



Division of Public Health Services

Office of the Assistant Director

Public Health Preparedness Services

Bureau of Emergency Medical Services and Trauma System

150 N. 18th Avenue, Suite 540
Phoenix, Arizona 85007
(602) 364-3150 / 1-800-200-8523
(602) 364-3568 FAX

JANICE BREWER, GOVERNOR
WILL HUMBLE, DIRECTOR

PROTOCOLS, MEDICATIONS & DEVICES (PMD)

STANDING COMMITTEE

Date: November 20, 2014 - **Time:** 12:00 PM

Location: 150 N. 18th Ave., Conference Room 215A & 215B (2nd Floor)

Conference Call: 1-877-820-7831 - **Code:** 450908#

iLine URL: <https://azdhsems.ilinc.com/join/xcphsxt>

You must register prior to the meeting to join the web conference session.

AGENDA

- I. Call to Order – Toni Gross, MD, Chair
- II. Roll Call – Jennifer Herbert (12 Members, 7 required for quorum)
- III. Chairman’s Report – Toni Gross, MD
 - a. Attendance report (Attachment III.a.)
 - b. 2015 Meeting Calendar (Attachment III.b.)
 - c. Welcome new member – Neil Gago
- IV. Bureau Report – Noreen Adlin
 - a. Rules update
- V. Discussion and Action Items
 - a. Discuss, amend, approve PMD minutes of July 17, 2014 (Attachment V.a.)
 - b. Discuss, amend, approve Controlled Substances Security Guidance Document – Charlie Smith (Attachment V.b.)
 - c. Discuss, amend, approve adding Naloxone as a STR agent for EMT’s on Table 5.1 (Scope of Practice) - Charlie Smith (Attachment V.c.)
 - d. Discuss, amend, approve adding Naloxone as an approved agent for EMT’s on Table 5.2 (Drug Box) - Charlie Smith (Attachment V.d.)
 - e. Discuss, amend, approve changing Glucagon to an optional agent on Table 5.2 - Toni Gross, MD (Attachment V.d.)
 - f. Discuss and approve adding Tranexamic Acid (TXA) to Table 5.2 – Josh Gaither, MD (Attachment V.d.)

Persons with disabilities may request reasonable accommodations such as a sign language interpreter, by Angie McNamara, Program Project Specialist II, 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.

“Health and Wellness for all Arizonans”

- g. Discuss, amend, approve changing Methylprednisolone Sodium Succinate (Solumedrol) to an optional agent on Table 5.2 – Toni Gross, MD (Attachment V.d.)
- h. Discuss and approve adding Dobutamine to Table 5.4 – Brian Smith (Attachment V.h.)
- i. Discuss, amend, approve drug profiles for:
 - i. Dobutamine - (Attachment V.i.i.) – Brian Smith & Toni Gross, MD
 - ii. Propofol - (Attachment V.i.ii.) – Brian Smith & Toni Gross, MD
 - iii. Insulin - (Attachment V.i.iii.) – Brian Smith & Toni Gross, MD
 - iv. Levophed (norepinephrine) – (Attachment V.i.iv.) – Brian Smith & Toni Gross, MD
 - v. Hemostatic Agent - (Attachment V.i.vi.) – Brian Smith & Toni Gross, MD
- j. Discuss, amend, approved Over the Counter Medication Guidance Document – Josh Gaither, MD (Attachment V.j.)
- k. Discuss, amend, approve Pediatric Shock revision for TTTG - Toni Gross, MD (Attachment V.k)
- l. Discuss, amend, approve the Education Curricula for Pain Management Protocol – Toni Gross, MD
- m. Discuss EMCT Nasogastric Tube placement – Toni Gross, MD & Terry Mason
- n. Review the External Hemorrhage Guideline – Toni Gross, MD (Attachment V.m.)

VI. Agenda Items for Next Meeting

- a. Discuss changing the PMD Bylaws to increase membership – Toni Gross, MD

VII. Call to the Public: 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. At the conclusion of an open call to the public, individual members of the public body may respond to criticism made by those who have addressed the public body, 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).

Members of the public body may present a brief summary of current events. Members of the public body shall not propose, discuss, deliberate, or take legal action on matters raised during a summary of current events unless the matters are properly noticed for discussion and legal action.

VIII. Summary of Current Events

- a. February 8-9, 2015: 2015 Pediatric Symposium. Hilton Village of Oak Creek, Sedona

IX. Next Meeting: March 19, 2015, 12:00 PM at 150 N. 18th Avenue, Rooms 215A & 215B

X. Adjournment

Persons with disabilities may request reasonable accommodations such as a sign language interpreter, by Angie McNamara, Program Project Specialist II, 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.

"Health and Wellness for all Arizonans"

Committee Attendance Report

Protocols, Medications & Devices Committee

		Present	Tele	Absent
Bruce Toliver	AEMS Representative			
	2/2/2012	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	5/24/2012	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	11/15/2012	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	3/21/2013	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	7/18/2013	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	11/21/2013	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	3/20/2014	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7/17/2014	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Charlie Smith	AEMS Representative (EMS Council Liaison)			
	2/2/2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	5/24/2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	11/15/2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	3/21/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	7/18/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	11/21/2013	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	3/20/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7/17/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gail Bradley	AEMS Representative			
	3/20/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	7/17/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Garth Gemar	AEMS Representative			
	2/2/2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	5/24/2012	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	11/15/2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	3/21/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	7/18/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	11/21/2013	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	3/20/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7/17/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Jason Johnson	NAEMS Representative			
	11/15/2012	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	3/21/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	7/18/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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7/17/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Josh Gaither	SAEMS Representative			
	11/21/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	3/20/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7/17/2014	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Michael Pflieger	AEMS Representative (STAB Liaison)			
	2/2/2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	5/24/2012	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	11/15/2012	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	3/21/2013	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	7/18/2013	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	11/21/2013	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Protocols, Medications & Devices Committee

		Present	Tele	Absent
Michael Pflieger	AEMS Representative (STAB Liaison)			
	3/20/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	7/17/2014	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Robert Jarvis	AEMS Representative			
	2/2/2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	5/24/2012	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	11/15/2012	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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	7/18/2013	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	11/21/2013	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	3/20/2014	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7/17/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sue Kern	WACEMS Representative			
	2/2/2012	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	5/24/2012	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	11/15/2012	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	3/21/2013	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	7/18/2013	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	11/21/2013	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	3/20/2014	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7/17/2014	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Terence Mason	Vice Chair/AEMS Representative			
	2/2/2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	5/24/2012	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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	3/21/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	7/18/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	11/21/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	3/20/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7/17/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Terry Shine	SAEMS Representative			
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	5/24/2012	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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	7/18/2013	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
11/21/2013	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
3/20/2014	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
7/17/2014	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Toni Gross	Chair/AEMS Representative (MDC Liaison)			
	5/24/2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	11/15/2012	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	3/21/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	7/18/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	11/21/2013	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	3/20/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7/17/2014	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Bureau of Emergency Medical Services and Trauma System
2015 Statutory/Standing Committee Meetings**

Date	Time	Meeting	Conference Room
January 29, 2015	9:00 a.m.	State Trauma Advisory Board	215A & 215B – 2nd Floor 150 Bldg
January 29, 2015	10:30 a.m.	Emergency Medical Services	215A & 215B – 2nd Floor 150 Bldg
January 29, 2015	12:00 p.m.	Medical Direction Commission	215A & 215B – 2nd Floor 150 Bldg
March 19, 2015	9:00 a.m.	Trauma and EMS Performance Improvement (TEPI)	215A & 215B – 2nd Floor 150 Bldg
March 19, 2015	10:30 a.m.	Education Committee	215A & 215B – 2nd Floor 150 Bldg
March 19, 2015	12:00 p.m.	Protocols, Medications and Devices Committee	215A & 215B – 2nd Floor 150 Bldg
May 21, 2015	9:00 a.m.	State Trauma Advisory Board	215A & 215B – 2nd Floor 150 Bldg
May 21, 2015	10:30 a.m.	Emergency Medical Services Council	215A & 215B – 2nd Floor 150 Bldg
May 21, 2015	12:00 p.m.	Medical Direction Commission	215A & 215B – 2nd Floor 150 Bldg
July 16, 2015	9:00 a.m.	Trauma and EMS Performance Improvement (TEPI)	215A & 215B – 2nd Floor 150 Bldg
July 16, 2015	10:30 a.m.	Education Committee	215A & 215B – 2nd Floor 150 Bldg
July 16, 2015	12:00 p.m.	Protocols, Medications and Devices Committee	215A & 215B – 2nd Floor 150 Bldg
September 17, 2015	9:00 a.m.	State Trauma Advisory Board	215A & 215B – 2nd Floor 150 Bldg
September 17, 2015	10:30 a.m.	Emergency Medical Services Council	215A & 215B – 2nd Floor 150 Bldg
September 17, 2015	12:00 p.m.	Medical Direction Commission	215A & 215B – 2nd Floor 150 Bldg
November 19, 2015	9:00 a.m.	Trauma and EMS Performance Improvement (TEPI)	215A & 215B – 2nd Floor 150 Bldg
November 19, 2015	10:30 a.m.	Education Committee	215A & 215B – 2nd Floor 150 Bldg
November 19, 2015	12:00 p.m.	Protocols, Medications and Devices Committee	215A & 215B – 2nd Floor 150 Bldg

DISCLAIMER: “Meeting schedule subject to change upon the request of the Governor’s Office or the Office of the Director. Should this occur, the Bureau will make all reasonable efforts to contact the affected members as soon as feasible.”

PROTOCOLS, MEDICATIONS & DEVICES (PMD)
STANDING COMMITTEE
Date: July 17, 2014 - **Time:** 12:00 P.M.

Location: 150 N. 18th Ave., Conference Room 540A

Meeting Minutes

- I. Call to Order – Toni Gross, MD, Chair, called the meeting to order at 12:00 PM
- II. Roll Call – (12 Members, 7 required for quorum). A quorum was present.

Members Present

Charlie Smith
 Gail Bradley, MD
 Garth Gemar, MD
 Jason Johnson, MD
 Josh Gaither, MD*
 Michael Pflieger, MD*
 Robert Jarvis
 Terence Mason
 Toni Gross, MD

Members Absent

Bruce Toliver
 Sue Kern
 Terry Shine

*Indicates teleconference

- III. Chairman's Report – Toni Gross, MD
 a. Attendance report
- IV. Bureau Report – Noreen Adlin
 a. Rules update
- V. Discussion and Action Items
- a. Discuss, amend, approve PMD minutes of March 20, 2014. Charlie Smith made the motion to approve the minutes, seconded by Jason Johnson, MD. A friendly amendment to change the date of the minutes was approved. **Motion carries.**
 - b. Discuss and approve the revised Over the Counter Medications guidance document – Josh Gaither, MD. This item has been **tabled** until the next meeting the workgroup reviews it.
 - c. Discuss, amend, approve adding the new Spinal Motion Restriction Protocols to the TTTG – Gail Bradley, MD. Charlie Smith made the motion to approve the protocol to be added to the TTTG, seconded by Robert Jarvis. **Motion carries.**
 - d. Discuss, amend, approve the revised Adult Adrenal Insufficiency TTTG – Toni Gross. Charlie Smith made the motion to approve the protocol to be added to the TTTG, seconded by Gail Bradley, MD. **Motion carries.**
 - e. Discuss, amend, approve the revised Pediatric Shock Including Hydrocortisone sodium succinate TTTG – Toni Gross. Charlie Smith made the motion to approve the protocol to be added to the TTTG, seconded by Garth Gemar, MD. **Motion carries.**
 - f. Discuss and approve changes to Tables 5.1–and 5.2 to allow EMTs to administer Naloxone as an STR agent, consistent with local medical director approval. This item was **tabled**. Charlie Smith, Gail Bradley, MD, Garth Gemar, MD and Terry Mason will review as a small workgroup.

