

FDA Warns of Higher Mortality Risk With Hydroxethyl Starch Solution and Recommends That It No Longer Be Used as a Volume Expander for Patients in Shock

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Based on new scientific data, the Committee for Tactical Emergency Casualty Care recommends that responders do not use HES solutions in the prehospital care of critically ill trauma patients.

The Committee for Tactical Emergency Casualty Care (C-TECC) is dedicated to providing the most up to date, evidence-based and/or best practice principles in high-threat prehospital trauma care. The C-TECC has a formal process for updating the guidelines described in the charter documents and in published in the *Journal of Special Operations Medicine* (JSOM). In this process, anyone—even non C-TECC members—can recommend that the C-TECC consider a change. Then the C-TECC Chair puts the recommendation to a vote for consideration. If the C-TECC agrees the topic should be investigated, a working group is established and recommendations are then put forward to a vote (<http://c-tecc.org/>).

Occasionally, new information comes to light that requires immediate dissemination to our communities. In these cases, the C-TECC Executive Committee requests that experts in the field review the information and draft a recommendation for action awaiting the next full C-TECC meeting. The recent FDA warning on hydroxyethyl starch (HES) IV solutions warrants such action at this point (<http://www.medscape.com/viewarticle/806826>).

On 11 June 2013, the United States Food and Drug Administration (FDA) issued a Safety Communication warning of the increased mortality, severe renal injury, and risk of bleeding associated with the use of HES IV solutions.¹ Four FDA-approved HES solutions are on the market: 6% HES 450/0.7 in sodium chloride injection (Hespan; B. Braun Medical), 6% HES 450/0.7 in physiological solution (Hextend; BioTime), 6% HES 130/0.4 in normal saline (Voluven; Fresenius Kabi), and a generic equivalent to Hespan (hetastarch; Teva Pharmaceuticals).

The clinical use of HES solutions has increased despite their higher cost relative to crystalloid solutions, lack of evidence of their clinical superiority,² and safety concerns.^{3,4} These HES solutions are used commonly for the treatment of hypovolemia and shock when plasma volume expansion is desired. Current TCCC guidelines for patients in shock recommend the administration of a 500ml bolus of Hextend, repeated once after 30 minutes if still in shock, up to 1000ml.⁵ Current TECC guidelines recommend administering “appropriate IV fluid bolus” and list Hextend as an option.

This FDA action came a week after European Union drug regulators recommended removing HES solutions from various national markets because of evidence showing that their benefits no longer outweigh their risks.⁶ The recommendation, made by the European Medicines Agency’s Pharmacovigilance Risk Assessment Committee (PRAC), will now go to the Coordination Group for Mutual Recognition and Decentralised Procedures–Human for a final decision.

The FDA warning follows recent data indicating an increased risk of (1) mortality and renal injury requiring dialysis in critically ill adult patients, including patients with sepsis and those admitted to the ICU, and (2) excess bleeding, particularly in patients undergoing open heart surgery in association with cardiopulmonary bypass.

Published clinical trials and systematic reviews suggested a greater incidence of renal damage and mortality in patients receiving HES,⁷⁻¹⁰ but these findings have been inconsistent. In 2011, 86% (88 of 102) of the research published by Joachim Boldt, MD, since 1999 was retracted after a government investigation reported research misconduct reflecting failure to acquire ethical approval for research and fabrication of study data.^{11,12} In February, the *Journal of the American Medical Association* (JAMA) published an article reevaluating the mortality and kidney injury associated with the administration in critically ill patients requiring volume resuscitation. Following a systematic review and meta-analysis of published studies, excluding the seven trials performed by Dr. Boldt, the authors

concluded that HES was associated with a significantly increased risk of mortality and acute kidney injury. Their conclusions raised serious safety concerns about the use of HES, and the authors' recommendation was that HES was no longer warranted clinically for acute volume resuscitation.¹³

The FDA warning recommends that HES solutions should not be used to increase intravascular volume in critically ill adult patients, including patients with sepsis and those admitted to the ICU.

The recent FDA warning and published studies do not support a clinical benefit of using HES for volume expansion and HES is associated with harm when used for patients in shock. The C-TECC and the National Tactical Officers Association (NOTA) endorse the FDA recommendation and suggest that medical care providers stop using HES and switch to conventional intravenous crystalloid solutions such as lactated Ringer's solution (LR) or normal saline (0.9% NaCl) in accordance with TECC guidelines until further data are available.

References

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Committee for Tactical Emergency Casualty Care Fall 2013 Update

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Summary

The past 3 months have been very active for the C-TECC. Preliminary after-action reports and personal debriefings from Boston highlight the continued requirement for an expanded, standardized, but dynamic tactical framework

for interagency response to high-threat incidents. Increasingly, the federal government and local response agencies are turning to TECC to fill this operational gap.

