My AED Exploded: Reporting Equipment Issues

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Resuscitation Committee Chair – Albany Medical Center
www.mikemcevoy.com

Disclosures

- None
- I don’t know how to play golf or ski

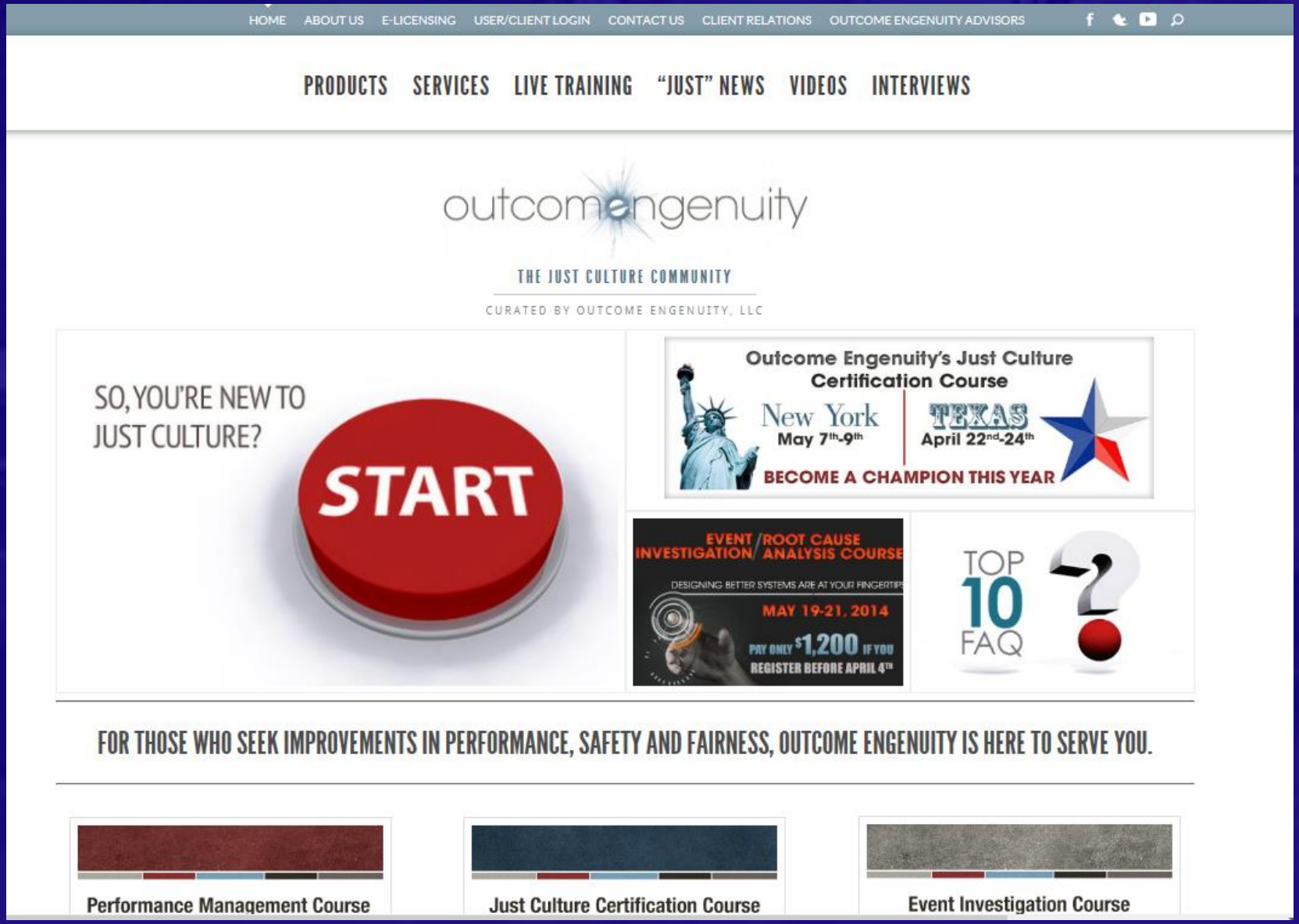
www.mikemcevoy.com

When I am not Fighting Fires, I am reading

Outline

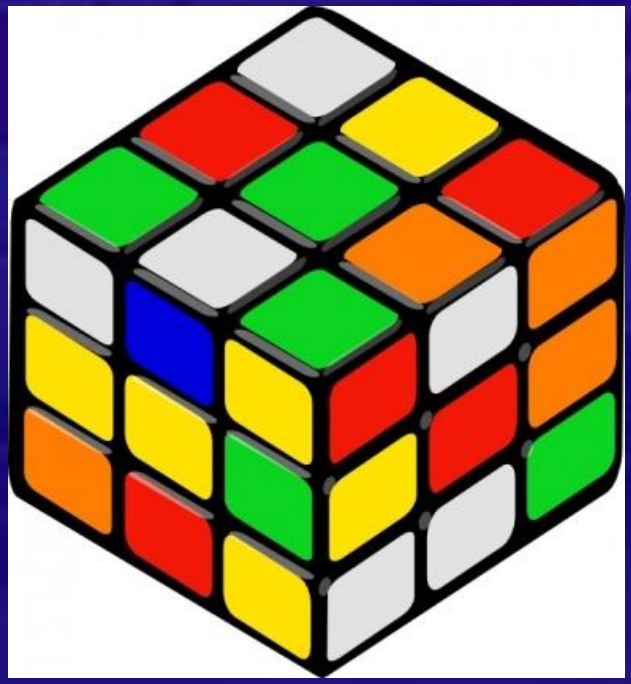
- What can go wrong, will go wrong
- Expectations
- Requirements
- Responsibilities
- Benefiting from others problems

www.justculture.org



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:

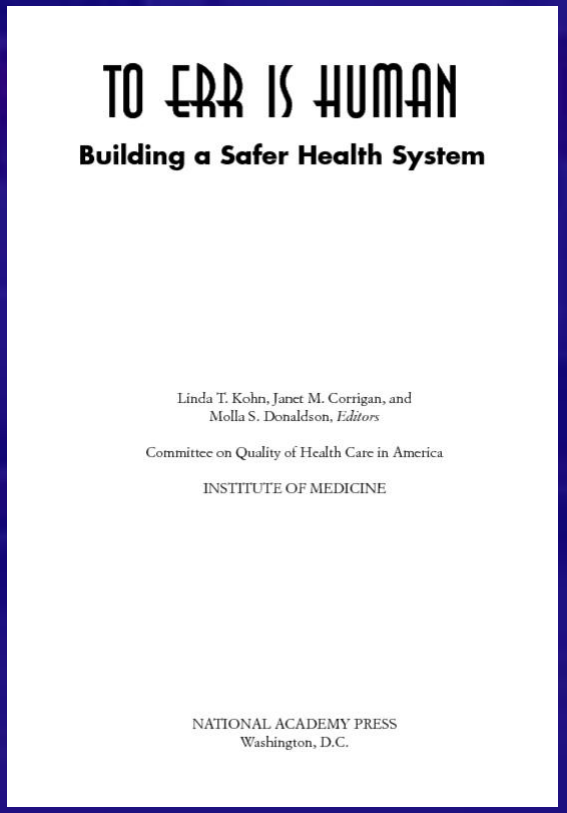
- Driving
- Chemical manufacturing

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

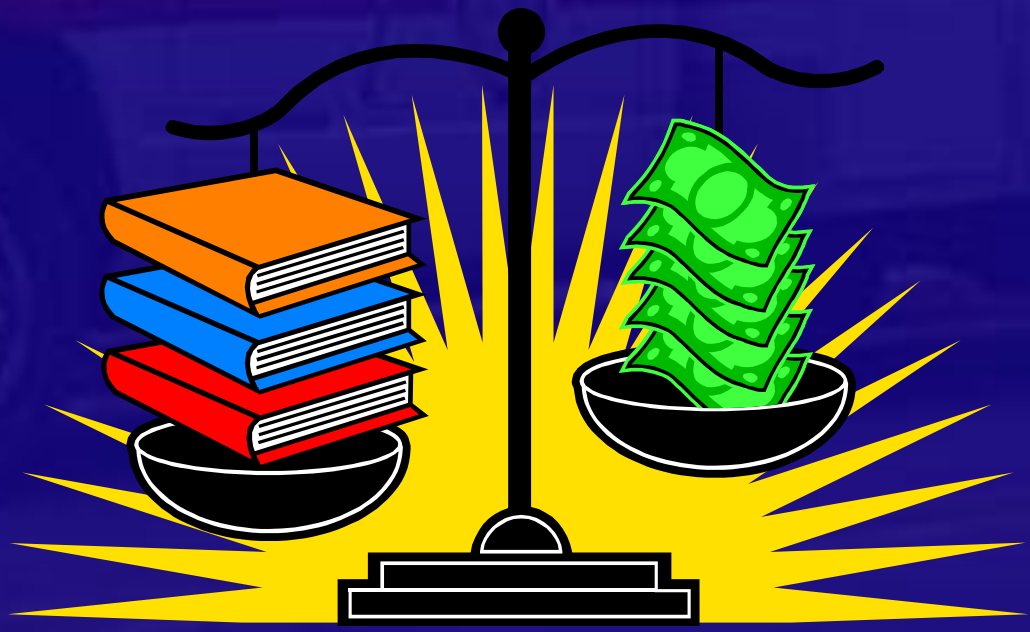


EMS Lawsuits

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

-Wolfberg D. *Emerg Med Svces*. 2005 Jan;34:42-43

-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

Wang HE, Fairbanks RJ, Shah MN, Yealy DM. *Tort Claims from Adverse Events in Emergency Medical Services*. Prehospital Emergency Care. 2008; 52(3):256-262.

Buffalo, NY Feb 2014

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."

