My AED Exploded: Reporting Equipment Issues

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EMS Editor – Fire Engineering magazine
Resuscitation Committee Chair – Albany Medical Center

www.mikemcevoy.com
Disclosures

• None

• I don’t know how to play golf or ski
When I am not Fighting Fires, I am reading Fire Engineering®
Outline

• What can go wrong, will go wrong
• Expectations
• Requirements
• Responsibilities
• Benefiting from others problems
www.justculture.org

SO, YOU'RE NEW TO JUST CULTURE?

START

FOR THOSE WHO SEEK IMPROVEMENTS IN PERFORMANCE, SAFETY AND FAIRNESS, OUTCOME ENGenuity IS HERE TO SERVE YOU.

Performance Management Course

Just Culture Certification Course

Event Investigation Course
EMS is Complicated

• Community
  – Patients and families
  – Citizens
  – Businesses

• Health Care
  – Hospitals
  – Doctors offices, nursing homes, clinics
  – Public Health Departments

• Medical Control

• Insurers

• Legal system
  – Attorneys
  – Courts

• Regulators and Government
  – Federal
  – State
  – Local
What Can Go Wrong...

• Basic principle of emergency care is to, “do no further harm.”
• Yet mistakes happen...
• Consequences can be significant
How Dangerous Are We?

Less than 1 death per 100,000 encounters:
- Nuclear power
- European railroads
- Scheduled airline flights

More than 1 death per 100,000 encounters:
- Driving
- Chemical manufacturing

More than 1 death per 1,000 encounters:
- Bungee jumping
- Mountain climbing
- **Health care**
Patient Safety

• IOM Report “To Err Is Human” – 1999
  – 98,000 patients die from medical errors annually

• EMS High Risk Activities?
  – Hand offs
  – Communications
  – Medications
  – Airway
  – Drops
  – Crashes
EMS Lawsuits

1 in every 20,000 patient encounters results in a lawsuit

-Garza MA. JEMS. 2000 Feb;25:20-21
EMS Closed Claims Analysis

Preliminary data: 275 cases:

- 40% patient handling
  - half were stretcher drops and tips
- 31% emergency vehicle movement or crashes
- 11% medical management
- 8% EMS response or transport
- 4% lack or failure of equipment
- 9% other

In a newly-filed lawsuit, Ronan's father claims the defendants "did not have appropriate medical personnel and / or an automated external defibrillator on site at the time of Ronan's collapse and did not otherwise provide assistance to him."

Ronan Guyer was 14 years old in November 2012, when he competed at the State Cross Country Championships held at the Elma Meadows Golf Course. During a practice run, he slipped and fell into the mud. The fall on his chest caused sudden cardiac arrest, according to his family. Ronan died at Women and Children's Hospital five days later.

WEB EXTRA: Read the Complaint

In a newly-filed lawsuit, Ronan's father claims the defendants "did not have appropriate medical personnel and / or an automated external defibrillator on site at the time of Ronan's collapse and did not otherwise provide assistance to him."
Fatal Fall From Chicago FD Gurney Expected to Result in $300K Settlement

Chicago Fire Department policy requires that two people push gurneys -- one at the head of the patient and the other at the feet -- to provide stability.

However, in the 2009 incident in which responders were called to assist 74-year-old Mary Strazz, they had the smallest member of the crew pushing the gurney by himself, says Jeff Comeau, an attorney representing the woman's family.
Widow of NJ Mall Carjacking Victim Files Lawsuit

• Suing many, including mall, ambulance service and each EMS responder (individually)
• Alleges excessive response time
• Failure to plan for response to parking garage
• Gross negligence involving operation of a motor vehicle
• Wrongful death resulted
Boiling Hot Water

1. Patient handling (40%)
   - Stretchers, stair chairs, backboards
2. Driving (31%)
3. Medical care (15%)
Show me the money

Largest settlements ➔ Patient Care

AIRWAY

1. Missed esophageal intubation
2. Hypoxic brain injury

- Failure to manage airway
- Failed ETI*
- Prolonged ETI efforts
  *25% misplaced, 2/3 esophageal