- g. Discuss and approve changing Glucagon to an optional agent in Table 5.2. This item was **tabled**.
- h. Discuss, amend, approve drug profile for Propofol. This item was **tabled**.
- i. Discuss, amend, approve drug profile for Insulin. This item was **tabled**.
- j. Approve drug profile for Norepinephrine. This item was **tabled**.
- k. Approve Dobutamine for addition to R9-25-502 Table 5.4 and drug profile- for the level of Paramedic. This item was **tabled**.
- l. Drug Diversion Prevention Best Practices Document for EMS/Medical Direction – Garth Gemar, MD. This item was **tabled**.
- m. Education Curricula for the New Pain Management protocol – Charlie Smith. This item was **tabled**. Charlie Smith will discuss with Doug Crunk.
- n. Prehospital Guideline for External Hemorrhage for the TTTG – Jeff Salomone discussed this item after item V.e. was discussed.
- o. Hydrocortisone sodium succinate drug profile – Toni Gross. This item was **tabled**.
- p. Reconsider the Quick clot drug profile – Brian Smith. This item was **tabled**.

VI. Agenda Items for Next Meeting

- a. Josh Gaither, MD, to discuss tranexamic acid (TXA) for use to control hemorrhage in the trauma patient.
- b. Discuss and approve changes to Tables 5.1 and 5.2 to allow EMTs to administer Naloxone as an STR agent, consistent with local medical director approval.
- c. Discuss and approve changing Glucagon to an optional agent in Table 5.2.
- d. Discuss, amend, approve drug profile for Propofol.
- e. Discuss, amend, approve drug profile for Insulin.
- f. Approve drug profile for Norepinephrine.
- g. Approve Dobutamine for addition to R9-25-502 Table 5.4 and drug profile- for the level of Paramedic.
- h. Drug Diversion Prevention Best Practices Document for EMS/Medical Direction – Garth Gemar, MD.
- i. Education Curricula for the New Pain Management protocol – Charlie Smith.
- j. Hydrocortisone sodium succinate drug profile – Toni Gross.
- k. Reconsider the Quick clot drug profile – Brian Smith

VI. Call to the Public: John Gallegher, MD, requested that the absences of Terry Shine be reviewed.

VII. Summary of Current Events

- a. Southwest Regional Trauma Conference, July 31-August 2, 2014 – JW Marriott Tucson Starr Pass Resort, Tucson, AZ
- b. AZTrACC, November 13-14, 2014 – Talking Stick Resort, Scottsdale, AZ

VIII. Next Meeting: November 20, 2014, 12:00 PM at 150 N. 18th Avenue, Room 215A & 215B

IX. Adjournment – the meeting adjourned at 1:37 PM

Minutes approved by PMD

Date:

VISITORS PLEASE SIGN IN

PMD Committee Meeting - July 17, 2014 12:00 PM

Name (PLEASE PRINT)	Organization & Position	Email	Phone #
1 Mark Varvite	NHEMS	mark.varvite@nheh.com	908-213-6075
2 Lori Kennedy	Sci Ov	lori.kennedy@sci.ov	
3 Tracy Moroney	Sci Ov	Tracy.Moroney@sci.ov	
4 Mary McDonald	TFD		
5 Sandra Woodward	Ranger Woodward		
6 Brian G Bowling	NATIVE AIR/LEARNET-AIR METHODS	brian.bowling@airmethods.com	
7 Jason Johnson	RESEARCH - SNAAC	JJOHNSON100@hotmail.com	928-355-1216
8 JOHN CHILKOTIC	PHX FIRE		
9 Jeff Salomone	Navigare Med Ctr	Jeffrey.Salomone@DMG-AZ.ORG	
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Background

The Bureau of Emergency Medical Services and Trauma System (Bureau) has developed the following guidance document as technical assistance to the EMS community to identify and discuss areas of vulnerability in the storage and maintenance of EMS Medications.

Statutory & Regulatory Authority

A.R.S. § 36-2202 (A)(4): The director shall: adopt rules necessary to carry out this chapter.

Arizona Administrative Code (A.A.C.) Title 9, Chapter 25, Article 201, Subsection (F); establishes prescriptive criteria for agents and controlled substances.

Definitions

- “Agent” means a chemical or biological substance that is administered to a patient to treat or prevent a medical condition.
- “Controlled substance” has the same meaning as in A.R.S. § 32-1901, to be inclusive but not limited to opioids and benzodiazepines.
- “Authorized Emergency Medical Care Technician,” for the purpose of this guidance document, means an EMCT having medical direction and acting under an ALS scope of practice as identified in Article 5 of the Arizona Administrative Code.

Process

The following document was developed to provide guidance for EMS agencies, to promote best practices on compliance with applicable rules and statutes regarding use, storage, administration and wastage of pre-hospital agents and controlled substances utilized by authorized Emergency Medical Care Technicians and Emergency Medical Service provider organizations. It is important to continually evaluate the need for improving security and control measures in an operational area that if mismanaged could impact patient safety, provider safety and effect public trust.

Drug Box Containers: The Arizona Administrative Code is silent on the brand, material or style of drug box the EMS community is required to utilize in the field, it does prescribe:

1. That it must be a secured, dry, clean and washable receptacle.
2. While on a motor vehicle or aircraft, secured in a manner that restricts movement of the agent and the receptacle
3. Controlled substances, when not in use, must be stored in a locked container that is difficult to breach without the use of a power cutting tool

Drug Box Cleanliness: When a drug box is used, the EMCT is responsible for keeping the container clean and free of blood or other body fluids and protected from other damaging conditions.

Written Chain of Custody: A.A.C. R9-25-201 describes documentation criteria for each EMCT who takes custody of a supply of agents. Each time an EMCT takes custody of a supply of agents/controlled substances, that EMCT must perform an inventory of the agents/controlled substances. The following information must be documented on a written chain of custody log for each individual who takes custody of the supply of agents:

1. The name of the authorized individual
2. The EMCT certification number or employee identification number

3. The Date and Time the drug box was initially received
4. The Date and Time the drug box was placed in secure storage at an employer-defined authorized facility;
or
5. The Date and Time the drug box was transferred to another authorized individual

Inspection of Agents/Controlled Substances: All EMCT's should inspect the drug box and inventory the agents/controlled substances prior to accepting custody at the beginning of the shift. The drug box must contain at least the minimum supply of agents required for the highest level of service to be provided by the EMCT.

Whenever there is a transfer of the drug box to another authorized EMCT, both EMCT's should inspect the drug box and inventory the agents/controlled substances prior to transferring custody.

Inspection of any supply of agents/controlled substances needs to address all of the following:

1. Expiration dates
2. Deteriorated or contaminated agents
3. Container/label damage
4. Altered labels
5. Tampered seals
6. Depleted supply levels
7. Missing agents

If any of the conditions are noted:

1. Document any of the conditions
2. Obtain a replacement for each affected agent for which the minimum supply is not present; and
3. Notify the administrative medical director of a depleted, visibly adulterated, or missing controlled substance.

Inspection of individual agent Containers & Seals: Controlled substance individual containers are to be sealed at all times when not in use. Should a seal be found broken, or opened but not used, the contents need to be inspected immediately by an authorized individual and returned to the base hospital pharmacy or emergency medical service provider to be exchanged. During any inspection of the agents/controlled substances, authorized EMCT's should consider it best practice to observe the following:

1. Container end caps for needle puncture holes
2. Container caps for glue around the base of the rubber stopper
3. Container caps
4. The color of the contents
5. Look for debris inside the container
6. Labeling abnormalities
7. Appropriate amount of controlled substance is in the container
8. Syringe activation systems have not been activated

Storage and Security: Each individual drug box should be locked or sealed. Should the security device or seal be found broken, or a drug box opened, the contents need to be inspected and inventoried immediately by an authorized EMCT.

If the security device or seal on the drug box is discovered missing while performing patient care or after arriving at the hospital:

1. Continue patient care; you may continue to utilize the contents of the box.
2. If the medication needed is not present consider requesting another unit to meet on scene, but do not delay response or transport.

3. Conduct an inspection and inventory
4. Notify the EMS employer/supervisor.
5. Notify the administrative medical director and/or base hospital pharmacy of a depleted, visibly adulterated, or missing controlled substance

Administration of Agents/Controlled Substances: A.A.C. R9-25-502 tables 5.1 and 5.2 provides a list of agents/controlled substances and scope of practice authorized for administration by EMCT's in Arizona.

Each authorized EMCT shall document the following information on the patient care report:

1. Date and time of administration
2. Patient name
3. Patient address or scene location/identifier
4. Drug name
5. Dose of each administration
6. Route of administration
7. Effects of medication

Records should account for the use and disposition of all controlled substances utilized by an authorized EMCT.

Documenting Wastage of Controlled Substances: Authorized EMCT's must account for any useable quantity of a controlled substance. Unused quantities of controlled substances should be wasted beyond reclamation and witnessed by a minimum of one additional authorized person and the following documented on the patient care report and/or chain of custody log based on Medical Direction or EMS Provider policy:

1. Date of wastage.
2. Time of disposal/wastage
3. Patient's name
4. Drug name, drug strength, and quantity destroyed
5. The reason for the wastage
6. Printed name and Signature or initials of the person performing the disposal
7. Printed name and Signature or initials of the second person witnessing the disposal

Transfer of Agents Between Agencies: The transfer of controlled substances between agencies/providers in the field should be highly controlled through EMS Administrative Medical Direction policy. This practice should only occur in settings where extended out-of-service hours are required to replace patient use medications. According to AAC R9 25 201 (E)(3)(b) and (iv.) the transfer of controlled substances between agencies may only occur within the same administrative medical direction system if:

1. The Medical Director has identified and authorized individuals who ~~authorized~~ have access to the agents
2. Maintains a chain of custody for the agents (Chain of custody can be met through the use of a transfer of agents document approved by the Administrative Medical Director)
3. The transfer of agents document should be forwarded to the pharmacy replacing the agent for the resupplying agency, to adhere to the chain of custody requirement.

Disposal of controlled substances: Outdated, expired, deteriorated, damaged, or altered containers or labels of agents/controlled substances may only be destroyed by a Base Hospital Pharmacy or if the controlled substances are owned by an Emergency Medical Service provider organization, after prior approval from the United States Drug Enforcement Administration.

Return agents/controlled substances that are outdated, expired, deteriorated, damaged, or have altered containers or labels to the Base Hospital Pharmacy or the Emergency Medical Service provider, whichever owns the agents, for the legal disposition of unwanted controlled substances in accordance with United States Drug Enforcement Administration regulations.

Breakage and Spillage of Controlled Substances: Breakage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, spillage, or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements.

If the breakage or spillage is not recoverable, document the circumstances of the breakage in the inventory records. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. Notify the Emergency Medical Service Provider manager. Obtain a replacement quantity. The submission of a DEA Form 41, *Registrants Inventory of Drugs Surrendered*, is not required for non-recoverable controlled substances.

If the base hospital pharmacy retains ownership of the controlled substances the base hospital pharmacist-in-charge will be immediately notified.

Reporting Losses & Thefts: Each time agents/controlled substances change hands or are used, documentation must be generated and maintained. There should be a paper trail to show the path of a controlled substance dosage unit from the day it was manufactured, through the distributor, to the hospital, pharmacy, Emergency Medical Service provider organization, authorized Emergency Medical Care Technician's, then the patient.

It is extremely important for authorized EMCTs to know and comply with controlled substance policy, base hospital and regional protocol and regulatory laws. If an EMCT commits an infraction, the employer's DEA registration or Certificate of Necessity may be at risk as well as any personal certification held. Emergency Medical Service provider organizations usually base their policies on state and federal laws; violating a written policy, may, in many cases be violating the law.

Whenever a controlled substance is missing and cannot be accounted for, then it is a reportable loss. All reportable losses, thefts and diversions of controlled substances must be reported to the Administrative Medical Director following the service provider's chain of command and if a base hospital retains ownership of the agents, the base hospital Pharmacist-in-Charge immediately. The Administrative Medical Director must notify the Bureau within 10 days of discovery.

A Base Hospital Pharmacist or the Emergency Medical Service provider (if the controlled substances are owned by the provider) should conduct an internal review and investigation to determine the manner of theft or loss and determine the amount missing. In cases of loss, theft or diversion of controlled substances, local law enforcement should be contacted to conduct an independent investigation.

