS \ge 25: 1.63; 95% CI, 1.32-2.00; Figures 2 and 3), the larger proportion of older patients (eTable 13 in the Supplement), and the higher rate of

Table 2. Primary Analysis of Adjus	ted Survival in Phase 3 Vs P	nase 1	
Variable	OR (95% CI)	P Value	
Intervention	1.06 (0.929-1.21)	.40	
Male			
No	1 [Reference]	74	
Yes	1.02 (0.896-1.17)	.74	
Race/ethnicity			
Black	1 [Reference]	.005	
Asian	0.787 (0.417-1.49)		
American Indian/Alaska native	0.719 (0.476-1.08)		
White	0.850 (0.611-1.18)		
Other	0.678 (0.462-0.994)		
Unknown	0.382 (0.214-0.679)		
Hispanic			
No	1 [Reference]		
Yes	1.14 (0.959-1.36)	.02	
Unknown	0.686 (0.483-0.974)		
Payer			
Private	1 [Reference]		
AHCCCS/Medicaid	1.12 (0.949-1.33)		
Medicare	0.942 (0.762-1.17)	<.001	
Self pay	0.464 (0.385-0.559)		
Other	0 829 (0 619-1 11)		
Unknown	0 309 (0 210-0 454)		
Trauma type	0.000 (0.210 0.101)		
Blunt	1 [Reference]		
Penetrating	0 159 (0 130-0 196)	<.001	
Head Injury Severity score (ICD-9)	0.135 (0.130 0.130)		
1 to 2	1 [Poforonco]		
1 10 5		<.001	
4 <u>-</u> 	0.035 (0.049-1.07)		
	0.047 (0.036-0.061)		
1 to 14	1[D.(
1 to 14			
16 to 24	0.444 (0.303-0.649)	<.001	
≥25	0.181 (0.122-0.269)		
Body region	4.55.4		
Isolated IBI	1 [Reference]	<.001	
Multisystem TBI	0.488 (0.423-0.563)		
Transfer			
No	1 [Reference]		
Yes	2.12 (1.79-2.51)	<.001	
Unknown	1.25 (0.798-1.96)		
CPR			
No	1 [Reference]	< 001	
Yes	0.029 (0.021-0.040)		
Hospital ^a	Not shown	<.001	
Age v	Nonnarametric function	< 001	

Abbreviations, AHCCCS, Arizona Health Care Cost Containment System; CPR, cardiopulmonary resuscitation; *ICD-9, International Classification of Diseases, Ninth Revision*; isolated TBI, patients who met TBI inclusion criteria but had no injury with Regional Severity Score \geq 3 in any other (nonhead) body region; multisystem TBI, patients who met TBI inclusion criteria and also had at least 1 nonhead region injury with Regional Severity Score \geq 3; OR, odds ratio.

^a Hospital (treating trauma center) was also highly significant. To protect the mandated anonymity of the participating hospitals, the numbers are not shown (preventing any possible identification or inference of facility-specific outcome differences). patients receiving prehospital CPR (Table 1) all support the interpretation that the Stocchetti Effect explained at least part of the lack of improvement in the critical cohort.

Prehospital intubation for TBI has been controversial for decades.^{10-12,15,23,59,64,66,67,87-91} However, in studies associating intubation with negative outcomes,^{23,66,67,88,91} it is unclear whether the primary issue was the procedure itself or the high rate of inadvertent hyperventilation following intubation.^{43,64,65,85,87,92} In EPIC, training emphasized the guideline-based approach of reserving intubation for those with markedly depressed level of consciousness and in whom basic interventions were inadequate for airway protection and oxygenation.^{10-12,15} Several findings provide evidence that this approach was implemented. Despite increased severity of both brain and overall injury in P3, the intubation rate decreased and the BVM-only rate increased (eTable 12 in the Supplement). Furthermore, among PPV cases, the rate of BVM-only use increased markedly (relative increase = 44.1%, *P* < .001).

Postimplementation adjusted survival tripled in the PPV and ETI severe cohorts (both TBI-specific and overall injury; Figure 3). This may be owing to the focus on oxygenation/ preoxygenation and preventing hyperventilation via (1) intentional emphasis on achieving target end-tidal carbon dioxide (35-45 mm Hg), (2) the use of ventilation rate timers as realtime visual cues for manual ventilation, and (3) use of flowcontrolled ventilation bags. These findings imply that intubation, combined with proper ventilation, may be the optimal approach to prehospital airway management in patients with major TBI who meet the criteria recommended in the guidelines. Clearly, many questions related to this issue require further study.