Chicago, Feb 2014

Fatal Fall From Chicago FD Gurney Expected to Result in $300K Settlement

EMSWORLD.COM NEWS

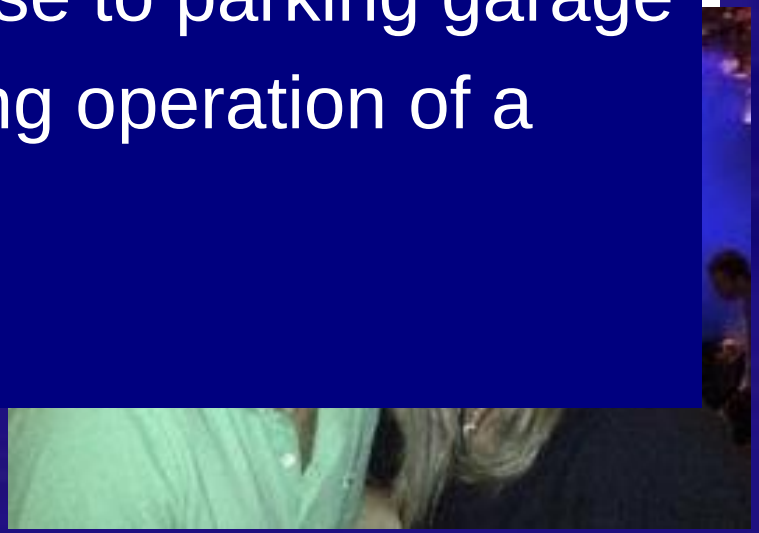
Chicago Fire Department policy requires that two people push gurneys -- one at the head of the patient and the other at the feet -- to provide stability.

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.

Newark, NJ Mar 2014

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

Total Crashes = 4,745	Killed = 31	Injured = 3,351
Driver	0	759
Passenger	8	671
OMV	21	1,921
Pedestrian	2	-

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

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Briefly describe your legal issue here.

I have read the disclaimer.
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SUBMIT

AREAS & TOPICS

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

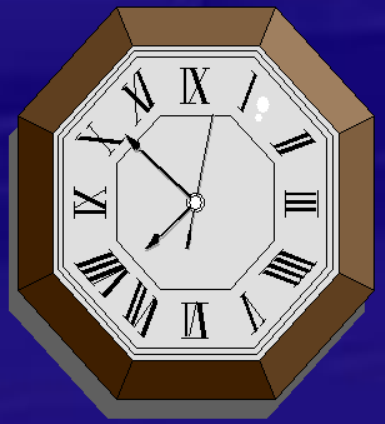
Guarantee dropped because of, "public perception of reckless driving and irresponsibility."

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



Newgard CD, et al. Emergency Medical Services Intervals and Survival in Trauma: Assessment of the "Golden Hour" in a North American Prospective Cohort. *Ann Emer Med.* 2010; 55(3): 235-260

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)

Taigman M. Sterling Sarasota. JEMS. 1998; Jul - 23(7):44-55.

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

Report What?	To Whom?	When?
Deaths	FDA and manufacturer	Within 10 work days
Serious Injuries	Manufacturer (FDA only if manufacturer unknown)	Within 10 work days
Summary of deaths and serious injures	FDA	Annually (if any)

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)

Report What?	To Whom?	When?
Deaths	FDA and manufacturer	Within 10 work days
Serious Injuries	Manufacturer (FDA only if manufacturer unknown)	Within 10 work days
Summary of deaths and serious injures	FDA	Annually (if any)

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

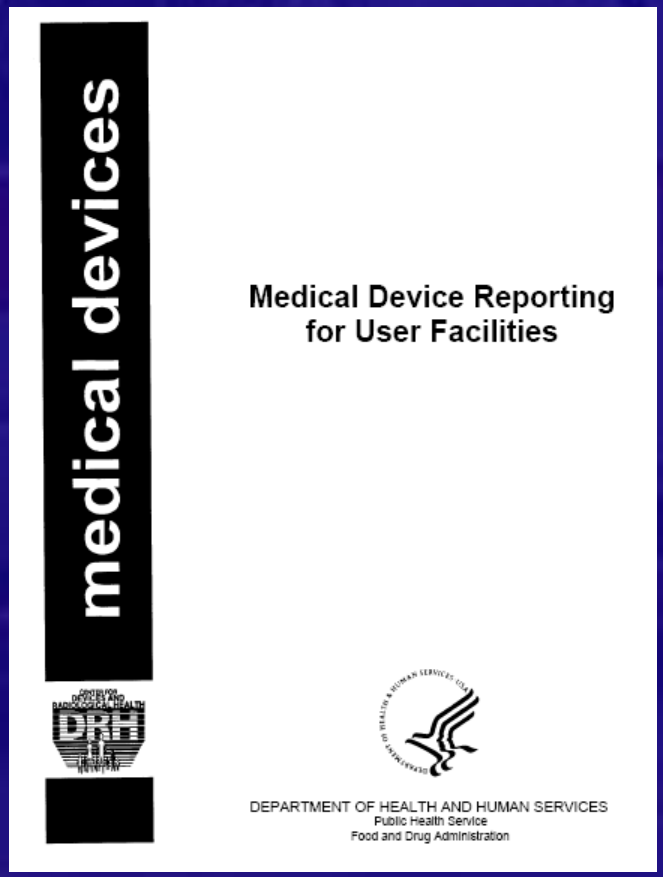
  PO Box 3002

  Rockville MD 20847-3002

Guide Available

www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095266.pdf

(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

www.fda.gov

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Cheese Products Linked to Listeriosis Outbreak
FDA suspends Roos Foods facility registration, prohibits food distribution.