A base hospital pharmacist or the Emergency Medical Service provider (if the controlled substances are owned by the provider) must report to the DEA within 1 day.

The DEA form may be submitted electronically on their website at www.deadiversion.usodj.gov.

It is best practice for Emergency Medical Service provider organizations and Base Hospital Medical Directors to both periodically review and conduct random inspections of agents, controlled substances inventory and chain of custody documents.

Individual EMCTs who demonstrate a noted increase or change in the pattern of administration of controlled substances should also trigger concern with the Emergency Medical Service provider organizations and Administrative Medical Directors. EMS personnel who divert drugs for personal use place their patients, their employers, and their coworkers at risk.

Emergency Medical Service provider organizations are required to have adequate controls in place to detect and address the diversion of controlled substances as prescribed by the United States Drug Enforcement Administration. Security measures include policies, best practices and required record keeping such as:

1. All controlled substances in a building or on a transport vehicle must be stored in a securely locked substantially built safe or cabinet.
2. The security provided must be commensurate with the quantity and types of controlled substances on the transport vehicle.
3. Controlled substances may not be left unattended where unauthorized persons would have access to them.
4. Controlled substances on ambulances must be stored in locked containers and storage areas.
5. Access to controlled substances should be restricted to the fewest people possible.

Emergency Medical Care Technicians are prohibited from allowing patients and visitors access to drug supplies.

Emergency Medical Care Technicians arriving at the receiving facilities should be constantly vigilant in maintaining a level of security for the drug box and its contents which typically remain on the transport vehicle while the patient is moved inside the facility.

An EMS provider organization, Base Hospital or Administrative Medical Director should have policies in place allowing the request of a drug test during the course of an internal investigation of a drug loss, theft or suspected diversion of controlled substances. It is best practice for EMS provider organizations, base hospitals or medical directors to request a timely drug test during the early course of an internal investigation. A third party lab should be used for definitive results based on the drug identified during the initial loss report.

Training: Utilizing case studies from investigation files to update current written procedures provides Emergency Medical Care Technicians with information on the current trends in diversion and assists with recognition of a co-worker who may be under the influence of controlled substances.

Training and quality improvement programs that include instruction on checks and balances related to controlled medication inventories would discourage tampering with or stealing controlled medications. With the introduction of this guidance document, provider organizations and base hospitals have an opportunity to analyze, modify (where necessary), and conduct current and topical training for EMS personnel. Developing standard tools such as log forms and policies would serve to maintain consistency across EMS agencies/regions.

Table 5.1. Arizona Scope of Practice Skills**KEY:**

✓ = Arizona Scope of Practice skill

STR = Specialty Training Requirement: Skill requires specific specialty training with medical director authorization and involvement

* = Already intubated

Airway/Ventilation/Oxygenation	EMT	AEMT	EMT-I(99)	Paramedic
Airway- esophageal	STR	✓	✓	✓
Airway- supraglottic	STR	✓	STR	✓
Airway- nasal	✓	✓	✓	✓
Airway- oral	✓	✓	✓	✓
Bag-valve-mask (BVM)	✓	✓	✓	✓
BiPAP/CPAP				✓
Chest decompression- needle			✓	✓
Chest tube placement- assist only				STR
Chest tube monitoring and management				STR
Cricoid pressure (Sellick's maneuver)	✓	✓	✓	✓
Cricothyrotomy- needle			STR	✓
Cricothyrotomy- percutaneous			STR	✓
Cricothyrotomy- surgical			STR	STR
Demand valve- manually triggered ventilation	✓	✓	✓	✓
End tidal CO2 monitoring/capnography			✓	✓
Gastric decompression- NG tube			✓	✓
Gastric decompression- OG tube			✓	✓
Head-tilt chin lift	✓	✓	✓	✓
Intubation- nasotracheal			STR	✓
Intubation- orotracheal	STR	STR	✓	✓
Jaw-thrust	✓	✓	✓	✓
Jaw-thrust – modified (trauma)	✓	✓	✓	✓
Medication Assisted Intubation (paralytics)				STR
Mouth-to-barrier	✓	✓	✓	✓
Mouth-to-mask	✓	✓	✓	✓
Mouth-to-mouth	✓	✓	✓	✓
Mouth-to-nose	✓	✓	✓	✓
Mouth-to-stoma	✓	✓	✓	✓
Obstruction- direct laryngoscopy			✓	✓
Obstruction- manual	✓	✓	✓	✓
Oxygen therapy- humidifiers	✓	✓	✓	✓

	Oxygen therapy- nasal cannula	✓	✓	✓	✓
	Oxygen therapy- non-rebreather mask	✓	✓	✓	✓
	Oxygen therapy- partial rebreather mask	✓	✓	✓	✓
	Oxygen therapy- simple face mask	✓	✓	✓	✓
	Oxygen therapy- venturi mask	✓	✓	✓	✓
	PEEP- therapeutic			✓	✓
	Pulse oximetry	✓	✓	✓	✓
	Suctioning- upper airway	✓	✓	✓	✓
	Suctioning- tracheobronchial		✓*	✓	✓
	Automated transport ventilator	STR	STR	✓	✓
Cardiovascular/Circulation		EMT	AEMT	EMT-I (99)	Paramedic
	Cardiac monitoring- multiple lead (interpretive)			✓	✓
	Cardiac monitoring- single lead (interpretive)			✓	✓
	Cardiac - multiple lead acquisition (non-interpretive)	STR	STR	✓	✓
	Cardiopulmonary resuscitation	✓	✓	✓	✓
	Cardioversion- electrical			✓	✓
	Carotid massage – (≤17 years)			STR	STR
	Defibrillation- automatic/semi-automatic	✓	✓	✓	✓
	Defibrillation- manual			✓	✓
	Hemorrhage control- direct pressure	✓	✓	✓	✓
	Hemorrhage control- tourniquet	✓	✓	✓	✓
	Internal; cardiac pacing- monitoring only			✓	✓
	Mechanical CPR device	STR	STR	STR	STR
	Transcutaneous pacing- manual			✓	✓
Immobilization		EMT	AEMT	EMT-I (99)	Paramedic
	Spinal immobilization- cervical collar	✓	✓	✓	✓
	Spinal immobilization- long board	✓	✓	✓	✓
	Spinal immobilization- manual	✓	✓	✓	✓
	Spinal immobilization- seated patient (KED,etc.)	✓	✓	✓	✓
	Spinal immobilization- rapid manual extrication	✓	✓	✓	✓
	Extremity stabilization- manual	✓	✓	✓	✓
	Extremity splinting	✓	✓	✓	✓
	Splint- traction	✓	✓	✓	✓
	Mechanical patient restraint	✓	✓	✓	✓
	Emergency moves for endangered patients	✓	✓	✓	✓
Medication administration - routes		EMT	AEMT	EMT-I (99)	Paramedic

Assisting patient with his/her own prescribed medications (aerosolized/nebulized)	✓	✓	✓	✓
Assisting patient with his/her own prescribed medications (ASA/Nitro)	✓	✓	✓	✓
Aerosolized/nebulized (beta agonist)	STR	✓	✓	✓
Buccal	STR	✓	✓	✓
Endotracheal tube			✓	✓
Inhaled self-administered (nitrous oxide)		✓	✓	✓
Intradermal				✓
Intramuscular (including patient assisted hydrocortisone)		✓	✓	✓
Intranasal	STR	✓	✓	✓
Intravenous push		✓	✓	✓
Intravenous piggyback			✓	✓
Intraosseous		STR	✓	✓
Nasogastric				✓
Oral	✓	✓	✓	✓
Rectal		STR	✓	✓
Subcutaneous		✓	✓	✓
Sublingual		✓	✓	✓
Auto-injector (self or peer)	✓	✓	✓	✓
Auto-injector (patient's own prescribed medications)	✓	✓	✓	✓
IV initiation/maintenance fluids	EMT	AEMT	EMT-I (99)	Paramedic
Access indwelling catheters and implanted central IV ports				✓
Central line- monitoring				✓
Intraosseous- initiation		✓	✓	✓
Intravenous access		✓	✓	✓
Intravenous initiation- peripheral	STR	✓	✓	✓
Intravenous- maintenance of non-medicated IV fluids	✓	✓	✓	✓
Intravenous- maintenance of medicated IV fluids			✓	✓
Umbilical initiation				STR
Miscellaneous	A	AEMT	EMT-I (99)	Paramedic
Assisted delivery (childbirth)	✓	✓	✓	✓
Assisted complicated delivery (childbirth)	✓	✓	✓	✓
Blood glucose monitoring	✓	✓	✓	✓
Blood pressure- automated	✓	✓	✓	✓
Blood pressure- manual	✓	✓	✓	✓
Eye irrigation	✓	✓	✓	✓
Eye irrigation (Morgan lens)				STR

Attachment V.c.

Thrombolytic therapy- initiation				STR
Urinary catheterization				STR
Venous blood sampling			✓	✓
Blood chemistry analysis				STR
Inter-facility med transport list, including pump administration \			STR	STR

Table 5.2. Eligibility for Authorization to Administer, Monitor, and Assist in Patient Self-administration of Agents by EMCT Classification; Administration Requirements; and Minimum Supply Requirements for Agents

KEY:

A = Authorized to administer the agent

SVN = Agent shall be administered by small volume nebulizer

MDI = Agent shall be administered by metered dose inhaler

* = Authorized to assist in patient self-administration

[] = Minimum supply required if an EMS provider chooses to make the optional agent available for EMCT administration

AGENT	MINIMUM SUPPLY	EMT	AEMT	EMT-I (99)	Paramedic
Adenosine	18 mg	-	-	A	A
Albuterol Sulfate SVN or MDI (sulfite free)	10 mg	Λ	A	A	Λ
Amiodarone or Lidocaine	300 mg or 3 prefilled syringes, total of 300 mg and 1 g vials or premixed infusion, total of 2 g	-	-	-	A
		-	-	A	Λ
Aspirin	324 mg	A	Λ	A	A
Atropine Sulfate	3 prefilled syringes, total of 3 mg	-	-	A	A
Atropine Sulfate	Optional [8 mg multidose vial (1)]	-	-	A	A
Atropine Sulfate Auto-Injector	None	Λ	A	A	A
Atropine Sulfate and Pralidoxime Chloride (Combined) Auto-Injector	None	A	A	A	Λ
Calcium Chloride	1 g	-	-	-	Λ
Calcium Gluconate, 2.5% topical gel	Optional [50 g]	A	A	A	Λ
Charcoal, Activated (without sorbitol)	Optional [50 g]	Λ	A	A	Λ
Cyanokit	Optional [5 g]	-	-	-	A
Dexamethasone	Optional [8 mg]	-	-	A	A
Dextrose	50 g	-	A	A	A
Dextrose, 5% in H ₂ O	Optional [250 mL bag (1)]	A	Λ	A	A
Diazepam or Lorazepam or Midazolam	20 mg 8 mg 10 mg	- - -	- - -	A A A	A Λ A
Diazepam Rectal Delivery Gel	Optional [20 mg]	-	-	Λ	A
Diltiazem or Verapamil HCl	25 mg 10 mg	- -	- -	- -	A Λ
Diphenhydramine HCl	50 mg	-	-	A	A
Dopamine HCl	400 mg	-	-	-	A
Epinephrine Auto-Injector	Optional [2 adult auto-injectors 2 pediatric auto-injectors]	A	Λ	A	A
Epinephrine HCl, 1:1,000	2 mg	-	Λ	A	A