Two challenges of EPIC were its length (the typical agency participated for 3 years following implementation) and our inability to enforce retraining after initial education. Thus, there was a potential for decreased emphasis on guideline adherence over time. To evaluate this, we assessed temporal changes in outcome by comparing P1 to early P3 (months 1-18) and late P3 (≥19 months). There was initial improvement, but the effect faded (aOR for survival: early P3, 1.16; 95% CI, 0.99-1.37; "late" P3, 0.95; 0.80-1.13). This was also reflected by the interim analysis (accrual: March 31, 2014), which was positive for survival (aOR, 1.16; 95% CI, 1.00-1.34; P = .048). However, the final analysis reverted (aOR, 1.06; 95% CI, 0.93-1.21; P = .40). The reason we did not report a positive study at the interim analysis was because the P value required for early termination was Pless than .01. Interestingly, in retrospect, if we had planned the study to only last until the interim analysis, we would have reported a positive study at that time (ie, P < .05). We believe these findings reflect the need for focused, recurrent training to help prevent deterioration of guideline adherence over time.

Limitations

This study has limitations. First, it was not randomized. Although a randomized clinical trial might definitively identify optimal treatment, such a trial was not feasible. Because existing studies overwhelmingly report detrimental effects of hypoxia, hypotension, and hyperventilation, randomization (to

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Figure 2. Primary Analysis: Adjusted Survival



Subset

PPV ISS 16 to 24

ETI ISS 16 to 24 ETI ISS ≥25

20

ETI Head injury severity 3-4

ETI Head injury severity 5-6

PPV ISS ≥25

Postintervention adjusted odds of survival to hospital discharge or admission for the moderate (Injury Severity Score [ISS] of 1-14), severe (Regional Severity Score–Head of 3 or 4; ISS of 16-24), and critical (Regional Severity Score–Head of 5 or 6; ISS of 25-75) injury cohorts. Logistic regression was used when there were at least 200 patients with the event (eg, survived to discharge) and 200 without (eg, did not survive to discharge). Number of events/number of subjects in each subgroup: Head Injury Severity 1-2: survival to discharge 2072 of 2090; survival to hospital admission (SHA) 2084 of 2090; Head Injury Severity 3-4: survival to discharge 14 754 of 15 147; SHA 15 038 of 15 147; Head Injury Severity 5-6: survival to discharge 1885 of 4444; SHA, 3587 of 4444; ISS 1 to 14: survival to discharge, 7757 of 7826; SHA, 7801/7826; ISS 16 to 24: survival to discharge, 7115 of 7274; SHA, 7241/7274; ISS \geq 25: survival to discharge, 3937/6745; SHA, 5785/6745. aOR indicates adjusted odds ratio; NA, not applicable owing to numbers being too small for adjusted analysis.

^a In comparisons that did not meet the criteria of at least 200 patients with the event and 200 without, Firth penalized-likelihood logistic regression was used.

aOR (95%): Survival

4.57 (0.61-94.48)a

4.93 (1.75-17.50)a

1.53 (1.23-1.89)

1.43 (1.32-1.84) 4.89 (0.54-173.66)^a

1.53 (1.20-1.96)

0.5

1 2

5 10 20

aOR for Survival to Hospital

Admission

50 100

to Hospital Admission

B SHA by airway/ventilatory intervention

 PPV Head injury severity 3-4
 6.44 (2.39-22.04)^a

 PPV Head injury severity 5-6
 1.40 (1.13-1.75)

Figure 3. Adjusted Analysis of Survival and Survival to Hospital Admission by Severity Cohorts in Patients With Positive-Pressure Ventilation (PPV)/Intubation

