



PICKING UP THE PIECES:

**How to Investigate and Document
after an Incident Occurs**

Paul A. Bishop, Paramedic

TOPICS OF CONVERSATION

- What is an “Incident”?
- Conducting an investigation
- Describe the documentation
- Learn from the incident
- Follow a case study



WHAT IS AN INCIDENT?

- NYS DOH Bureau of EMS
- NYS Department of Motor Vehicles
- NYS Office of Child and Family Services
- Food and Drug Administration
- Agency and Regional requirements



NEW YORK STATE EMS INCIDENT

- 800.21.(q) upon discovery by or report to the governing authority of the ambulance service, report to the Department's Area Office by telephone no later than the following business day and in writing within 5 working days every instance in which:
 - (1) a patient dies, is injured or otherwise harmed due to actions of commission or omission by a member of the ambulance service;
 - (2) an EMS response vehicle operated by the service is involved in a motor vehicle crash in which a patient, member of the crew or other person is killed or injured to the extent requiring hospitalization or care by a physician;
 - (3) any member of the ambulance service is killed or injured to the extent requiring hospitalization or care by a physician while on duty;
 - (4) patient care equipment fails while in use, causing patient harm;
 - (5) it is alleged that any member of the ambulance service has responded to an incident or treated a patient while under the influence of alcohol or drugs while on duty.
- (r) on or in a form approved by the department, maintain a record of all unexpected authorized EMS response vehicle and patient care equipment failures that could have resulted in harm to a patient and the corrective actions taken. A copy of this record shall be submitted to the department with the EMS service's biennial recertification application.





Department of Motor Vehicles

Accidents

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If You Have an Accident

If you are in an accident, you are **required** by the NYS Vehicle and Traffic Law to stop and exchange information with the involved drivers. If the accident caused property damage only, then exchange information about your driver license, insurance, and registration with the involved drivers. If a parked vehicle or other property is damaged, or if a domestic animal is injured, you must locate the owner or contact the police.

- If the **property damage** of any person is **\$1,001 or more**, **all the involved drivers are required by the NYS Vehicle and Traffic Law to file form MV-104** (Report of Motor Vehicle Accident). File form *MV-104* with the DMV no more than 10 days after the accident. **The DMV can suspend your driver license if you fail to report an accident.**
- **If a person is injured or killed, you are required by the NYS Vehicle and Traffic Law to immediately notify the police. All the involved drivers *and* the police must file an accident report with the DMV. It is a crime to leave the scene of an accident that causes personal injury or death.**
- The **accident** appears on the records of **all** the involved drivers. An accident listed on your driver record **does not** indicate that you were at fault. The DMV does not try to determine fault in an accident.



OFFICE OF CHILD AND FAMILY SERVICES

- EMTs (all levels) are required to report suspected abuse or maltreatment of children
- Nysmandatedreporter.org is a 2 hour long, web based training that covers all aspects of the law and requirement.
- BEMS Policy Statement 02-01 gives EMS specific guidance on this issue



REPORTING EVENTS TO MEDWATCH



FDA MEDWATCH

- **Required to report a serious adverse event to the FDA.**
- **What is a Serious Adverse Event?**
 - **Death**
 - **Life-threatening**
 - **Hospitalization (initial or prolonged)**
 - **Disability or Permanent Damage**
 - **Congenital Anomaly/Birth Defect**
 - **Required Intervention to Prevent Permanent Impairment or Damage (Devices)**
 - **Other Serious (Important Medical Events)**





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LIFEPAK 15 Monitor/Defibrillator by Physio-Control Inc.

Audience: Emergency medical personnel, consumers

[Posted 04/22/2010] FDA notified healthcare professionals of a Class I recall of LIFEPAK 15 Monitor/Defibrillator manufactured and distributed between March 26, 2009 and December 15, 2009. There is a potential for the device to unexpectedly:

- Power Off then On by itself.
- Power Off then NOT turn On.
- Power Off by itself requiring the operator to turn it back On.
- Stay powered On and not allow itself to be turned Off.