Most notably, the Department of Homeland Security Grant Funding Priorities (HSGP No. 5) highlighted TECC as a critical component for agencies planning response to mass casualty incidents. In addition, the International Association of Fire Fighters (IAFF) endorsed TECC as the standard for Rescue Task Force (RTF) training and operations. RTF is now becoming the standard fire system paradigm for response to active shooter and dynamic threat events. As a result of these broad endorsements, hundreds of requests for training and education have been submitted to the C-TECC webpage. The C-TECC is not a training body; it is also working with a variety of groups to create an “Ethical Use” policy to ensure that end users are receiving legitimate TECC training. The Committee will release this policy at the December SOMA meeting.

C-TECC members also continue to present various lectures, design, plan, and participate in exercises and workshops at the local, state, and national levels. These activities are constructed to offer an understanding as to the purpose of the guidelines, process of guideline development, the guidelines themselves, and best practices in implementing TECC into current and new response paradigms. Recent and upcoming presentations have or will be conducted in the greater Philadelphia area, Missouri EMS Conference, Southern New Jersey, Charlotte Mecklenburg County Disaster Response Conference, and Seattle/King County metropolitan area.

Guideline Updates

Pediatric TECC

The provision of effective casualty care in the high-threat environment requires casualty *access, assessment, stabilization, and extrication/evacuation*. It also requires an understanding of the anatomic and physiologic differences between healthy adults and special populations such as children. Given the significant effect that recent active violent incidents have had on the pediatric population and the historic general discomfort that first responders have with critically ill children, the C-TECC developed a set of pediatric guidelines for high-threat prehospital trauma response. The Pediatric Working Group conducted an extensive literature search and presented proposed Pediatric TECC Guidelines at the May C-TECC meeting. The guidelines were compared with existing adult TECC guidelines and modified as necessary. The draft recommendations were submitted to the C-TECC Board of Directors and to external SMEs for review. The Pediatric TECC Guidelines will be published in the Winter JSOM. They will be available electronically at www.c-tecc.org before publication. The guidelines will represent an evidence-based and best practice starting point. The C-TECC expects that as more research effort is dedicated to pediatric trauma response, the guidelines will evolve.

Hextend removed from TECC guidelines

In June, the FDA issues a warning regarding the use of Hextend in the critically ill trauma patient. The C-TECC has removed the recommendation for the use of Hextend from the current guidelines (see policy statement in current JSOM).

Ongoing Collaborative Efforts

The National TEMS Initiative and Council (NTIC) held a meeting in July 2013 in coordination with the California TEMC Initiative and Council (CTIC). C-TECC members Ray Casillas and Dr. Richard Schwartz led the organizational efforts and Dr. Richard Kamin provided a review of the response to the Sandy Hook massacre. C-TECC continues to support the NTIC and CTIC efforts to expand and standardize the tactical response paradigms within the SWAT and high-risk law enforcement communities.

The C-TECC would also like to commend the recent Hartford Consensus (HC) meeting for their support of the TECC guidelines. The goal of the HC is to reduce mortality from active shooter events. To this end, their recommendations support the TECC framework first published in 2011 that recommends early threat mitigation, hemorrhage control, rescue, and rapid evacuation to high level of care (see JSOM Summer/Fall 2011). C-TECC hopes to continue supporting the HC with both previously established standards and relevant operational subject matter experts.

The next C-TECC meeting will be at SOMA. The 2013 meeting promises to be exciting with focused breakout sessions on active shooter events and bombing response. The C-TECC leadership has been actively engaged in the design and execution of these programs.

National TEMS Initiative and Council (NTIC) TEMS Update

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The next meeting of the National TEMS Initiative and Council (NTIC) is tentatively planned to precede the Special Operations Medical Association Scientific Assembly in Tampa, Florida, and will take place in the same venue in December; exact dates have not been set. The goal of this meeting will be to derive the tactical medical standards for the Patrol Officer (First Responder) given the same comprehensive methodology that was used to derive the Medical Provider and Tactical Operator standards.

This methodology will consist of tactical medical subject matter experts divided into six groups and given the goal of deriving the standard for the areas assigned. The groups consist of tactical medical practitioners from local, state, federal, and military agencies. The assigned areas are the 17 domains of tactical medicine that are the foundation of the NTIC; each group will be given 2 or 3 areas of the 17 domains. The domains are as follows:

1. Tactical Combat Casualty Care/Tactical Emergency Casualty Care Methodology
2. Remote Assessment and Surrogate Care
3. Rescue/Extraction
4. Hemostasis (hemorrhage control)
5. Airway
6. Breathing
7. Circulation
8. Medication Administration
9. Casualty Immobilization
10. Medical Planning
11. Force Health Protection
12. Environmental Factors
13. Mechanisms and Patterns of Injury
14. Medical Legal Aspects of TEMS
15. Hazardous Materials
16. Mass Casualties
17. Tactical Familiarization

Following the derivation of the small group findings, the entire meeting body will convene and, using a modified Delphi process, will vote electronically on the standards so derived for all 17 domains. As per the original NTIC findings, an 80% vote is the minimum requirement to validate the individual group findings.