Source: ESIP, 2011
EMS Liability

- **MVA (51%)**
  - EV Collision
  - EV Movement

- **Patient Handling (28%)**
  - Drops 35%
  - Tips 30%
  - Movement 20%
  - Falls 15%

- **Medical Mgmt. (9%)**
  - Airway 41%
  - Procedural 25%
  - Assessment/Decision 19%
  - Adverse Drug Event 12%

- **Response/Transport (5%)**
  - Transport Error 52%
  - Response Error 44%
  - Patient Security 4%

- **Equipment (4%)**
  - Lack of
  - Failure of

ESIP (Emergency Services Insurance Program) data, 2011
## NHTSA Ambulance Crash Data

<table>
<thead>
<tr>
<th>Category</th>
<th>Total Crashes</th>
<th>Killed</th>
<th>Injured</th>
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<tr>
<td></td>
<td>= 4,745</td>
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<td>Driver</td>
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<td>759</td>
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<tr>
<td>Passenger</td>
<td>8</td>
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<td>OMV</td>
<td>21</td>
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<tr>
<td>Pedestrian</td>
<td>2</td>
<td>-</td>
<td></td>
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</tbody>
</table>

### 2008 Study - Departments with EMD:
- 25% fewer crashes
- 39.6% less severe
EMERGENCY VEHICLES

The California accident attorney with The Dolan Law Firm has handled many cases involving emergency vehicles. Emergency vehicles include vehicles such as fire engines, police cars, and ambulances.

Although these types of emergency vehicles are not required to stop at all red lights, they are still required to operate safely. In order to qualify as an emergency vehicle, certain items must be met:

1. It must be a verified emergency
2. A siren must be present
3. A red light should be visible from the front of the vehicle

If all three are not met, this is in violation of the vehicle code. The drivers do not have the right to operate the vehicle without reasonable care. Click here to read the California state laws regarding the operation of emergency vehicles.

Contact us today, and speak to Mr. Dolan, or one of other qualified trucking accident attorneys. The consultation is free.
Medical Management (9%)

• Procedural 25%
  – Delayed SCI recognition/treatment
  – Improper fx immobilization
  – Failure to follow protocol

• Assessment/Decision 19%
  – Failure to transport
  – Improper method of moving patient
  – Failure to treat

• Adverse Drug Event 12%
  – Wrong route
  – Wrong dose
  – Narcotic given without order
Response/Transport (5%)

- Transport Errors 52%
  - Failure to transport
  - Transport to wrong or inappropriate facility

- Response Errors 44%
  - Failure to dispatch
  - Navigational (got lost)
  - Slow/delayed response
  - NPF (No Patient Found)

- Patient Security 4%
  - Failure to secure (fell, stood, jumped out….)
Equipment (4%)

• Lack of equipment
  – Left equipment on scene
  – Failed to bring equipment to patient
  – No oxygen
  – Missing ambulance keys

• Equipment failure
  – Dead defibrillator batteries
  – Defib malfunction
  – Suction malfunction
Response Times

- Are there really standards?
  “Arrive 90% of time before 8:59”
- Fractal
- Fitch & Associates use 8:59 – 12:59 as typical norm for US systems
- Rural and wilderness areas may be as long as 15/90 to 30/90
- Most recent evidence suggests NO association between times & outcomes
Domino’s Pizza

1973: guaranteed delivery in 30 min or pizza was free

• 1992: $2.8 million settlement to family of Indiana woman killed by speeding Domino’s driver

• 1993: $15 million paid to St. Louis woman injured when struck by a Domino’s driver who ran a red light

Guarantee dropped because of, “public perception of reckless driving and irresponsibility.”
Response Times

- Standards are set by the community:
  - Authority having jurisdiction over EMS
  - Patient perspective
- Role of the Chief:
  1. Measure response times
  2. Strive to match supply to demand
  3. Be aware of unit hour utilization
  4. Know community expectations
Time Troubles

- Is time important?
- “Golden Hour” conceived by Maryland Shock Trauma Center
- No evidence basis in repeated studies

Does Time Ever Matter?

• Are there time critical trauma patients?
• First rule of hemorrhage control = Find the leak (you cannot control what you cannot see)
• Shock without evident bleeding requires “Cold hard steel”
So, What Stats Do I Need?