1 2 3

For Consumers & Patients
Updates and information for staying safe and healthy

For Health Professionals
Medical product safety information, adverse event/problem reporting and more

For Scientists & Researchers
NCTR, pediatrics, clinical trials, Critical Path Initiative and more

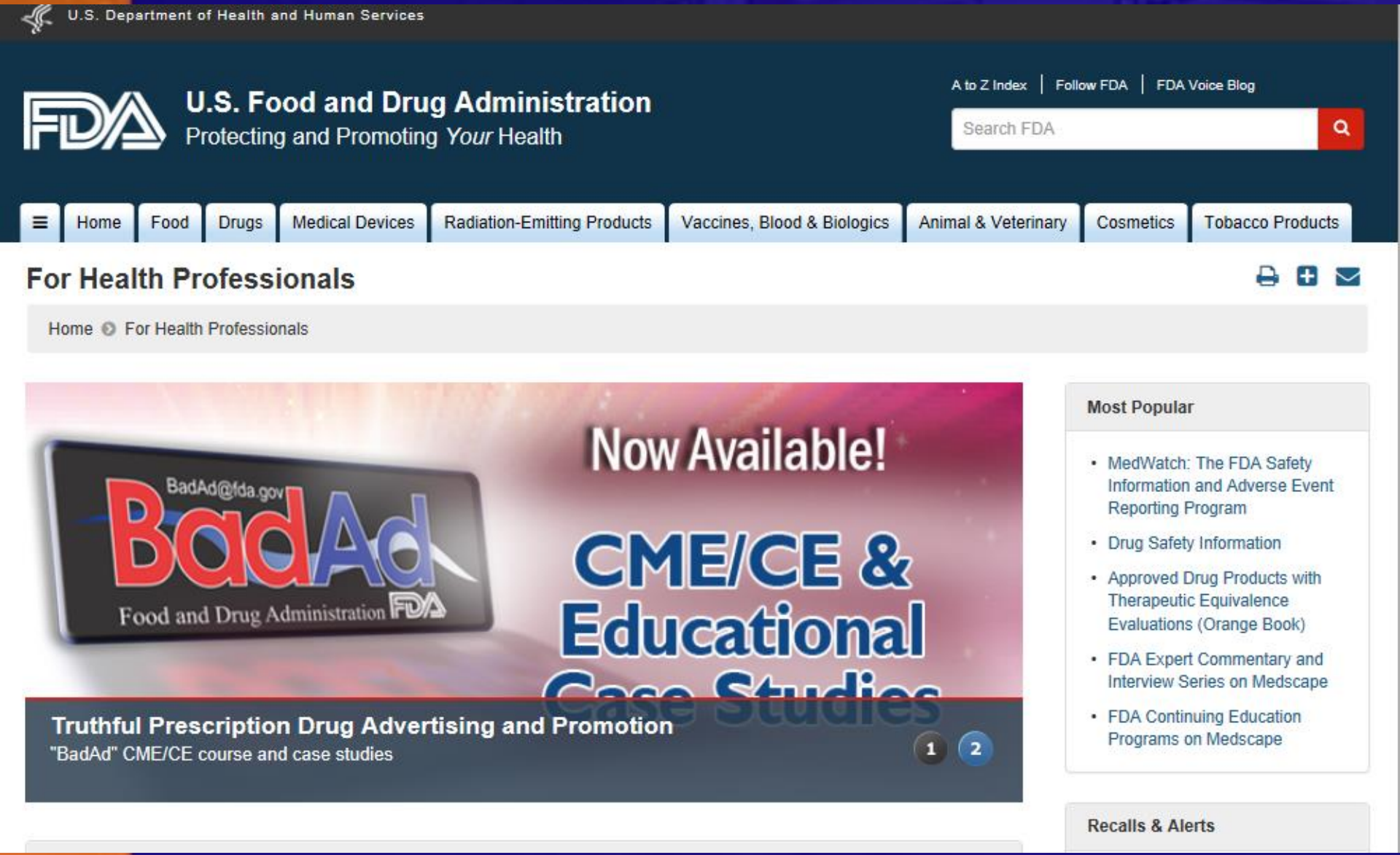
For Industry
Guidance, registration and listing, import programs and more