Epinephrine HCl, 1:1,000	Optional [30 mg multidose vial (1)]	-	A	A	A
Epinephrine HCl, 1:10,000	5 mg	-	-	A	A
Etomidate	Optional [40 mg]	-	-	-	A
Furosemide or Bumetanide	Optional [100 mg] Optional [4 mg]	-	-	A	A
Glucagon	Optional [2 mg]	-	A	A	A
Glucose, oral	Optional [30 gm]	A	A	A	A
Hemostatic Agents	Optional	A	A	A	A
Hydrocortisone Sodium Succinate	Optional	-	*	*	*
Immunizing Agent	Optional	-	-	A	A
Ipratropium Bromide 0.02% SVN or MDI	5 mL	-	-	A	A
Ketamine	Optional [200 mg]	=	=	=	A
Lactated Ringers	1 L bag (2)	A	A	A	A
Magnesium Sulfate	5 g	-	-	-	A
Methylprednisolone Sodium Succinate	[Optional] 250 mg	-	-	A	A
Morphine Sulfate or Fentanyl	20 mg 200 mcg	-	A	A	A
Nalmefene HCl	Optional [4 mg]	-	A	A	A
Naloxone HCl	10 mg	-A	A	A	A
Nitroglycerin Sublingual Spray or Nitroglycerin Tablets	1 bottle 1 bottle	* *	A A	A A	A A
Normal Saline	1 L bag (2) Optional [250 mL bag (1)] Optional [50 mL bag (2)]	A	A	A	A
Ondansetron HCl	Optional [4 mg]	-	-	A	A
Oxygen	13 cubic feet	A	A	A	A
Oxytocin	Optional [10 units]	-	-	A	A
Phenylephrine Nasal Spray 0.5%	Optional [1 bottle]	-	-	A	A
Pralidoxime Chloride Auto-Injector	None	A	A	A	A
Proparacaine Ophthalmic	Optional [1 bottle]	-	-	A	A
Rocuronium	Optional [100 mg]	-	-	-	A
Sodium Bicarbonate 8.4%	Optional [100 mEq]	-	-	A	A
Succinylcholine	Optional [400 mg]	-	-	-	A
Thiamine HCl	100 mg	-	-	A	A
Tranexamic Acid	?	?	?	?	?
Tuberculin PPD	Optional [5 mL]	-	-	A	A
Vasopressin	Optional [40 units]	-	-	-	A

Table 5.4. Eligibility for Authorization to Administer and Monitor Transport Agents During Interfacility Transports, by EMCT Classification; Administration Requirements**KEY:**

TA = Transport agent for an EMCT with the specified certification

IP = Agent shall be administered by infusion pump

SVN = Agent shall be administered by small volume nebulizer

AGENT	MINIMUM SUPPLY	EMT	AEMT	EMT-1 (99)	Paramedic
Amiodarone IP	None	-	-	-	TA
Antibiotics	None	-	-	TA	TA
Blood	None	-	-	-	TA
Calcium Chloride	None	-	-	-	TA
Colloids	None	-	-	TA	TA
Corticosteroids IP	None	-	-	TA	TA
Diltiazem IP	None	-	-	-	TA
Diuretics	None	-	-	TA	TA
Dobutamine	None	-	-	-	TA
Dopamine HCl IP	None	-	-	-	TA
Electrolytes/Crystalloids (Commercial Preparations)	None	TA	TA	TA	TA
Epinephrine IP	None	-	-	TA	TA
Fentanyl IP	None	-	-	TA	TA
Fosphenytoin Na IP or Phenytoin Na IP	None	-	-	-	TA
Glucagon	None	-	-	TA	TA
Glycoprotein IIb/IIIa Inhibitors	None	-	-	-	TA
H2 Blockers	None	-	-	TA	TA
Heparin Na IP	None	-	-	-	TA
Insulin IP	None	-	-	-	TA
Levophed IP	None	-	-	-	TA
Lidocaine IP	None	-	-	TA	TA
Magnesium Sulfate IP	None	-	-	-	TA
Midazolam IP	None	-	-	TA	TA
Morphine IP	None	-	-	TA	TA
Nitroglycerin IV Solution IP	None	-	-	-	TA
Phenobarbital Na IP	None	-	-	-	TA
Potassium Salts IP	None	-	-	-	TA
Procainamide HCl IP	None	-	-	-	TA
Propofol IP	None	-	-	-	TA
Racemic Epinephrine SVN	None	-	-	-	TA
Total Parenteral Nutrition, with or without lipids IP	None	-	-	-	TA
Vitamins	None	-	-	TA	TA

GENERIC NAME: Dobutamine hydrochloride

CLASS: Sympathomimetic, adrenergic catecholamine

Mechanism of Action:

Stimulates beta₁ adrenergic receptors of heart, causing a positive inotropic effect that increases myocardial contractility and stroke volume. Also reduces peripheral vascular resistance, decreases ventricular filling pressure, and promotes atrioventricular conduction.

Indications and Field Use:

To increase cardiac output in severe chronic congestive heart failure

Contraindications:

- Tachydysrhythmias
- Severe hypotension
- Idiopathic hypertrophic sub aortic stenosis
- known hypersensitivity to drug

Adverse Reactions:

CNS: headache

CV: hypertension, hypotension, tachycardia, premature ventricular contractions, angina, palpitations, nonspecific chest pain, phlebitis

GI: nausea, vomiting

Metabolic: hypokalemia

Respiratory: dyspnea, asthma attacks

Skin: extravasation with tissue necrosis

Other: hypersensitivity reactions including anaphylaxis

NOTES ON ADMINISTRATION

Incompatibilities/Drug Interactions:

- Beta-adrenergic antagonists may blunt inotropic responses.
- Sympathomimetics and phosphodiesterase inhibitors may exacerbate dysrhythmia responses.
- Incompatible with sodium bicarbonate and furosemide.

Adult Dosages:

2 to 20 mcg/kg/min IV (titrate to effect) Max: 40 mcg/kg/min

Pediatric Dosages:

2 to 20 mcg/kg/min IV (titrate to effect) Max: 40 mcg/kg/min

Routes of administration:

IV

Onset of Action:

1-2 minutes

Peak Effects:

10 minutes

Duration of Action:

10 – 15 minutes

Arizona Drug Box Minimum Supply:

NONE: Interfacility transport medication

Special Notes:

- Pregnancy safety: Not well established.
- May be administered through a Y-site with concurrent dopamine, lidocaine, nitroprusside, and potassium chloride infusions.
- Blood pressure should be closely monitored.
- Increases in heart rate of more than 10% may induce or exacerbate myocardial ischemia.

Administration:

- Use infusion pump
- Drug is incompatible with alkaline solutions (ie. sodium bicarbonate)

Patient Monitoring:

- As needed, correct hypovolemia before starting therapy by giving volume expanders
- Monitor ECG and blood pressure continuously during administration
- Monitor fluid intake and output

Patient Instruction:

- Report chest pain, headache, leg cramps and shortness of breath

References:

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<http://eilat.sci.brooklyn.cuny.edu/newnyc/drugs/Dobutami.htm>

DRAFT

GENERIC NAME: Propofol

CLASS: General Anesthetic

Mechanism of Action:

Sedative-hypnotic agent. Suspected to produce effects by the positive modulation of the inhibitory function of the neurotransmitter gamma aminobutyric acid (GABA) through the ligand-gated GABA receptors

Indications:

Intensive care unit (ICU) sedation of intubated mechanically ventilated adult patients

Contraindications:

Allergies to eggs, egg products, soybeans, or soy products

Adverse Reactions:

Bradycardia, arrhythmia, hypotension, HTN, tachycardia nodal, decreased cardiac output, CNS movement, injection-site burning/stinging/pain, hyperlipemia, apnea, rash, pruritus, respiratory acidosis during weaning.

NOTES ON ADMINISTRATION

Incompatibilities/Drug Interactions:

Increased effects with narcotics (eg., morphine, meperidine, fentanyl), combinations of opioids and sedatives (e.g., benzodiazepines, barbiturates, chloral hydrate, droperidol) and potent inhalational agents (e.g., isoflurane, enflurane, halothane). Concomitant fentanyl may cause bradycardia in pediatrics. Increased risk of propofol infusion syndrome with vasoconstrictors, steroids, and inotropes

Adult Dosages:

ICU Sedation: Initial: 5 mcg/kg/min IV for at least 5 min, then increased by increments of 5-10 mcg/kg/min IV over 5-10 min until desired clinical effect. Maint: 5-50 mcg/kg/min IV or higher may be required. Max: 4000 mcg/kg/hr.

Pediatric Dosages:

Safety and efficacy has not been well established for continuous sedation.

Routes of administration:

IV infusion

Onset of Action:

Less than 1 minute

Peak Effects:

1-2 minutes

Duration of Action:

4-8 minutes

Arizona Drug Box Minimum Supply:

None—Transport Agent

Monitoring:

Monitor for anaphylactic/anaphylactoid reactions, hypotension and/or cardiovascular depression, apnea, airway obstruction and/or oxygen de-saturation, decrease in cerebral perfusion pressure, signs/symptoms of propofol infusion syndrome, postoperative unconsciousness with increased muscle tone, pulmonary edema, increased vagal tone, pancreatitis, and other adverse events.

Special Notes:

- Fatal and life-threatening anaphylactic reactions reported.
- Proper use of aseptic technique required to prevent microbial contamination.
- Lower induction doses and slower rate of administration needed in elderly, debilitated or ASA-PS III/IV patients; monitor for early signs of hypotension, bradycardia, apnea, airway obstruction, and/or oxygen de-saturation.
- May cause propofol infusion syndrome in ICU sedation characterized by severe metabolic acidosis, hyperkalemia, lipidemia, rhabdomyolysis, hepatomegaly, and cardiac/renal failure. Consider alternative means of sedation if increased dose is required or metabolic acidosis occurs.
- Avoid abrupt d/c prior to weaning or for daily evaluation of sedation level; may result in rapid awakening with associated anxiety, agitation, and resistance to mechanical ventilation.
- Local pain, swelling, blisters, tissue necrosis reported following accidental extravasation.
- Failure to reduce infusion rate in ICU sedation for extended periods may result in excessively high blood concentrations. May elevate serum tri-glycerides when administered in extended periods; caution with disorders of lipid metabolism.
- Do not infuse for >5 days without drug holiday to replace zinc losses; consider supplemental zinc with chronic use in those predisposed to zinc deficiency.

- In renal impairment, perform baseline urinalysis/urine sediment, then monitor on alternate days during sedation.
- Correct fluid deficits prior to use.

References:

PDR.net; <http://www.pdr.net/drug-summary/diprivan?druglabelid=1719>

Lippincot's Nursing Center.com

http://www.nursingcenter.com/lnc/journalarticle?Article_ID=641327

Society of Gastroenterology Nurses and Associates , Inc.

<http://www.sgna.org/issues/sedationfactsorg/medications/propofol.aspx>

GENERIC NAME: INSULIN

CLASS: Pancreatic hormone

Mechanism of Action:

Promotes glucose transport, which stimulates carbohydrate metabolism in skeletal and cardiac muscle and adipose tissue. Also promotes phosphorylation of glucose in liver, where it's converted to glycogen. Directly affects fat and protein metabolism, stimulates protein synthesis, inhibits release of free fatty acids, and indirectly decreases phosphate and potassium

Indications and Field Use:

Type 1 (insulin-dependent) diabetes mellitus; type 2 (non-insulin-dependent) diabetes mellitus unresponsive to diet and oral hypoglycemics

Contraindications:

Hypersensitivity to drug or its components
Hypoglycemia

Adverse Reactions:

Metabolic: hypokalemia, sodium retention, hypoglycemia, rebound hyperglycemia (Somogyi effect)

Skin: urticaria, rash, pruritus

Other: edema; lipodystrophy; lipohypertrophy; erythema, stinging, or warmth at injection site; allergic reactions including anaphylaxis

NOTES ON ADMINISTRATION

Incompatibilities/Drug Interactions:

Drug-drug. Acetazolamide, albuterol, antiretrovirals, asparaginase, calcitonin, corticosteroids, cyclophosphamide, danazol, dextrothyroxine, diazoxide, diltiazem, diuretics, dobutamine, epinephrine, estrogens, hormonal contraceptives, isoniazid, morphine, niacin, phenothiazines, phenytoin, somatropin, terbutaline, thyroid hormones: *decreased hypoglycemic effect*

Anabolic steroids, angiotensin-converting enzyme inhibitors, calcium, chloroquine, clofibrate, clonidine, disopyramide, fluoxetine, guanethidine, mebendazole, MAO inhibitors, octreotide, oral hypoglycemics, phenylbutazone, propoxyphene, pyridoxine, salicylates, sulfapyrazone, sulfonamides, tetracyclines: *increased hypoglycemic effect*

Beta-adrenergic blockers (nonselective): *masking of some hypoglycemia symptoms, delayed recovery from hypoglycemia*

Lithium carbonate: *decreased or increased hypoglycemic effect*

Pentamidine: *increased hypoglycemic effect, possibly followed by hyperglycemia*

Dosage:

Adults and children: Loading dose of 0.15 units/kg (non-concentrated regular insulin) IV bolus, followed by continuous infusion of 0.1 unit/kg/hour until glucose level drops. Then administer subcutaneously, adjusting dosage according to glucose level.