The Patrol Officer component, in following this same methodology, will ensure that the standard for training of Patrol Officers will be in keeping with and follow appropriate scientific methodologies that will achieve a true practice and competency-based foundation. A minor difference in this meeting will be to have a greater proportion of medically trained police officers present in each group.

The Board of Critical Care Paramedic Certification (BCCTPC), the nonprofit organization that has fielded the Critical Care Paramedic Certification (CCP-C) Exam as well as the Flight Paramedic Certification (FP-C) Exam is in the process of beta testing the Tactical Paramedic Certification Exam (TP-C); beta testing will occur from 21 August 2013–4 September 2013. The process to arrive at the beta phase was rigorous and 1 year in length.

Following the beta test phase and a tweaking of the end Angoff cut score (to ascertain the appropriate passing score), the exam will be available to qualified applicants at designated testing centers and at national conferences. The exam is based on the 17 domains of the NTIC findings. Ms. Monica Newman, the Executive Director of the BCCTPC, contributed the following concerning the beta process and the TP-C:

Beta Test Selection Process

The process to create a sample group that is a cross-section of the tactical community is a complex process and relies on a variety of variables. First, since the exam evaluates the competency domains established by both the NTIC and the U.S. Special Operations Command (USSOCM), it was important to have a mix of civilian and military testers. Second, the geographic distribution was considered to ensure that beta testers were from all areas of the country. Another factor we used to evaluate who would be in the beta test group was to find a mix of testers with all levels of expertise—even low levels. Expert-only results are flawed because of a phenomenon called the “curse of knowledge,” a cognitive bias according to which better-informed people find it extremely difficult to think about problems from the perspective of lesser-informed people.

The BCCTPC recognizes that the tactical paramedic operates in a high-stakes environment, and it is important that the TP-C credential is meaningful, not only to the operator and their commanders but also to the public. To ensure this, it is paramount that the beta test captures the unbiased data necessary to produce an exam process that is without compromise.

Exam Requirements

- The TP-C exam candidate must have a valid paramedic license.
- Proof of current affiliation with a law enforcement agency or the military.

TP-C Exam Candidate

The expectation for the TP-C exam candidate is competency in casualty assessment, stabilization, and evacuation in hostile and austere environments, as well as thorough familiarity with tactical principles, triage, and operational medicine. Candidates must have significant knowledge of the Committee on Tactical Combat Casualty Care and the Committee for Tactical Emergency Casualty Care guidelines, management of the full tactical injury spectrum (from less-than-lethal to CBRNE), force health protection, and medicolegal aspects of Tactical Emergency Medical Services.

Textbook Recommendations

Paramedic Practice Today—Above and Beyond (Vol 2), by Barbara Aehlert. Published by Jones & Bartlett Learning (2011).
PHTLS, Military Edition (7th edition), by NAEMT and American College of Surgeons Committee on Trauma. Published by Elsevier Health Sciences (2010).
Law Enforcement Responder; Principles of Emergency Medicine, Rescue and Force Protection, by Randy G. Stair, Dwight A. Polk, Geoff Shapiro, and Nelson Tang. Published by Jones & Bartlett Learning (2012).
Tactical Emergency Medicine, by Richard B. Schwartz, John G. McManus, and Raymond E. Swienton. Published by Lippincott Williams & Wilkins (2007).
Tactical Medicine Essentials, by American College of Emergency Physicians, E. John Wipfler III, John E. Campbell, and Lawrence E. Heiskell. Published by Jones & Bartlett Learning (2010).

More information concerning the BCCTPC and/or the Tactical Paramedic Certification Exam can be obtained at www.BCCTPC.org or by calling 770-978-4400.

Californians who are members of the NTIC as well as other California TEMS practitioners are convening follow-up meetings of the California TEM Initiative and Council (CTIC) during the month of September. Their announced aims are to bring the current TEMS regulations up to date by aligning them with the 17 domains of the NTIC and keeping or modifying other areas of the current TEMS regulations needed to support present and future California TEMS requirements.

In response to this grassroots movement, the California EMS Authority (CALEMSA) is convening a State Tactical EMS Advisory Committee meeting on 12 September 2013. Many NTIC and CTIC members are involved in the meeting. Other areas of the country are looking to the NTIC findings as the definitive standard even as the NTIC proceeds with its goal of completing all 5 areas for standardization: Patrol (First Responder), Tactical Operator (done) Medical Provider (done), Medical Director, and Team Commander and convening the National TEMS Council.