Recalls & Alerts | Approvals & Clearances | Report a Problem

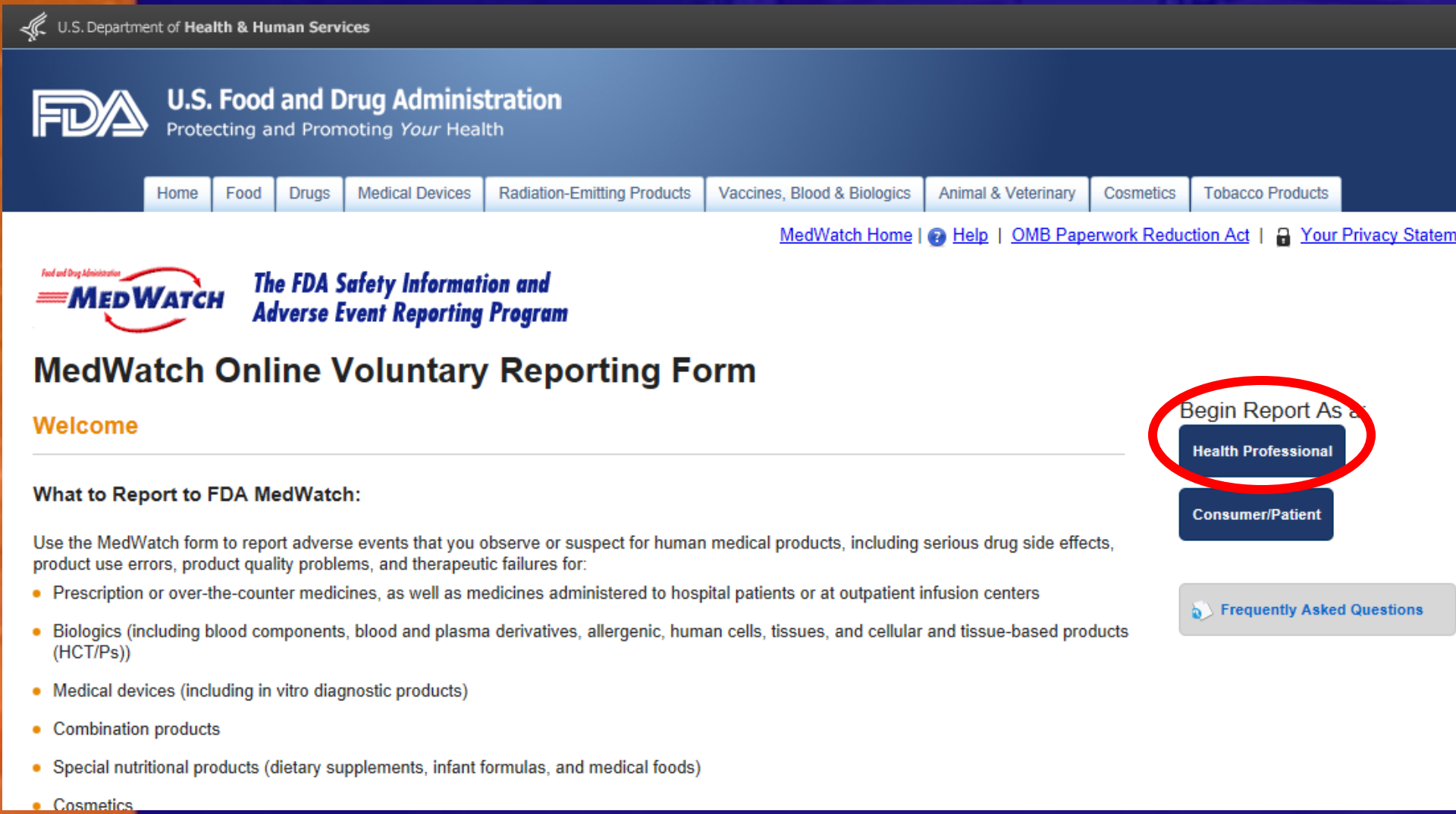
- Recalls
- MedWatch: Safety Alerts
- Enforcement Report
- Industry Recall Guidance
- Warning Letters
- Outbreaks - Food

FDA Voice Blog

For Health Professionals



MedWatch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MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
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


NEW YORK STATE EMERGENCY MEDICAL SERVICES

DOH

New York State
Department of Health
Bureau of Emergency Medical Services

POLICY STATEMENT

No. 98-11

Date 9/01/98

Re: EMS Service Incident Reporting Requirements

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.

Name of EMS Service _____ NYS EMS Agency Code _____

Address _____

City _____ State _____ ZIP _____ County _____

Name of Contact Person and Title _____

Business Phone (_____) _____ Other Phone (_____) _____

FORM DIRECTIONS

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

Why Reporting?

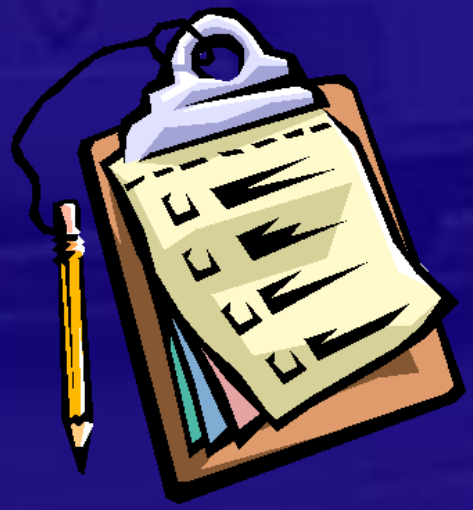
- May 2004, Clifton Park – Halfmoon paramedics shock patient in cardiac arrest; ROSC achieved
- During packaging, patient arrests again (v-fib)
- Charging monitor-defib, screen went blank then displayed message: “Bridge Test Failed”
- Second monitor used to treat patient

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

MDR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MedWatcher Mobile App
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