Routes of administration:

IV (Regular)

Onset of Action:

10-30 minutes

Peak Effects:

15-30 minutes

Duration of Action:

Unknown

Arizona Drug Box Minimum Supply:

NONE: Interfacility Transport Agent

Special Notes:

- Don't give insulin IV (except non-concentrated regular insulin), because anaphylactic reaction may occur.
- In patients with DKA care should be taken to not reduce blood glucose below 200-250 mg/dL in first 4-6 hours as rebound hypoglycemia may occur. Target decrease in blood glucose level should be ~75 mg/dL/hr.
- FSBG should be obtained every 30-60 minutes.
- For IV infusion, mix regular insulin only with normal or half-normal saline solution, as prescribed, to yield a concentration of 1 unit/mL.

References:

[insulin. \(n.d.\) Nursing Spectrum Drug Handbook 2009. \(2009\). Retrieved November 27 2013 from http://medical-dictionary.thefreedictionary.com/Insulin](http://medical-dictionary.thefreedictionary.com/Insulin)

GENERIC NAME: NOREPINEPHRINE

CLASS: Sympathomimetic, Alpha- and beta- adrenergic agonist, inotropic cardiac stimulant, Vasopressor

Mechanism of Action:

Stimulates beta1 and alpha1 receptors in sympathetic nervous system, causing vasoconstriction, increased blood pressure, enhanced contractility, and decreased heart rate

Indications and Field Use:

Severe hypotension- due to cardiogenic, septic, or neurogenic shock either refractory to intravascular fluid boluses or in which intravascular fluid bolusing is contraindicated (e.g. pulmonary edema).

Contraindications:

- Hypersensitivity to drug
- Hypotension caused by blood volume deficit (except in emergencies until blood volume replacement is completed), profound hypoxia or hypercarbia
- Mesenteric or peripheral vascular thrombosis

Adverse Reactions:

CNS: headache, anxiety

CV: bradycardia, severe hypertension, arrhythmias

Respiratory: respiratory difficulty

Skin: irritation with extravasation, necrosis

Other: ischemic injury

Overdosage with norepinephrine may result in headache, severe hypertension, reflex bradycardia, marked increase in peripheral resistance, and decreased cardiac output. In case of accidental overdosage, as evidenced by excessive blood pressure elevation, discontinue norepinephrine until the condition of the patient stabilizes.

NOTES ON ADMINISTRATION

Incompatibilities/Drug Interactions:

Alpha-adrenergic blockers: antagonism of norepinephrine effects

Antihistamines, ergot alkaloids, guanethidine, MAO inhibitors, oxytocin, tricyclic antidepressants: severe hypertension

Bretylum, inhalation anesthetics: increased risk of arrhythmias

Adult Dosages:

Initial dose: 2 to 4 mcg/min

Maintenance dose: Adjust the rate for a low normal blood pressure (usually 80 to 100 mm Hg systolic). The average maintenance dose ranges from 1 to 12 mcg/min (maximum dose 30 mcg/min).

Pediatric Dosages:

0.1 – 2 mcg/kg/min; 2 mcg/kg/min max

Routes of administration:

IV use large vein- central line preferable

Onset of Action:

Immediate

Peak Effects:

Immediate

Duration of Action:

1-2 minutes after infusion is stopped

Arizona Drug Box Minimum Supply:

NONE- Interfacility transport medication

Special Notes:

Use IV pump only to infuse
Monitor IV site closely for extravasation
Watch for signs of inadequate peripheral tissue perfusion, pale-cyanotic-black
Never leave patient unattended during infusion
Monitor VS Q 5 minutes
Infusions should be reduced gradually, avoiding abrupt withdrawal
Severe tissue necrosis can occur with extravasation

References:

norepinephrine bitartrate. (n.d.) Nursing Spectrum Drug Handbook 2009. (2009). Retrieved November 27 2013 from <http://medical-dictionary.thefreedictionary.com/norepinephrine+bitartrate>

<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=c1ae8c26-a7cc-442f-98e4-0777f8bcfb5b>

GENERIC NAME: Kaolin, Chitosan

CLASS: Hemostatic agent

Kaolin

Mechanism of Action:

- Kaolin is an inert mineral and it promotes clotting by two main modes of action:
 - Kaolin promotes the activation of Factor XII (FXII) in the presence of kallikrein and high molecular weight kininogen. Activated FXII initiates the intrinsic clotting pathway via the activation of Factor XI. Activated FXI continues the coagulation pathway that ends with the formation of a fibrin clot.
 - Kaolin promotes the activation of platelet-associated FXI and it is a distinct and separate molecule from plasma FXI. Activated platelet-associated FXI initiates the intrinsic clotting pathway in normal and FXII deficient patients.

Indications and Field Use:

- Life-threatening hemorrhage on external wounds as an adjunct with direct pressure

Contraindications:

- Application to injuries related to eyes

Adverse Reactions:

- None

NOTES ON ADMINISTRATION

Incompatibilities/Drug Interactions:

- None

Adult/Pediatric Dosage:

Quantity necessary to fully cover bleeding area

Routes of Administration:

Topical

Onset of Action:

Immediate

Peak Effects:

5 minutes

Duration of Action:

Unknown

Arizona Drug Box Minimum Supply:

Optional- 1 packet

Special Notes:

For external use only
Do not remove once applied
Avoid contact with eyes

Chitosan

Mechanism of Action:

- A naturally occurring, bio-compatible polysaccharide that becomes extremely adherent when in contact with blood; seals the wound and controls bleeding. The red blood cells create a seal over the wound as they are drawn into the bandage.

Indications and Field Use:

- Life-threatening hemorrhage on external wounds as an adjunct with direct pressure

Contraindications:

- Application to injuries related to eyes

Adverse Reactions:

- None

NOTES ON ADMINISTRATION

Incompatibilities/Drug Interactions:

- None

Adult/Pediatric Dosage:

Quantity necessary to fully cover bleeding area

Routes of Administration:

Topical

Onset of Action:

Immediate

Peak Effects:

Duration of Action:

Unknown

Arizona Drug Box Minimum Supply:

Optional-

Special Notes:

For external use only
Do not remove once applied
Avoid contact with eyes

Guideline for the Utilization of Over the Counter Medications by EMS Agencies

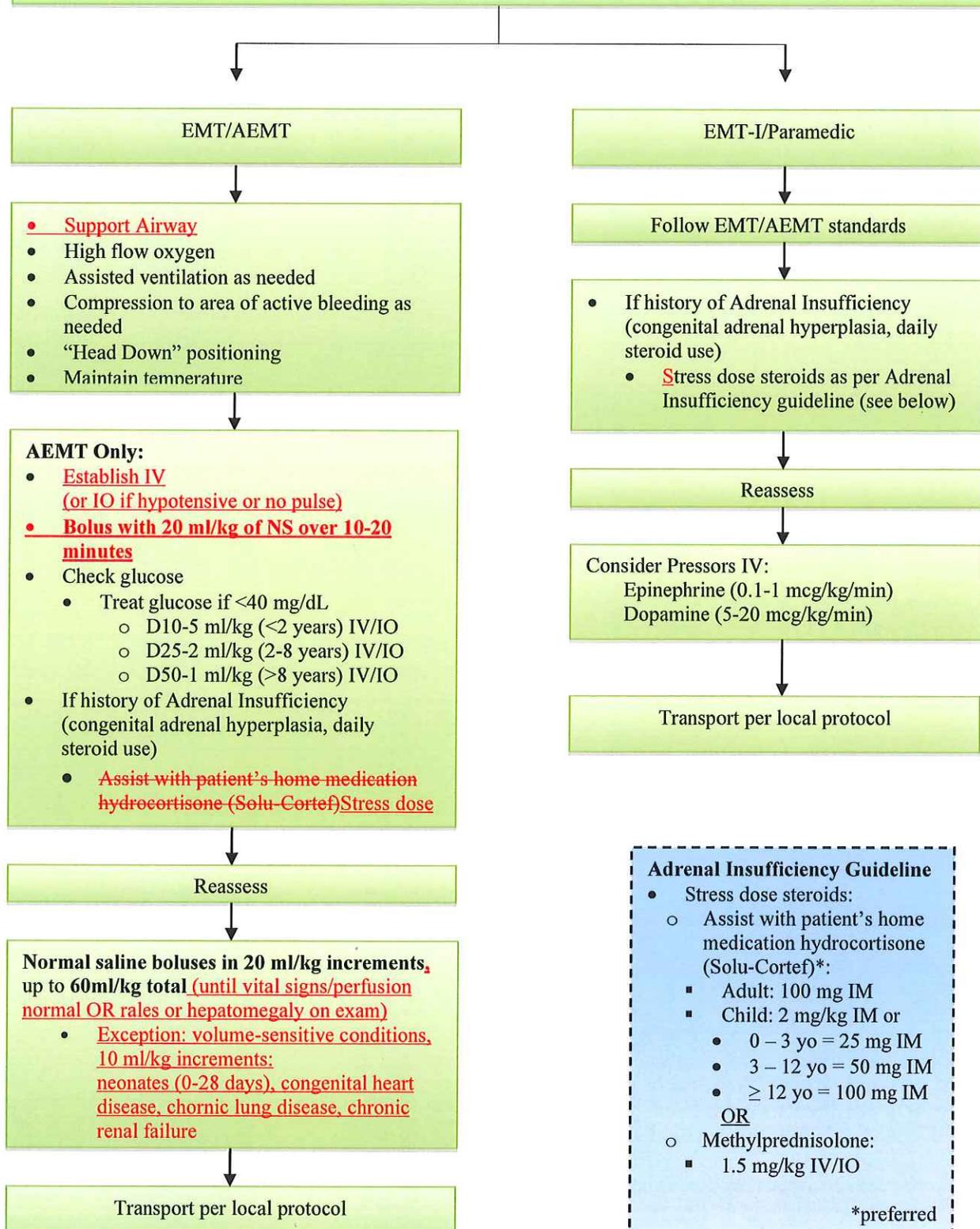
- A. Over the counter medications (OTCs) are FDA regulated substances that are readily available to the general public. Although regulated by the FDA, the general public may access and self-administer these medications without the advice or prescription from a licensed physician or other licensed-healthcare professional.
- B. DHS does not currently regulate the administration of OTC medications by Emergency Medical Care Technicians (EMCTs). In the absence of regulation, OTC medications should be treated like other FDA approved products that are not regulated by DHS, but are used in EMS operations.
- C. DHS recommends that the following clinical guidelines be met by EMS agencies which supply, carry, or distribute OTC medications:
 - 1. EMCTs may distribute OTC medications while involved in wildfire operations, special events, search and rescue, or when performing disaster relief.
 - 2. OTC medications may be distributed by EMCTs at the request of an individual and for the individual's self-administration only.
 - 3. EMCTs should only carry OTC medications approved by their medical director.
 - 4. Medical Directors should ensure EMCTs have appropriate knowledge of available OTC medications and the common contraindications of those OTC medications.
 - 5. Medical Directors shall develop a policy that outlines the types of OTC medications and circumstances in which those medications can be made available for self-administration.
 - 6. OTC medications shall be distributed in single dose packaging with instructions on the appropriate use of the medication kept on hand.