Healthcare professionals are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Online: www.fda.gov/MedWatch/report.htm
- Phone: 1-800-332-1088
- Mail: return the postage-paid FDA form 3500, which may be downloaded from the MedWatch "[Download Forms](#)" page, to address on the pre-addressed form
- Fax: 1-800-FDA-0178

[04/22/2010 - [Recall Notice](#)- FDA]



**ZOLL Medical Corporation
Worldwide Headquarters**

269 Mill Road
Chelmsford, Massachusetts 01824-4105
U.S.A.

(800) 348-9011

Urgent Medical Device Correction Follow-Up Notification

**AED Plus Defibrillator
Serial Numbers below X__ _200000**

ZOLL AED Plus Defibrillator May Not Deliver Defibrillation Shock

March 31, 2009

Dear valued customer,

You should have received a letter from ZOLL dated February 12, 2009, notifying you of a potential problem with ZOLL AED Plus Defibrillators below "X__ _200000". Some batteries do not work properly when used with the





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Philips Heartstart Fr2+ Automated External Defibrillators - Recall

Audience: Fire departments, emergency medical services personnel, hospitals

[Posted 10/05/2009] Philips and FDA notified healthcare professionals of the recall of 5,400 HeartStart FR2+ automated external defibrillators (AED) due to reports of a memory chip failure which could render the AED inoperable and prevent it from delivering therapy when indicated. The AEDs are used by trained responders and designated response teams to help treat sudden cardiac arrest.

The recalled units (models M3860A and M3861A, distributed by Philips; and models M3840A and M3841A, distributed by Laerdal Medical) were manufactured between May, 2007 and January, 2008. Philips is contacting customers to arrange for the return and replacement of all the recalled AEDs and set up a page on the Philips Web site -- www.philips.com/FR2PlusAction -- with a serial number look-up tool to allow customers to find out if their FR2+ is part of this recall, as well as instructions on what to do if it is.

[09/28/2009 - [Press Release](#) - Philips Healthcare]



CONDUCTING AN INVESTIGATION

- Subjective information
 - Independent first person statements- written and oral
 - Consider two interviewers
- Objective information
 - Times
 - Photos of scene
 - Measurements
 - Others
 - Be methodical in assessing the scene
- Information should be gathered as soon as possible after the event
- Other resources
 - Law Enforcement
 - Insurance Carrier



CREATING A DOCUMENT -SOAPIE

- **S**ubjective –
 - what the people involved said and wrote regarding the event
- **O**bjective –
 - The objective findings that were discovered during the investigation
- **A**ssessment - The conclusions based on the information that has been provided. Focus on the facts. Cite specific policy or protocol violations that come to light in the investigation.



CREATING A DOCUMENT -SOAPIE

- **Plan of correction –**
 - How was the incident resolved?
 - Were steps taken to reduce the likelihood that it will reoccur?
The plan may not be created during the initial writing as it may involve supervision or management.
 - Particular steps for the resolution and measurements for those steps should be included.
- **Intervention –**
 - How is the plan carried out is it modified or not done because the situation resolved itself?
- **Evaluation-**
 - Did the plan have the intended impact?
 - Did the measurements show that the intervention was a success or will there be additional steps that will need to be taken?



PLAN OF RESOLUTION AND INTERVENTION

- Bring in outside or objective eyes to help review the event to see if it could be prevented or mitigated in the future
- Use a “just culture” when generating a response to the event.
- Focus on finding the possible causes
- Look to provide solutions, not punishments
 - Engineering solutions are more successful than human solutions
 - Policy and Education require diligence for them to have a long term effect



THE SYSTEMS APPROACH

“Most serious medical errors are committed by competent, caring people doing what other competent, caring people would do.”

-Donald M. Berwick, MD

- Not just about the people
- About the design
- System, medical devices, procedures
- Design out the opportunity for harm
- Requires anticipation of “error” (hazards)



HUMAN ERROR

- Human Error cannot be eliminated
- Futile goal; misdirects Resources/focus
- Causes culture of blame and secrecy
 - “name, blame, and train” mentality
- It is about reducing HARM, not ERROR
- “Name, Blame, and Train” atmosphere:
 - discourages openness
 - Reduces ability to learn from experiences of others