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MAUDE - Manufacturer and User Facility Device Experience
The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters [1] (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.
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Product Class
Brand Name
510K Number
K
Manufacturer
PMA Number
P
Event Type
Product Code
Date Report Received by FDA (mm/dd/yyyy)
01/01/2014
to
02/28/2014
Go to Simple Search
10
Records per Report Page
Clear Form
Search
Other Databases
510(k)s
Adverse Events (MAUDE)
CDRH FOIA Electronic Reading Room
CFR Title 21
CLIA
Device Classification
Inspections
Medsun Reports
Premarket Approvals (PMAs)
Post-Approval Studies
Postmarket Surveillance Studies
Radiation-Emitting Products
Radiation-Emitting Electronic Products Corrective Actions
Recalls
Registration & Listing
Standards
Total Product Life Cycle
X-Ray Assembler
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 [1] (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

MRx: 1/1/2010 – 2/28/2014

MAUDE - Manufacturer and User Facility Device Experience

FDA Home ▸ Medical Devices ▸ Databases

1 2 3 4 5 6 7 8 9 10 >

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

New Search | Help | Download Files | More about MAUDE

Manufacturer	Brand Name	Date Report Received
PHILIPS MEDICAL SYSTEMS	HAERTSTART MRX	12/13/2012
PHILIPS MEDICAL SYSTEMS	HARTSTART MRX - EMS DEFIBRILLATOR	08/03/2012
PHILIPS MEDICAL SYSTEMS	HEADSTART MRX -EMS DEFIBRILLATOR	12/15/2011
PHILIPS MEDICAL SYSTEMS	HEARSTART MRX	07/01/2010
PHILIPS HEALTHCARE - ANDOVER	HEARSTART MRX	07/01/2011
PHILIPS MEDICAL SYSTEMS	HEARSTART MRX	05/30/2012
PHILIPS MEDICAL SYSTEMS-DUP	HEARSTART MRX - EMS DEFIBRILLATOR	03/28/2012
PHILIPS MEDICAL SYSTEMS	HEARSTART MRX - EMS DEFIBRILLATOR	06/13/2012
PHILIPS MEDICAL SYSTEMS	HEARSTART MRX - EMS DEFIBRILLATOR	12/18/2012
PHILIPS MEDICAL SYSTEMS	HEARSTART MRX -EMS DEFIBRILLATOR	11/13/2013

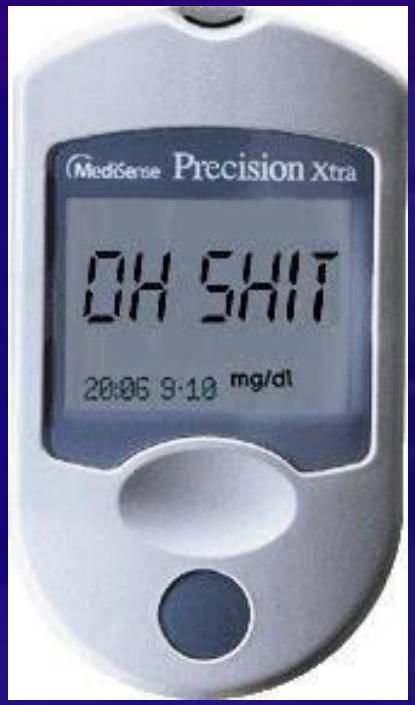
MAUDE Search: MRx

MAUDE Search: MRx

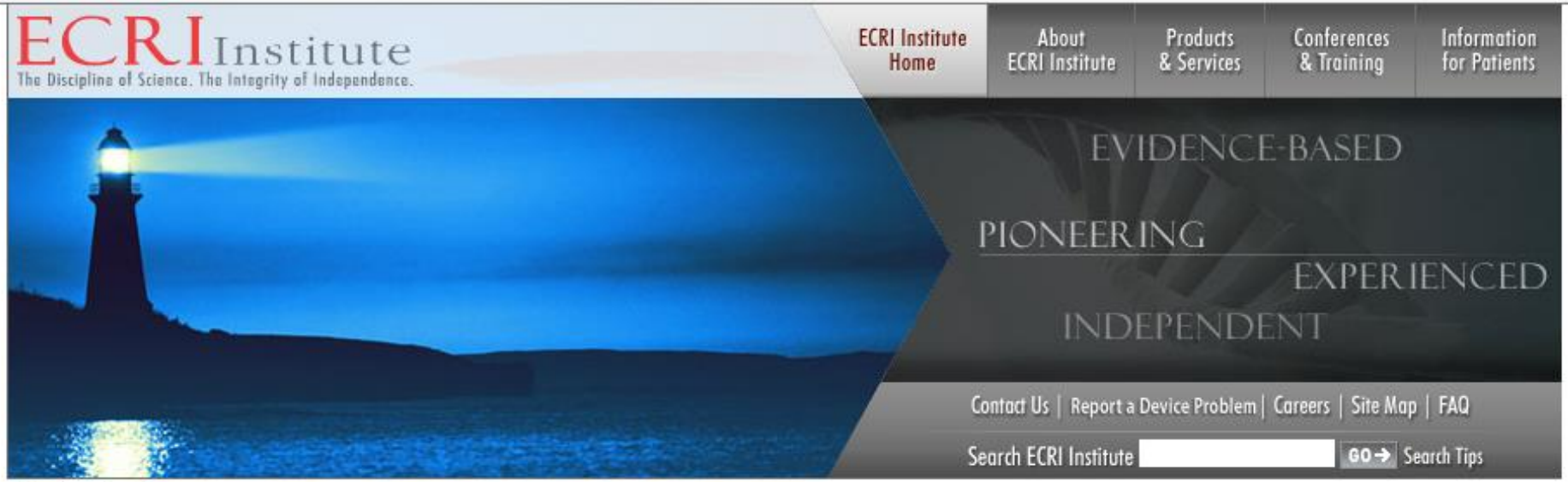
Event Type Malfunction
Event Description
The customer reported the display was blank.
Manufacturer Narrative
The customer reported the display was blank. The unit was evaluated at philips, and the reported symptom was duplicated. Replacing the power pca resolved the reported issue.