Pediatric Shock

ABCDE Assessment

The pediatric patient may present hemodynamically unstable or with hypoperfusion evidenced by:

- **Tachycardia** out of proportion to temperature or degree of pain
- **Altered mental status**
- **Delayed capillary refill greater than 2 seconds**
- **Pallor**
- **Peripheral cyanosis**
- **Hypotension (systolic blood pressure less than $70 + (2 \times \text{years})$ is a late finding in pediatric shock)**



SPECIAL CONTRIBUTION

AN EVIDENCE-BASED PREHOSPITAL GUIDELINE FOR EXTERNAL HEMORRHAGE CONTROL: AMERICAN COLLEGE OF SURGEONS COMMITTEE ON TRAUMA

Eileen M. Bulger, MD, FACS, David Snyder, PhD, Karen Schoelles, MD, FACP, Cathy Gotschall, ScD, Drew Dawson, BA, Eddy Lang, MD, CM CCFP (EM) CSPQ, Nels D. Sanddal, PhD, NREMT, Frank K. Butler, MD, FAAO, FUHM, Mary Fallat, MD, FACS, Peter Taillac, MD, Lynn White, MS, CCRP, Jeffrey P. Salomone, MD, FACS, NREMT-P, William Seifarth, MS, NREMT-P, Michael J. Betzner, MD, FRCPC, Jay Johannigman, MD, FACS, Norman McSwain, Jr., MD, FACS, NREMT-P

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The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Address correspondence to Eileen M. Bulger, MD, Professor of Surgery, Chief of Trauma, Box 359796, Harborview Medical Center, 325 9th Avenue, Seattle, WA 98104, USA. E-mail: ebulger@uw.edu

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ABSTRACT

This report describes the development of an evidence-based guideline for external hemorrhage control in the prehospital setting. This project included a systematic review of the literature regarding the use of tourniquets and hemostatic agents for management of life-threatening extremity and junctional hemorrhage. Using the GRADE methodology to define the key clinical questions, an expert panel then reviewed the results of the literature review, established the quality of the evidence and made recommendations for EMS care. A clinical care guideline is proposed for adoption by EMS systems. **Key words:** tourniquet; hemostatic agents; external hemorrhage

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INTRODUCTION

External hemorrhage has been increasingly recognized as a major cause of potentially preventable death following severe injury. This issue has been thoroughly addressed by the U.S. military Tactical Combat Casualty Care Committee (TCCC) in response to the increase in life-threatening external hemorrhage seen in the conflicts in Iraq and Afghanistan (www.health.mil/Education_And_Training/TCCC.aspx). Implementation of the TCCC guidelines for tourniquet use has been associated with a significant reduction in the number of combat deaths attributed to extremity hemorrhage.¹ Lessons learned from the military management of these injuries are beginning to be adopted in the civilian community and the recent Boston marathon bombing event highlighted this issue.² A report from the National Trauma databank suggests that mortality for patients with isolated lower extremity trauma with an arterial injury is 2.8%, with a 6.5% amputation rate.³

The use of tourniquets and hemostatic agents in the civilian EMS community is not widespread.^{4,5} While there is increasing interest in the use of these agents by civilian EMS agencies, the differences between the civilian and military populations may be important. These considerations, not well addressed in the published military experience, include the use of these modalities in elderly and pediatric patients and the impact of medical comorbidities on outcome. Even as recently as 2011, the Guidelines for Field Triage of Injured Patients does not include a recommendation for tourniquet use as a trauma triage criteria because "evidence is limited regarding the use of tourniquets in civilian populations; use of tourniquets among EMS systems varies; inclusion of tourniquet use as a criterion could lead to overuse of tourniquets instead of basic hemorrhage control methods, and thus potentially result in overtriage."⁶ However, the National EMS Scope of Practice Model published in 2007 lists tourniquet use as part of the minimum psychomotor skill set for emergency trauma care for emergency medical technicians. In addition, tourniquets have been included as required basic life support (BLS) equipment in the Joint Policy Statement: Equipment for Ambulances.⁷ Topical hemostatic agents are listed as optional basic equipment. The recent Hartford consensus conference also encourages wider civilian use of tourniquets for management of hemorrhage in active shooter events.⁸

The purpose of this project was to develop evidence-based guidelines for the use of tourniquets and hemostatic dressings in the U.S. civilian prehospital setting. The recommendations were based on a systematic review of the current literature and were developed using the GRADE methodology.⁹ External hemorrhage is defined as blood loss originating from a ruptured blood vessel and appearing on the body surface. For the purposes of our review, this includes extremity hemorrhage and junctional hemorrhage. Junctional hemorrhage includes the groin proximal to the inguinal ligament, the buttocks, the gluteal and pelvic areas, the perineum, the axilla and shoulder girdle, and the base of the neck.¹⁰

APPROACH

Expert Panel

An expert panel was convened by the American College of Surgeons Committee on Trauma EMS Committee to include nationally recognized experts in prehospital trauma care. Representatives were included from the military's Tactical Casualty Combat Care Committee, Prehospital Trauma Life Support, civilian State EMS directors, trauma surgeons, emergency physicians, a pediatric surgeon, an EMS researcher, a GRADE methodologist, and a paramedic.

Representatives were from both the United States and Canada. Panelists provided input to the formulations of the PICOTS (populations, interventions, comparators, outcomes, timing, and settings) questions prior to the initiation of the literature review. For the PICOTS questions, the population of interest was defined to be individuals with extremity hemorrhages; the interventions were commercially available tourniquets and hemostatic dressings; comparators were external wound pressure and nontourniquet or nonhemostatic interventions; outcomes of interest were limb salvage, hypovolemic shock, survival, and adverse effects. Because timing and setting were considered to be key aspects of the investigation the PICO format was expanded to include both immediate and long-term outcomes and the setting for the intervention was defined as the prehospital environment, before any procedures are performed in the hospital emergency department or operating theater. Following the completion of the systematic literature review, the panel met to review the literature in a full day meeting in Washington DC, October 2013. An expert in the application of the GRADE methodology facilitated the meeting and the panel used this approach to develop recommendations for each PICOTS question.

Evidence Review

A systematic review of the literature was conducted by the ECRI Institute, one of the eleven Evidenced-Based Practice Centers designated by the U.S. Agency for Healthcare Research and Quality. Their systematic literature review and evidence tables were used by the expert panel to develop these recommendations. A summary of the findings is included in this manuscript; the full ECRI report will be simultaneously published by the National Highway Traffic Safety Administration (NHTSA) and will be available at www.ems.gov. The PICOTS questions used to guide the literature review were developed with input from the multidisciplinary expert panel.

Literature search included 13 external and internal electronic databases, including CINAHL, EMBASE, and Medline, from 2001 to the present for fully published, primary, clinical studies. The Cochrane Database of Systematic Reviews (Cochrane Reviews), Database of Abstracts of Reviews of Effects (DARE), and Health Technology Assessment and Database (HTA) were also searched for secondary reviews. Additional search steps included manual search of bibliographies listed in fully published studies; search and written inquiry to regulatory agencies, including the U.S. Food and Drug Administration; and search of www.ClinicalTrials.gov and www.controlled-trials.com for ongoing clinical trials. Publications were also suggested for inclusion by expert panel members who commented on the draft report.

The criteria for inclusion in the systematic review were studies published in English that reported on traumatic hemorrhage treated by EMS personnel in the prehospital setting with tourniquets or hemostatic dressings currently available in U.S. commercial markets. In addition, the studies reported findings on at least one of the outcomes identified in the PICOTS questions and included at least 5 patients per treatment group; results for extremity and junctional hemorrhage were considered separately. To avoid duplication, when several sequential reports from the same study center were available, only findings from the largest, most recent, or most complete report was used. Because of the paucity of published studies on hemostatic dressings, for these questions the inclusion criteria were expanded to include animal studies of FDA-cleared or approved hemostatic dressings using either a swine or goat model of extremity bleeding. Risk of bias and other indicators of strength of evidence were assessed and reported.

The absolute risk differences and relative risk (RR) with 95% confidence intervals for the primarily dichotomous outcomes were calculated for individual studies. In cases in which meta-analysis was possible a summary odds ratio (OR) was calculated using a random effects model. Studies were combined using meta-analysis when populations and interventions were similar. Given the nature of the populations examined in this report, military populations were separated from civilian populations and data from children (younger than 18 years of age) was also examined independently. Statistical heterogeneity was examined using I^2 , but the small number of studies in the comparisons limited our confidence in measures of heterogeneity.

PICOTS Questions

- 1) In trauma patients with extremity hemorrhage (excludes junctional hemorrhage) who are treated in the prehospital setting, what is the effect of tourniquet use (single or double) with or without external wound pressure on limb salvage, hypovolemic shock, survival, and adverse effects compared with external pressure alone or with other nontourniquet interventions?
- 2) In trauma patients with junctional hemorrhage who are treated in the prehospital setting, what is the effect of junctional hemorrhage control device use with or without external wound pressure on limb salvage, hypovolemic shock, survival, and adverse effects compared with external pressure alone.
- 3) In trauma patients with extremity hemorrhage (excludes junctional hemorrhage) who are treated in the prehospital setting, do different brands or models of tourniquets differ from each other in their effect on limb salvage, hypovolemic shock, survival, and adverse effects?
- 4) In trauma patients with junctional hemorrhage who are treated in the prehospital setting by EMS personnel, do different brands or models of specialized junctional hemorrhage control devices differ from each other in their effect on limb salvage, hypovolemic shock, survival, and adverse effects?
- 5) In trauma patients with external hemorrhage (excludes junctional hemorrhage) who are treated in the prehospital setting using a tourniquet –
 - a) Does the incidence of adverse events vary by the duration of tourniquet use prior to removal?
 - b) Does the incidence of adverse events vary depending on whether tourniquets are removed in the field versus in a facility?
- 6) In trauma patients with external hemorrhage (hemorrhage from any body surface) who are treated in the prehospital setting, what is the effect of hemostatic dressings with or without external wound pressure on, control of hemorrhage, limb salvage (if an extremity involved), hypovolemic shock, survival, and adverse effects compared with using non-hemostatic gauze with or without external wound pressure?
- 7) In trauma patients with external hemorrhage (hemorrhage from any body surface) who are treated in the prehospital setting, do different brands or types of hemostatic dressings differ from each other in their effect on, hemorrhage control, limb salvage (if an extremity is involved), hypovolemic shock, survival, and adverse effects?

GRADE Methodology

The panel used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology to guide the process of PICOTS question formulation, evidence appraisal, and to designate the strength of recommendations. The process also adhered to the National Prehospital Evidence-Based Guideline (EBG) Model Process approved by the Federal Interagency Council for EMS and the National EMS Advisory Council.^{11,12} Panel members received an introduction to the GRADE methodology and reviewed the evidence for structured clinical questions using the PICO framework. After reading and discussing the systematic review of the evidence, the panel drafted graded recommendations. The recommendations were graded strong or weak, based on the balance between risk, benefit, burden, and cost, while the quality of evidence was appraised as high, moderate, low, or very low.^{13–18} Although the initial assignment of a strength of evidence rating is based on

study design, GRADE allows the evidence appraisal to be upgraded or downgraded, depending on such factors as the size and consistency of the reported effect or the presence of a dose response.¹⁹ Using the GRADE terminology, strong recommendations begin with the words “we recommend” and indicate that the panel believes that the benefits clearly outweigh any risks associated with the treatment and that nearly all informed patients would want the recommended treatment. Weak recommendations begin with the words “we suggest,” which indicates that the panel had a higher level of uncertainty about estimated benefits of the treatment the balance between benefits and risks.

RESULTS

Summary of Evidence Review

Our searches identified 1,599 potential citations for evaluation and full review identified 23 clinical studies

that met our inclusion criteria (Figure 1). While not the focus of this review we also reviewed 39 animal model studies, which compared efficacy of the topical hemostatic agents. Nine studies were identified that used only human volunteers and these were excluded.