A Survival by airway/ventilatory intervention

Subset	aOR (95%): Survival to Hospital Discharge	2
PPV Head injury severity 3-4	3.52 (1.96-6.34)	
PPV Head injury severity 5-6	0.72 (0.58-0.88)	-
PPV ISS 16 to 24	2.75 (1.15-7.53) ^a	
PPV ISS ≥25	0.87 (0.72-1.06)	
ETI Head injury severity 3-4	3.14 (1.65-5.98)	
ETI Head injury severity 5-6	0.67 (0.52-0.86)	
ETI ISS 16 to 24	3.28 (1.19-11.34) ^a	
ETI ISS ≥25	0.81 (0.64-1.01)	
		0.5 1 2 5 10
		aOR for Survival to Hos

OR for Survival to Hospital Discharge

Postintervention adjusted odds of survival to hospital discharge or admission, by airway intervention category, for the severe (Regional Severity Score-Head of 3 or 4; Injury Severity Score [ISS] of 16-24) and critical injury cohorts (Regional Severity Score-Head of 5 or 6; Injury Severity Score of 25-75). The moderate severity category analyses (Regional Severity Score-Head of 1 or 2; ISS of 1-14) are not shown owing to the very small number of deaths in these cohorts, preventing meaningful/stable regression model results. Logistic regression was used when there were at least 200 patients with the event (eg, survived to discharge) and 200 without (eg, did not survive to discharge). For PPV, inclusion criteria were all patients with active ventilation whether basic (bag-valve mask) or advanced airway (supraglottic/extraglottic airway or endotracheal intubation). Number of events/number of subjects in each subgroup: PPV Head Injury Severity 3-4: survival to discharge, 1618 of 1842; SHA 1741 of 1842; PPV Head Injury Severity 5-6: survival to discharge, 771 of 2,992; SHA, 2149 of 2992; PPV ISS 16 to 24: survival to discharge, 751 of 822; SHA, 793 of 822; PPV ISS \geq 25: survival to discharge, 1359/3770; SHA, 2829/3770; endotracheal intubation (ETI) Head Injury Severity 3-4: survival to discharge 603 of 2402; SHA 1689 of 2402; ETI ISS 16 to 24: survival to discharge, 586 of 647; SHA, 620 of 647; ETI ISS \geq 25: survival to discharge, 1055 of 3024; SHA, 2224/3024. aOR indicates adjusted odds ratio.

^a In comparisons that did not meet the criteria of at least 200 patients with the event and 200 without, Firth penalized-likelihood logistic regression was used.

treat/not treat) would be unacceptable to most EMS systems. Use of a pragmatic trial design (eg, stepped-wedge or clusterrandomized)⁹³ was also nonfeasible because the timing of EPIC training had to be determined primarily by agency-specific operational factors.

Because the guidelines were implemented as a "bundle," we cannot identify the relative effect of specific interventions (eg, oxygenation/preoxygenation). This would have required stepwise, intervention-specific implementation, and this was not feasible. To evaluate potential influence of secular trends, we assessed concurrent outcomes in 2 cohorts taken to the TCs that met diagnostic inclusion criteria but were unaffected by EPIC. First, we assessed patients transported by nonparticipating EMS agencies. However, the agency recruitment was so successful that this cohort was much smaller than anticipated (233 total; mean, 27.4 per year). Second, we evaluated patients brought to TCs by privately owned vehicle (n = 1486). The before/after analysis (early patients [January 1, 2007, to December 31, 2012] vs late [January 1, 2013, to June 30, 2015]) yielded no evidence of outcome improvement over time. Indeed, there was a trend toward somewhat worse outcomes in the late group (eTable 23 in the Supplement). It is noteworthy that the trauma system in Arizona developed during the 1980s and was very stable during EPIC. The TCs accounting for 98.1% of patients (21 432 of 21 852) were established more than a decade before the study began.

Finally, we could not control for the effects of inpatient care. Thus, we cannot know conclusively that the improvements were directly caused by EMS guideline implementation. However, the concurrent increase in survival to hospital admission (aOR, 1.70; 95% CI, 1.38-2.09; P < .001) is supportive of the conclusion that EMS implementation was associated with the improvements in outcome.

Conclusions

Statewide implementation of the prehospital TBI guidelines was not associated with improved overall survival (across the entire, combined moderate to critical spectrum). However, survival doubled among patients with severe TBI and tripled in the patients with severe TBI who received PPV and/or intubation. Implementation was also independently associated with significant improvement in survival to hospital admission. These findings support the widespread implementation of the prehospital TBI treatment guidelines.

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