Basic Data Set

– Dispatches
– Transports
– Hour and day distribution
– Response times by zone/area/neighborhood

Times

– Call processing intervals
– Reflex performance (chute/scramble time)
– UHU (xpt-disp-adjusted)*

*used only to determine 24/12 splits (typically at 0.4)
Ask and You Will Receive

Sarasota County FL - 1970’s beat out big dogs (AT&T, Honeywell…) for customer service and quality awards. Key metrics:

1. Come quickly
2. Make my pain go away
3. Treat me nicely (concerned and caring)
4. Tell me what you’re doing and why
5. Look & act like you know what you’re doing (professional)

What Must You Report?

- Federal (FDA)
  - Medical device adverse events
  - Adverse drug reactions
- New York State (DOH)
  - Serious injury, illness or death
Regulating Medical Devices

- 1976 – Congress placed under FDA
- 1990 – Safe Medical Devices Act (SMDA) expanded FDA authority
- 1992 – Medical Device amendments established a single reporting standard for manufacturers, user facilities, and importers
# Requirements

## Medical Device User Facilities

<table>
<thead>
<tr>
<th>Report What?</th>
<th>To Whom?</th>
<th>When?</th>
</tr>
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<tbody>
<tr>
<td>Deaths</td>
<td>FDA and manufacturer</td>
<td>Within 10 work days</td>
</tr>
<tr>
<td>Serious Injuries</td>
<td>Manufacturer (FDA only if manufacturer unknown)</td>
<td>Within 10 work days</td>
</tr>
<tr>
<td>Summary of deaths and serious injuries</td>
<td>FDA</td>
<td>Annually (if any)</td>
</tr>
</tbody>
</table>
Medical Device User Facility

• Multiple categories, including -
  • “Outpatient Treatment Facility”
    – 21 C.F.R. 803.3(u)(1)
    – ambulance providers and rescue services, regardless of whether or not they are licensed or accredited and whether or not they are independent or under the control of a larger medical entity.
## Requirements

### Medical Device User Facilities (EMS)

<table>
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<td>Summary of deaths and serious injuries</td>
<td>FDA</td>
<td>Annually (if any)</td>
</tr>
</tbody>
</table>
What is a “medical device”? 

• Any object used in patient care that is not a drug. (simple definition) 
• Item used for diagnosis, treatment or prevention of disease, injury or other condition that is not a drug, biologic or food. (less simple) 
• Food, Drug & Cosmetic Act: 201(h) 
• Stretchers, bandages, splints, gloves…
What is an Adverse Event?

- An event where a death or serious injury was, or may have been caused by a medical device.
- An event whereby a medical device was, or may have contributed to a death or serious injury.
Adverse Events

Includes events resulting from:

• Device failure
• Improper / inadequate design
• Device malfunction
• Manufacturing defects
• Labeling problems
• User error
What is “Serious Injury”? 

1. Life threatening injury or illness 
2. Results in permanent impairment, damage to body function or structure 
3. Requires medical or surgical intervention to preclude #2 above
How To Report

• Mandatory reports: FDA form 3500
• Annual reports: FDA form 3419
• Forms at: www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/default.htm
• Must be mailed (no on-line version)
  FDA
  Medical Device Reporting
  PO Box 3002
  Rockville MD 20847-3002
Guide Available


(change from semiannual to annual reporting came after guide published)
Voluntary Reporting

• For everything else:
  – Problems without death/serious injury
  – Drugs
  – Any adverse event or safety issue

• Consumers or Healthcare Providers
• Online form (3500) can be used
• Available at FDA MedWatch web site
MedWatch Online Voluntary Reporting Form

Welcome

What to Report to FDA MedWatch:

Use the MedWatch form to report adverse events that you observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))
- Medical devices (including in vitro diagnostic products)
- Combination products
- Special nutritional products (dietary supplements, infant formulas, and medical foods)
- Cosmetics

Begin Report As:

- Health Professional
- Consumer/Patient

Frequently Asked Questions
NYS Required Reporting:

• Patient deaths or injuries
• PI service vehicle crashes
• On-duty deaths or injuries requiring care by a physician
• Equipment failures that cause patient harm
• Allegation that a member has responded to an incident OR treated a patient while under the influence of alcohol or drugs
NYS DOH Reporting

- Policy Statement 98-11
- Phone report to DOH Area Office by COB day following incident
- Written report within 5 days; use DOH 4461 Reportable Incident Form
  www.health.ny.gov/professionals/ems/emsforms.htm can be completed as PDF & emailed to DOH
DOH 4461

- Glorious, 10-page form
- FDA 3500 can be sent in lieu of

**NEW YORK STATE DEPARTMENT OF HEALTH**  
Bureau of Emergency Medical Services

**Reportable Incident Form**

This form must be completed for any serious injury, illness or death of an EMS provider, patient or other individual in accordance with Part 800.21(q) and 800.21(r). The completed form must be submitted to the New York State Department of Health’s Bureau of Emergency Medical Services within 5 business days for every incident.

<table>
<thead>
<tr>
<th>Name of EMS Service</th>
<th>NYS EMS Agency Code</th>
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<tr>
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<table>
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<table>
<thead>
<tr>
<th>Name of Contact Person and Title</th>
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<table>
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<tr>
<th>Business Phone ( )</th>
<th>Other Phone ( )</th>
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</tr>
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</table>

**FORM DIRECTIONS**

Only complete and return sections that pertain to the incident being reported.
Why Reporting?

• May 2004, Clifton Park – Halfmoon paramedics shock patient in cardiac arrest; ROSC achieved
• During packaging, patient arrests again (v-fib)
• Charging monitor-defib, screen went blank then displayed message: “Bridge Test Failed”
• Second monitor used to treat patient
Why Reporting?

- Albany Medical Center Hospital 2006
- Frequent IV pump “occlusion” alarms
- Nurses complained about tubing
- Admin & clin engineers advised RNs to be vigilant about seating IV tubing
- FDA MedWatch report filed
- FDA determined manufacture defect
- > 1 million IV tubing sets recalled
Why Reporting?

- Reporting brings important information to manufacturers & FDA (if required reporters report)
- Reporting assures patient and EMS provider safety
- Reporting is required!
What’s In It For Me?

• You can search reports
• Valuable tool when:
  – Considering equipment purchases
  – Troubleshooting equipment problems
**Medical Device Reporting (MDR)**

- MDR Overview
- Mandatory Medical Device Reporting Requirements
- Voluntary Medical Device Reporting
- How to Report a Medical Device Problem:
- Searching Medical Device Reports
- Contact

**MDR Overview**

Each year, the FDA receives several hundred thousand medical device reports of suspected device-associated deaths, serious injuries and malfunctions. Medical Device Reporting (MDR) is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

Mandatory reporters (i.e., manufacturers, device user facilities, and importers) are required to submit certain types of reports for adverse events and product problems to the FDA about medical devices. In addition, the FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.
MAUDE - Manufacturer and User Facility Device Experience

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

Search Database

Product Problem
Product Class
Brand Name
Manufacturer
Event Type
Date Report Received by FDA (mm/dd/yyyy)

Each year, the FDA receives several hundred thousand medical device reports (MDRs) of suspected device-associated deaths, serious injuries and malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.
## MAUDE - Manufacturer and User Facility Device Experience

500 records meeting your search criteria returned. Please narrow your search.

<table>
<thead>
<tr>
<th>New Search</th>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>Date Report Received</th>
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<tr>
<td>1</td>
<td>PHILIPS MEDICAL SYSTEMS</td>
<td>HAERTSTART MRX</td>
<td>12/13/2012</td>
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<td>2</td>
<td>PHILIPS MEDICAL SYSTEMS</td>
<td>HARTSTART MRX - EMS DEFIBRILLATOR</td>
<td>08/03/2012</td>
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<td>3</td>
<td>PHILIPS MEDICAL SYSTEMS</td>
<td>HEADSTART MRX - EMS DEFIBRILLATOR</td>
<td>12/15/2011</td>
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<td>4</td>
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<td>HEARSTART MRX</td>
<td>07/01/2010</td>
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<tr>
<td>5</td>
<td>PHILIPS HEALTHCARE - ANDOVER</td>
<td>HEARSTART MRX</td>
<td>07/01/2011</td>
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<td>6</td>
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<td>HEARSTART MRX</td>
<td>05/30/2012</td>
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<tr>
<td>7</td>
<td>PHILIPS MEDICAL SYSTEMS</td>
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<td>03/28/2012</td>
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<td>PHILIPS MEDICAL SYSTEMS</td>
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<td>PHILIPS MEDICAL SYSTEMS</td>
<td>HEARSTART MRX - EMS DEFIBRILLATOR</td>
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<td>PHILIPS MEDICAL SYSTEMS</td>
<td>HEARSTART MRX - EMS DEFIBRILLATOR</td>
<td>11/13/2013</td>
</tr>
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</table>