What else is out there?

- We don't always trust government…
- Two non-profit organizations watch
  - Medical devices and equipment
  - Drugs



www.ecri.org



Member Login

User Name (Email address)

Password

LOGIN →

Remember me on this computer (Not recommended for shared computers.)

Forgot Password?

Not a Member Yet?

- See our products and services
- Have a membership specialist contact you

ECRI Institute

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

Hot Topic Resources

- 2014 C-Suite Watch List
- 2014 Top 10 Health Technology Hazards
- Alarm Management
- Big Data in Healthcare
- BRCA Gene Mutation
- CT Radiation Safety
- Health IT
- Patient Safety Organization

www.ismp.org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Institute for Safe Medication Practices
A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices
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2014-15
Targeted Medication Safety Best Practices for Hospitals
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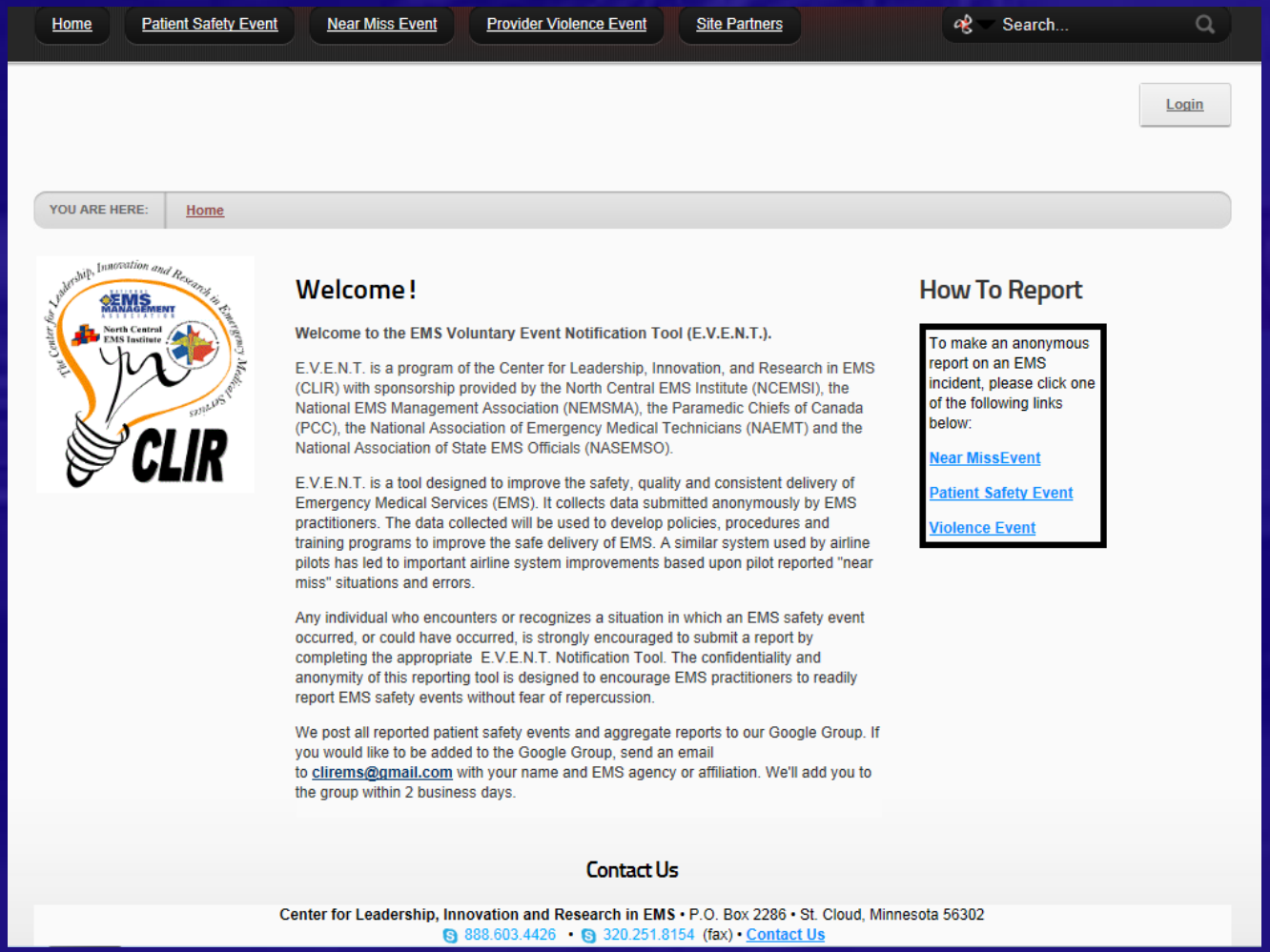
2014
Medication Safety Intensive
April 10 and 11, 2014
Washington, DC
May 30 and 31, 2014
Las Vegas, NV
October 2 and 3, 2014
Nashville, TN
Education & Awareness
Newsletters
Consulting Services
Educational Programs
Let ISMP be your PSO
Professional Development
Self Assessments
Consumers
Medication Safety Tools & Resources
Featured Tools
New standards for healthcare connectors – the "Stay Connected" program"
The Root Cause Analysis Workbook for Community/ Ambulatory Pharmacy
Report Medication Errors or Safety Concerns
FREE
Research-based Medication Safety Tools
Consumer medication leaflets
Risk-reduction scorecards software
Bar-coding readiness assessment