Just Culture

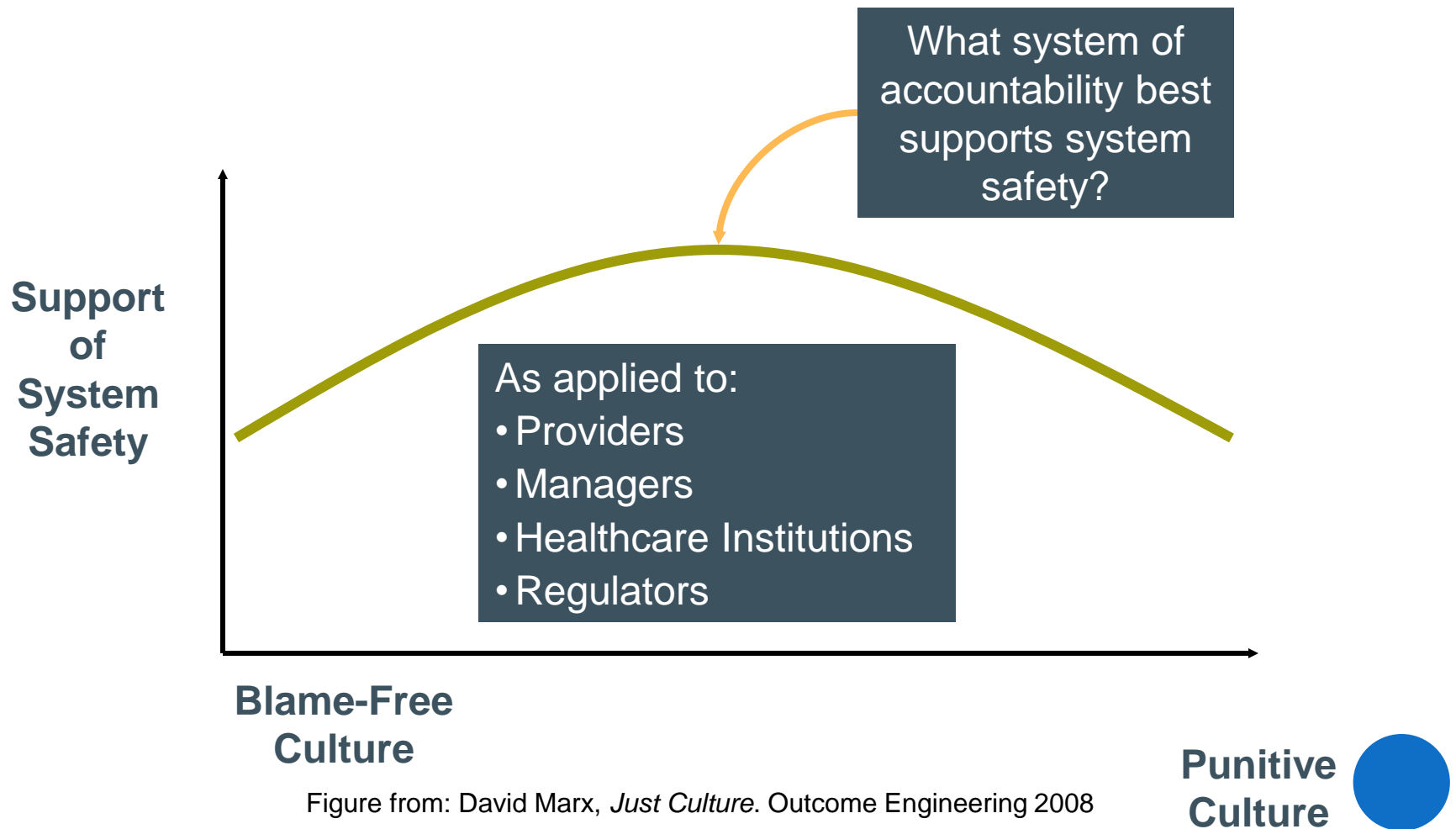
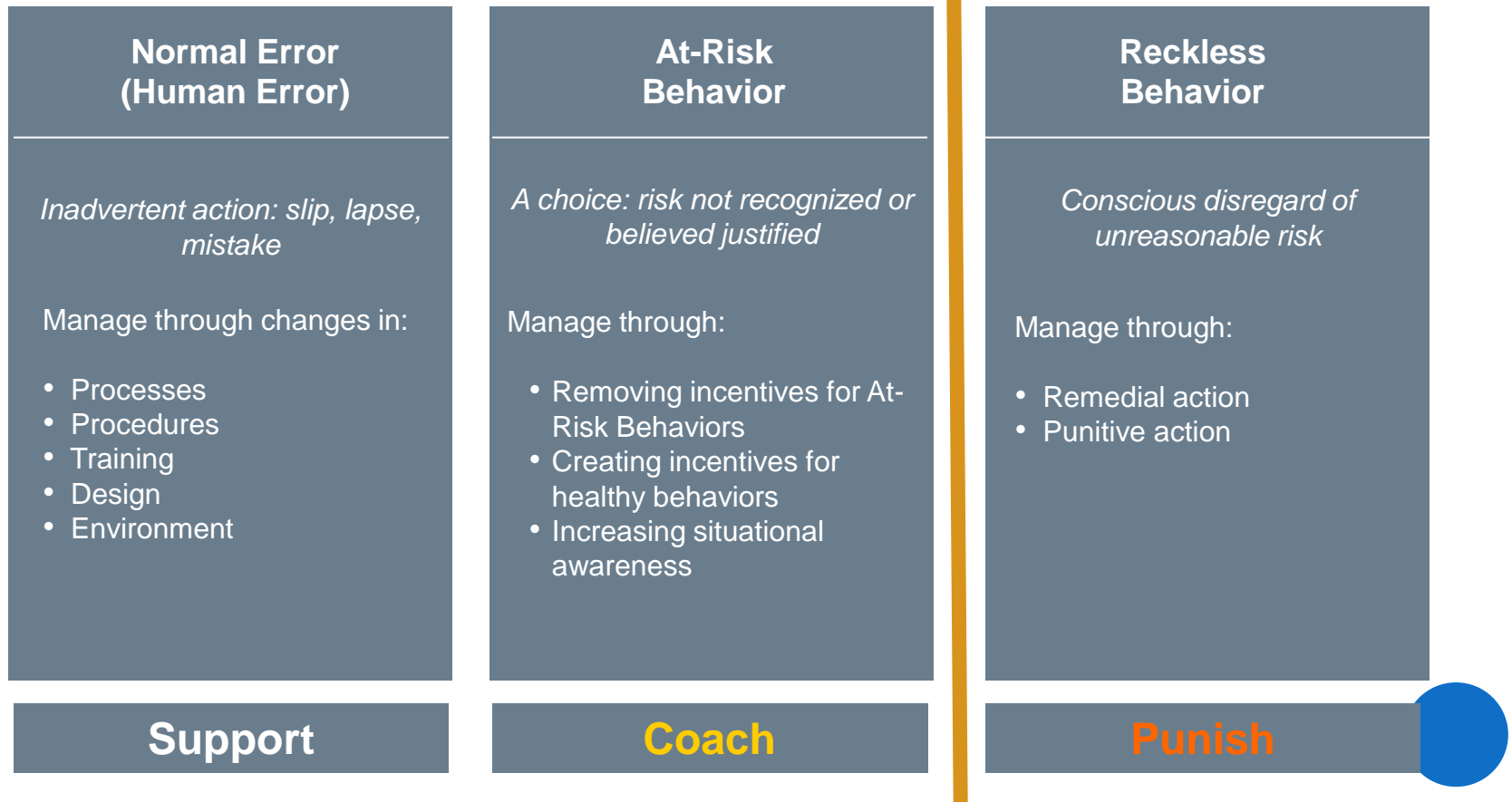