Tourniquet Use

We identified 20 publications of prehospital tourniquet use for trauma-induced extremity hemorrhage. However, four publications did not provide information on outcomes needed for inclusion in this report: Laird et al.,²⁰ Gerhardt et al.,²¹ Kragh et al.,²² Kragh et al.²³ In two instances, the same study population was assessed in two separate publications. Kragh et al.²⁴ and Kragh et al.²⁵ used the same set of 499 patients and Kragh et al.²⁶ and Kragh et al.²⁷ used the same set of 232 patients. The 16 included publications are listed in Table 1 along with the setting in which the data on tourniquet

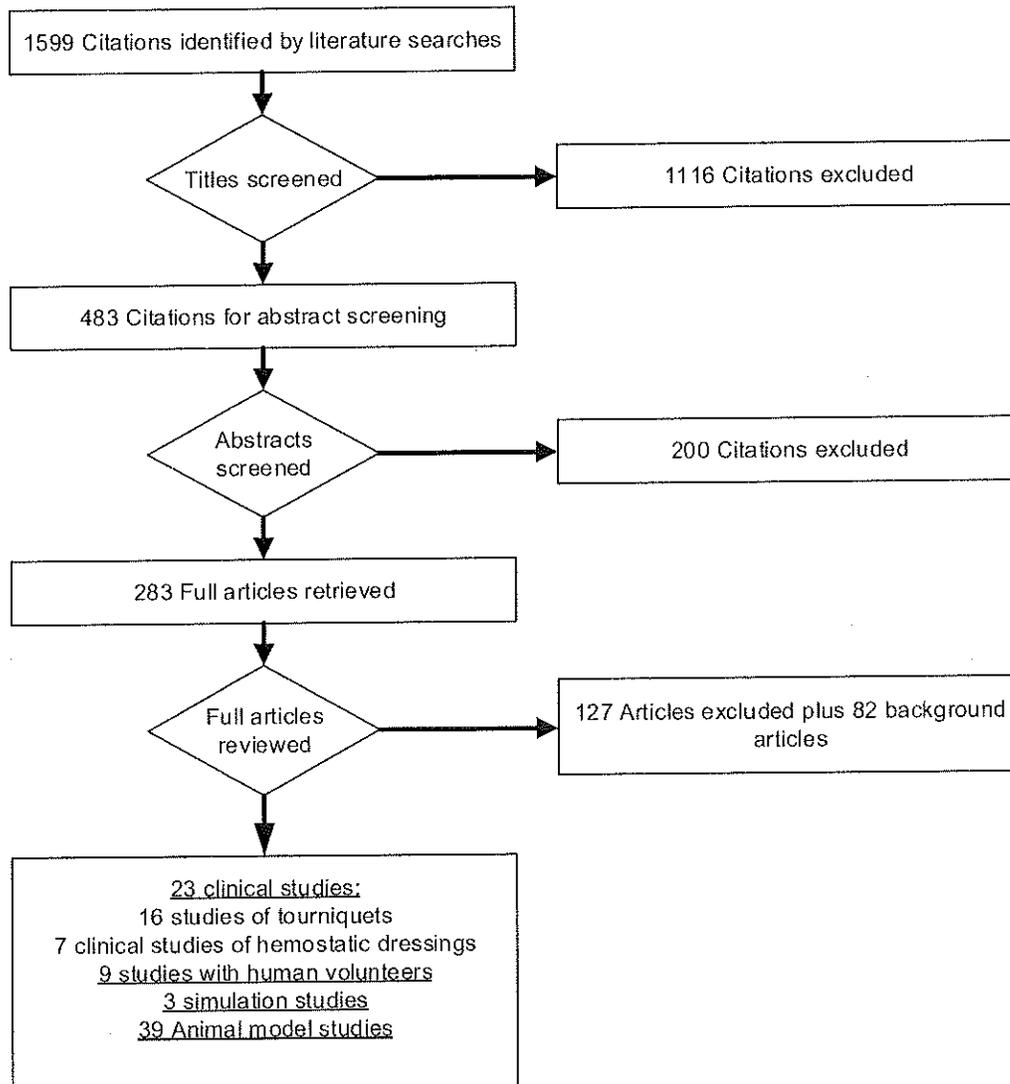


FIGURE 1. Summary of literature review.

TABLE 1. Studies of prehospital tourniquet use

Reference	Setting	Period of data collection	N	Patient characteristics	Outcomes reported
Eastridge et al., 2012 ¹	U.S. military Iraq/Afghanistan	Oct 2001 to June 2011	976	Not reported	Deaths
King et al., 2012 ⁴⁰	U.S. military Afghanistan	Aug 2011 to Nov 2011	54	Not reported	Deaths, adverse events
Kragh et al., 2012 ²⁸	U.S. military Iraq/Afghanistan pediatric casualties	May 2003 to Dec 2009	88 (pediatric)	72 were male and 16 were female patients. Mean age was 11 years (median, 11 years; range, 4–17 years). Injuries: explosion 64%, gunshot 30%, other 6%.	Deaths
Kotwal et al., 2011 ²⁹	U.S. military Iraq/Afghanistan	Oct 2001 to March 2010	460 (66 w/ tourniquet)	All casualties were male, with age at time of injury ranging from 18.9 to 52.9 years. Injuries: explosion 67%, gunshot 24%, blunt trauma 6%.	Deaths, amputations
Kragh et al., 2011 ²⁵	U.S. military Iraq	March 2006 to March 2007	499	96% male, average age 29 years, 16 were children and 5 elderly. Injury: explosion 75%.	Deaths, adverse events
Kragh et al., 2011 ²⁴ (same study as Kragh et al., 2011 ²⁵ but reporting morbidities)	U.S. military Iraq	March 2006 to March 2007	499	96% male, average age 29 years, 16 were children and 5 elderly. Injury: explosion 75%.	Adverse events
Brown et al., 2010 ⁴¹	U.K. military Iraq/Afghanistan	Aug 2003 to May 2008	23	Median age 26 years, range 18–42 years, not specific to tourniquet patients. Injuries for entire patient pool: explosion 62%, gunshot 38%.	Adverse events
Brodie et al., 2009 ⁴²	U.K. military Iraq/Afghanistan	Feb 2003 to Sept 2007	70	Gender and age data not reported. Injuries: explosion 86%, gunshot 14%.	Deaths, amputations, adverse events
Clasper et al., 2009 ³¹	U.K. military Iraq/Afghanistan	Dec 2003 to May 2008	44 (22 w/ tourniquet)	Tourniquet group: mean age of 26.6 years, range 19–37 years. Injuries: explosion 32%.	Amputations, adverse events
Kragh et al., 2009 ²⁶ (reassessment of data from Kragh et al., 2008 ²⁷)	U.S. military Iraq	March to Oct 2006	232 (194 w/ tourniquet)	Nontourniquet group: mean age of 25.7 years, range 19–37 years. Injuries: explosion 64%. 95% male, mean age of 29 years, range 4–70 years, 9 children and 1 elderly. Injuries: explosion 63%, gunshot 23%.	Deaths, amputations, adverse events
Tien et al., 2009 ⁴³	Canadian military Afghanistan	Feb 2006 to May 2006	1347?	Entire study examined 134 patients, 96% male, mean age of 26 years. Injuries: explosion 34%, gunshot 32%, blunt 22%.	Deaths
Beekley et al., 2008 ³⁰	U.S. military Iraq	Jan 2004 to Dec 2004	165 (67 w/ tourniquet)	Tourniquet group: 97% male, mean age of 29 years. Injuries: explosion 64%, gunshot 30%.	Deaths, amputations, adverse events
Dayan et al., 2008 ³²	Israeli military	2006	5 (prolonged tourniquet use)	Nontourniquet group: 96% male, mean age of 25. Injuries: explosion 70%, gunshot 27%.	Deaths, amputations, adverse events
Kalish et al., 2008 ⁴⁴	U.S. civilian	Jan 1999 to April 2006	11	All males, 20–22 years old. Injuries: explosion = 1, gunshot = 4.	Deaths and adverse events
Kragh et al., 2008 ²⁷	U.S. military Iraq	March 2006 to Oct 2006	232 (194 w/ tourniquet)	All males, mean age of 27 years, gunshot wounds 55%, stab wounds 27%, lacerations 18%.	Deaths, amputations, adverse events
Lakstein et al., 2003 ³³	Israeli military	Jan 1997 to Jan 2001	91 (improvised tourniquets)	95% male, mean age of 29 years, range 4–70 years, 9 children and 1 elderly. Injuries: explosion 63%, gunshot 23%. Gender and mean age not reported. Injuries: explosion 73%, gunshot 27%.	Deaths, amputations, adverse events

use were collected and the outcomes reported by each study. The large majority of studies were conducted by the U.S. military in Iraq and Afghanistan (8 studies) with 3 studies from the U.K. military, 2 from the Israeli military, and 1 from Canadian military. Only 1 study was conducted in a civilian setting. One study used data on pediatric casualties described in the Joint Theater Trauma Registry and collected during the wars in Iraq and Afghanistan.²⁸ Thirteen of the 16 included studies reported data on deaths, 11 reported data on adverse events, 8 reported data on amputations, and none reported data on shock.

Eight of the studies used prospective data collection. Most of the studies provided some information on how the tourniquets were to be used, but only a few were specific about the instructions. However, the studies from the U.S. military were using TCCC practices when data were collected after 2005 and tourniquets were likely used aggressively as a first option for traumatic extremity hemorrhage.

Comparisons between casualties treated with a tourniquet and similar casualties not treated with a tourniquet were attempted by only a few studies. Kotwal et al.²⁹ reported the number of casualties treated with compression dressings but did not report outcomes for this group. Beekley et al.³⁰ reported outcome data for tourniquet- and nontourniquet-treated casualties but did not report what prehospital treatments the nontourniquet group received. Clasper et al.³¹ matched surviving tourniquet-treated casualties with surviving nontourniquet-treated casualties to examine the rate of adverse events. These authors note, however, that "in a standard retrospective study it is likely that there would be considerable bias if simple comparison was made between the two groups as it is likely that those casualties with more severe injuries would have required a tourniquet, but those with a more severe injury are also likely to have worse outcomes and experience more complications."³¹

Meta-analysis of the 9 studies reporting survival for adult military casualties treated with tourniquets demonstrated a summary effect size estimate for survival rate of 92% with 95% confidence intervals of 88–95%. Findings in the study of children were similar (92%, with CI 84–96%). The study of a civilian population was small (11 cases), so the confidence interval was wide, but the survival rate similar (91%, CI 56–99%). A similar analysis for 6 studies reporting amputation rates demonstrated a summary effect size estimate of 19% with a 95% confidence interval from 16–23%. These amputations are presumably primarily associated with the severity of the extremity injury, as they are not described as complications of tourniquet use. The overall quality of the evidence for PICOTS Question 1 was rated using the GRADE system as Moderate for survival based on upgrading due to

the large effect size and Very Low for amputation rate (Table 2).

There were no studies available that directly addressed PICOTS questions 2, 3, and 4. These included the efficacy of junctional hemorrhage control devices or the comparison of different brand or models of tourniquets. Regarding PICOTS question 5, there were 4 studies that correlated duration of tourniquet use with adverse events but specifics were not provided on the timing and setting of tourniquet removal.^{27,30,32,33} Thus, the grade of evidence for PICOTS question 5 was rated as Low.

Hemostatic Agents

Seven studies were reviewed that reported on the prehospital use of hemostatic dressings (Table 3). Five were conducted in a military setting. One was civilian and 1 included both military and civilian data. The products tested included HemCon (3 studies), Celox (1 study), QuickClot granules (2 studies), and QuickClot Gauze (1 study). One study did not report the type of hemostatic dressings used. Only 1 study reported mortality and 4 studies reported on adverse events. No studies provided a direct comparison between the use of hemostatic dressings and simply applying direct pressure to the wound. The primary adverse event noted was pain and discomfort associated with an exothermic reaction to QuickClot granules.

The primary outcome for 5 studies was cessation of bleeding. The study by Brown et al.³⁴ reported that HemCon controlled external hemorrhage in 27 of 34 cases (79%); in 25 cases the bleeding stopped within 3 minutes of application. The study by Cox et al.³⁵ is confounded because 7 of the 8 patients treated with hemostatic dressings in the field were also treated with a tourniquet. The study by Pozza and Millner³⁶ reported that Celox stopped bleeding in 18 gunshot wounds when first applied and in 3 additional cases with further application. The study by Ran et al.³⁷ reported that QuickClot gauze successfully stopped bleeding in 11 out of 14 cases of extremity and truncal hemorrhage. The study by Rhee et al.³⁸ reported that QuickClot granules were 100% effective in stopping bleeding. In the study by Wedmore et al.,³⁹ medics were surveyed on their use of HemCon dressing. In 42 of the 64 cases, the dressings were used when traditional gauze dressings or pressure dressings failed to stop bleeding. In 62 of the 64 cases, HemCon successfully stopped the bleeding. The risk of bias associated with these studies is high because they are all single-arm studies with no comparison group. Sufficient data were not available to provide an estimate of survival rates or amputation rates in patients treated with hemostatic dressings. The overall strength of evidence for Key Question 6 was graded as Low using the GRADE system.