How about fire/ems data?

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

http://event.clirems.org

E.V.E.N.T. Reporting (NAEMT)



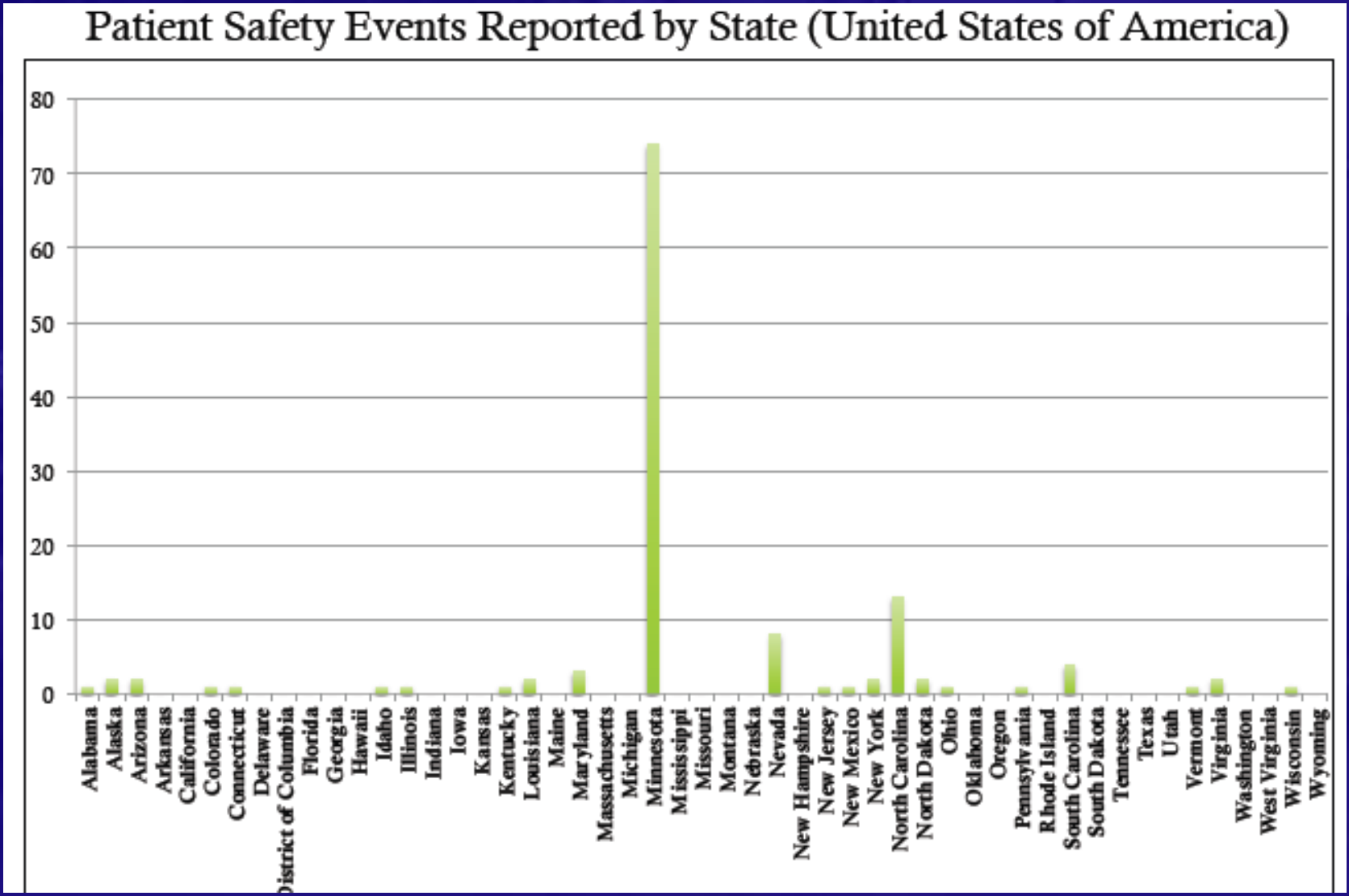
Not a lot of data…

E.V.E.N.T. EMS Patient Safety Event Report

Patient Safety Event Reports Sorted Quarterly

	2012	2013	
January - March	6	27	
April - June	9	36	
July - September	13	41	
October - December	6	27	
Total	34	131	

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