Figure from: David Marx, *Just Culture*. Outcome Engineering 2008

Just Culture: The Three Behaviors



From: David Marx, *Just Culture*. Outcome Engineering 2008

CASE STUDY: GRAVITY STORM

- 2100 on a typical Saturday night
- Ambulance responds with ALS for chest pains
- 2145 – Request from the scene for an additional ambulance and additional personnel to the scene for an injury
- 2215 – Call from the Jill – the driver on the first ambulance from the hospital
 - Moving patient from house to rig and stretcher tipped
 - Patient injured arm and head in addition to chest pain
 - Jack, the medic, injured his shoulder and upper back while trying to keep stretcher up



HOW WILL YOU INVESTIGATE?

- Gather Subjective Information
 - Statements from crew, patient and witnesses
- Gather Objective Information
 - Timeline
 - Photo the scene
 - Patient diagnosis
 - Inspect the stretcher (out of service)
 - Maintenance logs for equipment



WHAT IS THE ASSESSMENT AND PLAN ?

- What could have been done to prevent the situation?
- What should the corrective plan be?
- How will it be measured?



CONCLUSION

- Incidents impact EMS on a regular basis and provide an opportunity to improve
- Incidents must be reported to the appropriate organization
- EMS Assessment skills and the SOAPIE format can be used for incident reporting
- Use mandated forms if necessary
- Create a culture of improvement not punishment