Event Type: Malfunction
Event Description:
The customer reported the unit failed to power up via ac or battery power.

Manufacturer Narrative:
(b)(4). The customer reported the unit failed to power up via ac or battery power. The unit was evaluated at philips and the failure was verified. The processor pca was replaced to resolve the reported issue.
MAUDE Search: MRx
What else is out there?

• We don’t always trust government…
• Two non-profit organizations watch
  – Medical devices and equipment
  – Drugs
ECRI Institute is an independent, nonprofit organization that researches the best approaches to improving the safety, quality, and cost-effectiveness of patient care.

Our unbiased, evidence-based healthcare research, information, and advice helps you:

- Assess and address patient safety, quality, and risk management challenges
- Select the safest, most effective medical devices, procedures, and drugs
- Procure healthcare technology in the most cost-effective manner
- Develop evidence-based health coverage policies
- Align capital investments with strategic technology needs
How about fire/ems data?

- Lessons learned can be extremely valuable
- Airline industry has successfully analyzed “near miss” data for years
Welcome!

Welcome to the EMS Voluntary Event Notification Tool (E.V.E.N.T.).

E.V.E.N.T. is a program of the Center for Leadership, Innovation, and Research in EMS (CLIR) with sponsorship provided by the North Central EMS Institute (NCEMS), the National EMS Management Association (NEMMSIA), the Paramedic Chiefs of Canada (PCC), the National Association of Emergency Medical Technicians (NAEMT) and the National Association of State EMS Officials (NASEMSO).

E.V.E.N.T. is a tool designed to improve the safety, quality, and consistent delivery of Emergency Medical Services (EMS). It collects data submitted anonymously by EMS practitioners. The data collected will be used to develop policies, procedures, and training programs to improve the safe delivery of EMS. A similar system used by airline pilots has led to important airline system improvements based upon pilot reported “near miss” situations and errors.

Any individual who encounters or recognizes a situation in which an EMS safety event occurred, or could have occurred, is strongly encouraged to submit a report by completing the appropriate E.V.E.N.T. Notification Tool. The confidentiality and anonymity of this reporting tool is designed to encourage EMS practitioners to readily report EMS safety events without fear of repercuasion.

We post all reported patient safety events and aggregate reports to our Google Group. If you would like to be added to the Google Group, send an email to clirems@gmail.com with your name and EMS agency or affiliation. We'll add you to the group within 2 business days.

Contact Us

Center for Leadership, Innovation and Research in EMS • P.O. Box 2286 • St. Cloud, Minnesota 56302

952.863.4426 • 320.251.8154 (fax) • Contact Us

How To Report

To make an anonymous report on an EMS incident, please click one of the following links below:

- Near Miss Event
- Patient Safety Event
- Violence Event
Not a lot of data...

**Patient Safety Event Reports Sorted Quarterly**

<table>
<thead>
<tr>
<th></th>
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<td>January - March</td>
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<td>April - June</td>
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<td>36</td>
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<tr>
<td>July - September</td>
<td>13</td>
<td>41</td>
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<tr>
<td>October - December</td>
<td>6</td>
<td>27</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>34</strong></td>
<td><strong>131</strong></td>
</tr>
</tbody>
</table>
Limited sources...
firefighternearmiss.com
Summary

Reporting equipment failures is a moral and ethical imperative you owe to your patients, the manufacturing industry, regulators, and your EMS brothers and sisters.

www.mikemcevoy.com