TABLE 2. Key Question 1: Strength of evidence grades for survival rate and amputation rate with prehospital tourniquet use

Outcome	# Studies (total N)	Type of studies	Findings	Starting GRADE	Decrease GRADE					Increase GRADE					GRADE of evidence for outcome	
					Study limitations	Consistency	Directness	Precision	Publication bias	Large magnitude of effect	Dose-response	Confounders				
Survival rate	9 studies of military personnel (1,229)	Observational	91.9% (95% confidence interval [CI]: 88.1% to 94.6%)	Low	-1	0	0	0	0	0	0	0	0	0	0	Moderate
Amputation rate	6 (556)	Observational	19.2% (95% CI: 15.8% to 23.2%)	Low	-1	0	0	0	0	0	0	0	0	0	0	Very Low

Table 3. Studies of prehospital hemostatic dressings

Reference	Setting	Period of data collection	Number of casualties treated	Patient characteristics
Brown et al., 2009 ³⁴	U.S. civilian	June 2006 to Aug 2006	HemCon <i>n</i> = 34	53% extremity wounds, 68% male, mean age of 51.5 years, range of 16–91 years.
Cox et al., 2009 ³⁵	U.S. military Iraq	April 2006 to Oct 2006	HemCon <i>n</i> = 5, QuikClot granules <i>n</i> = 3	7 of 8 extremity wounds, other data not reported.
Lairet et al., 2012 ²⁰	U.S. military Afghanistan	Nov 2009 to Nov 2011	Not specified <i>n</i> = 23, Compression <i>n</i> = 371	For all 1,003 patients in the study, the mechanism of injury was explosion 60%, penetrating 24%, blunt 15%. 97% male, mean age of 25 years.
Pozza and Millner, 2010 ³⁶	U.S. military Afghanistan	April 2008 to April 2008	Celox = 21	All gunshot wounds. All male between ages of 18 and 45 years.
Ran et al., 2010 ³⁷	Israel military	2009	Quikclot Combat Gauze <i>n</i> = 14	Injuries: blast = 7, gunshot = 6, stab = 1. Other data not reported.
Rhee et al., 2008 ³⁸	U.S. civilian and U.S. military Iraq	Not specified, but study was completed in 2006	QuikClot granules <i>n</i> = 103 (69 treated by U.S. military personnel, 20 treated by civilian trauma surgeons, 14 treated by civilian first responders)	Injuries for all patients: explosion 21%, gunshot 66%, blunt 8%, stab wound 5%.
Wedmore et al., 2006 ³⁹	U.S. military Iraq/Afghanistan	2003 to 2004	HemCon <i>n</i> = 64	55% extremity wounds; bleeding was predominantly from a venous source in 33 cases, arterial source in 7 cases, and unknown in 24 cases.

In regard to PICOTS Question 7, there were no patient studies that directly compared the different hemostatic dressings. The U.S. military has developed a standardized swine model, which involves a femoral artery injury with a standard period of free bleeding. This literature was summarized and reviewed by the expert panel. For the details of this review please see the full ECRI Institute report. These data factored into the recommendation by the panel for the use of a gauze format product that could be packed into the wound. The panel also supported the use of this standardized model for comparison of different products.

RECOMMENDATIONS BY EXPERT PANEL

The recommendations of the panel for management of external hemorrhage are summarized in Figure 2.

Tourniquets

Recommendation 1: We recommend the use of tourniquets in the prehospital setting for the control of significant extremity hemorrhage if direct pressure is ineffective or impractical.

Strength of Recommendation: Strong
Quality of Evidence: Moderate. The overall quality of the evidence for survival benefits of tourniquet use was upgraded from Low to Moderate, based on the

large effect size. The evidence for preventing amputation was very low, due to a smaller effect size and issues relating to confounding (see Table 2).

Remarks: The panel believes that tourniquets used to treat severe extremity hemorrhage have a clear survival benefit, demonstrated by a large and consistent effect size across several studies. The panel discussed that direct pressure may be ineffective in the setting of major arterial injury or impractical in circumstances with limited manpower, unsecure scene, or when complex extrication or extraction is required.

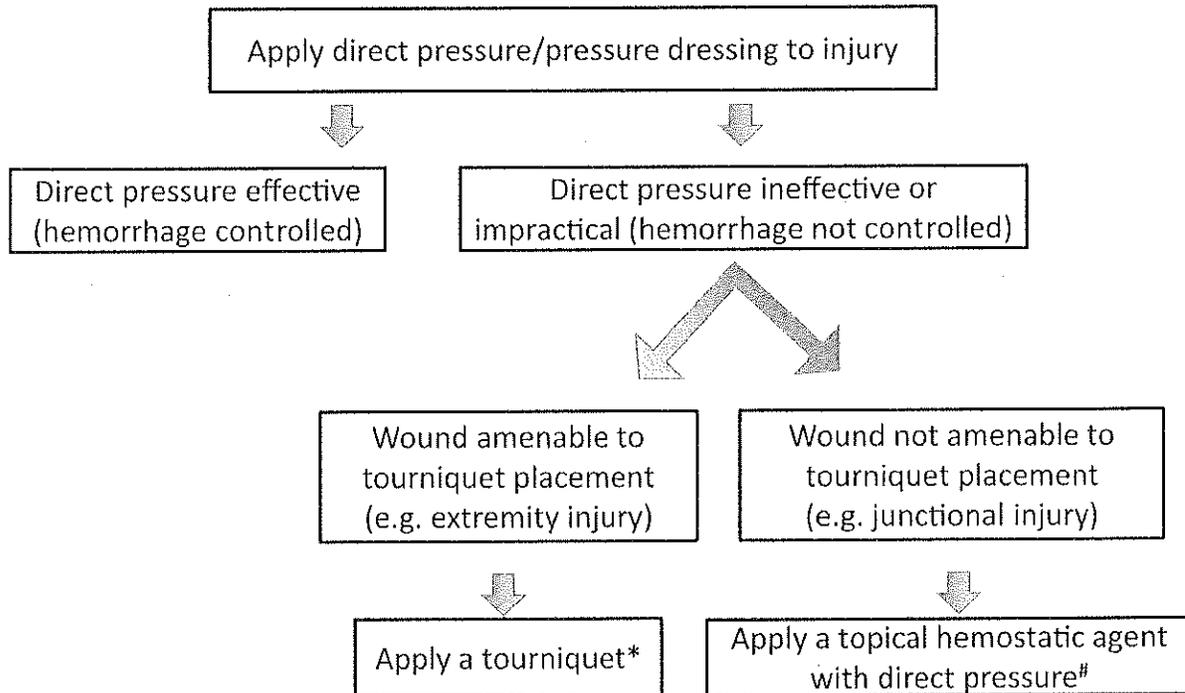
Recommendation 2: We suggest using commercially produced windlass, pneumatic, or ratcheting devices that have been demonstrated to occlude arterial flow.

Strength of Recommendation: Weak
Quality of Evidence: Low

Remarks: The panel discussed the military experience with varying types of tourniquets and felt that tourniquet selection should be based on proven effectiveness at arterial occlusion. Tourniquets that impede venous return without adequate arterial occlusion may only worsen hemorrhage and increase complications.

Recommendation 3: We suggest against the use of narrow, elastic, or bungee-type devices.

Prehospital External Hemorrhage Control Protocol



*Use of tourniquet for extremity hemorrhage is strongly recommended if sustained direct pressure is ineffective or impractical; Use a commercially-produced, windlass, pneumatic, or ratcheting device, which has been demonstrated to occlude arterial flow and avoid narrow, elastic, or bungee-type devices; Utilize improvised tourniquets only if no commercial device is available; Do not release a properly-applied tourniquet until the patient reaches definitive care

#Apply a topical hemostatic agent, in combination with direct pressure, for wounds in anatomic areas where tourniquets can not be applied and sustained direct pressure alone is ineffective or impractical; Only apply topical hemostatic agents in a gauze format that supports wound packing; Only utilize topical hemostatic agents which have been determined to be effective and safe in a standardized laboratory injury model

FIGURE 2. Protocol for prehospital external hemorrhage control.

Strength of Recommendation: Weak
Quality of Evidence: Low

Remarks: The panel discussed the military experience with varying types of tourniquets and felt that tourniquet selection should be based on proven effectiveness at arterial occlusion. Tourniquets that impede venous return without adequate arterial occlusion may only worsen hemorrhage and increase complications.

Recommendation 4: We suggest that improvised tourniquets be applied only if no commercial device is available.

Strength of Recommendation: Weak
Quality of Evidence: Low

Remarks: The panel discussed the military experience with varying types of tourniquets and felt that tourniquet selection should be based on proven effectiveness at arterial occlusion. Tourniquets that impeded venous return without adequate arterial occlusion may only worsen hemorrhage and increase complications. Commercially available tourniquets

are favored over improvised tourniquets unless there is no other option.

Recommendation 5: We suggest against releasing a tourniquet that has been properly applied in the prehospital setting until the patient has reached definitive care.

Strength of Recommendation: Weak
Quality of Evidence: Low

Remarks: Given the relatively short transport times for most civilian EMS agencies, the committee felt the safest option was to leave a tourniquet that had been placed in the field in place until the patient can be assessed in the hospital. There may be exceptions to this approach for prolonged transport times or austere environments. In these circumstances, prehospital providers should consult direct (online) physician medical direction.

Junctional Hemorrhage Devices

Regarding the questions related to junctional hemorrhage devices, we believe this is an important area for

further study, but did not find sufficient evidence to make a recommendation at this time.

Topical Hemostatic Agents

Recommendation 1: We suggest the use of topical hemostatic agents, in combination with direct pressure, for the control of significant hemorrhage in the prehospital setting in anatomic areas where tourniquets cannot be applied and where sustained direct pressure alone is ineffective or impractical.

Strength of Recommendation: Weak

Quality of Evidence: Low

Remarks: While the evidence was low, there are consistent data from animal models, suggesting reduced hemorrhage with these agents compared to standard gauze and the committee felt that junctional hemorrhage and torso wounds may benefit from the combination of direct pressure and hemostatic dressings.

Recommendation 2: We suggest that topical hemostatic agents be delivered in a gauze format that supports wound packing.

Strength of Recommendation: Weak

Quality of Evidence: Low

Remarks: This recommendation was based on the military experience and the animal studies suggesting that products that allow packing of the wound have superior hemorrhage control.

Recommendation 3: Only products determined effective and safe in a standardized laboratory injury model should be used.

Strength of Recommendation: Weak

Quality of Evidence: Low

Remarks: The U.S. Army Institute for Surgical Research has developed a standardized large animal model for comparison of hemostatic dressings. The committee felt that all new products should be subject to this testing.

Additional Training Recommendations

- We advise that tourniquets and topical hemostatic agents be used under clinical practice guidelines and following product specific training.
- We advise that hemostatic agent training for prehospital personnel include proper wound packing and pressure application techniques.
- We advise that tourniquets and topical hemostatic agents use be expanded to include all prehospital personnel, including emergency medical responders (in concordance with the Hartford Consensus Statement⁸).

NEED FOR ADDITIONAL RESEARCH

While the military data were convincing that the use of tourniquets to control severe extremity hemorrhage is life saving, there remain several unanswered questions regarding the logistics of hemorrhage control in the civilian EMS community. The evidence available to assess many of the practical issues surrounding the use of tourniquets and hemostatic agents in the civilian community is very limited. There were insufficient data to make any recommendations regarding the newly developed devices for junctional hemorrhage control. There were insufficient data to make any specific recommendations regarding application in the extremes of age including pediatric and elderly patients. Future research should focus on these gaps in knowledge to further guide clinicians in the civilian application of these products.

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