	SOUTHERN FOX VALLEY EMERGENCY MEDICAL SERVICES SYSTEM POLICY & PROCEDURES
TITLE: INCIDENT/SENTINEL/EQUIPMENT MALFUNCTION REPORTING	
SECTION: GENERAL	POLICY NUMBER: D-5.0
APPROVED BY: DR. ARTHUR PROUST EMS MEDICAL DIRECTOR	
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PURPOSE:

To define the Southern Fox Valley EMS System policy on reporting medical device issues in which a device may have caused or contributed to the death or serious injury of a patient, identifying an event that may have had an adverse effect of medical care.

POLICY:

1) An EMS incident or event that resulted in a higher-than-normal degree of risk to a patient, bystanders, or EMS personnel and/or a preventable adverse effect of medical care, whether or not it is evident or harmful to the patient shall be reported in a timely manner to the EMS System Coordinator and/or EMS System Medical Director and EMS agency senior leadership or their designee.

2) The purpose of reporting and the subsequent EMS medical review is to improve patient safety and the quality of care.

3) Review of these incidents is conducted under continuous quality management principles using the EMS Quality Assurance. All findings are confidential under the Medical Studies Act. All information contained in or relating to any medical audit performed by the EMS MD (or his designee) or care rendered by System personnel, shall be afforded the same status as is provided information concerning medical studies in Article VIII, Part 21 of the Code of Civil Procedure.

4) Reportable incidents (events) include, but are not limited to

    a) Clinical acts or omissions are inconsistent with policy, procedure, or SOP that may have contributed to adverse patient outcome. This could include the following:

        i) Medication errors: "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer," (National Coordinating Council for Medication Error Reporting and Prevention).

ii) Any act by an EMS practitioner which is or may be below the applicable standard of care has a reasonable probability of causing patient harm.
iii) Injuries to a patient while in EMS care not ordinarily expected as a result of the patient's condition.
iv) Inappropriate use of a device that results in injury or death of a patient while in EMS care.

v) EMS practitioners acting outside of their scope of practice.

b) Any act or omission by EMS personnel while caring for a patient that constitutes a threat to public health or safety.

c) Suspected impairment of an on-duty EMS practitioner due to use of intoxicants (alcohol or drugs)

d) Medical, EMS system or communications failure, or equipment failure or user error resulting in injury or delay in response or treatment.

i) Crash, fire in an EMS vehicle, or malfunction of an EMS vehicle while transporting a patient that resulted in a delay of patient transport to an appropriate hospital or patient injury/death.

e) Override of on-line medical control to Resource Hospital

f) Suspected significant exposure to the blood or body fluids of a patient experienced by EMS personnel

g) Death of a patient under unusual circumstances.

h) Scene times that are prolonged longer than 60 minutes due to behavioral health emergencies or dissent to assessment, care, or transportation.

i) Care of patients during incidents with high profile news coverage (email only); incidents that resulted in concerns related to team (EMS and/or receiving hospital) readiness, resources, communication, or patient/family engagement that resulted in conflict or the need for additional law enforcement assistance.

j) Any injury incurred by a student or educator resulting from participation in a System-conducted education program, occurring either on class site premises or off premises at a System conducted structured learning experience, including travel to or from the off-premises site, and that requires treatment by a licensed healthcare practitioner.

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k) Any device or piece of medical equipment which may have caused or contributed to the death or serious injury of a patient.

PROCEDURE

1) Each EMS agency shall assign oversight of these issues to a designated officer or supervisor and work collaboratively with the EMS System Coordinator or their designee.
2) Each EMS agency shall have and follow internal policies and procedures to ensure that it is compliant with all applicable EMS System, municipal, county, state and federal statutes, rules and guidelines to mitigate risk and/or liability.

3) In the event of a reportable incident or occurrence, notification must be made as soon as patient care needs are addressed to the agency-appointed supervisor or officer. If the event involves a malfunctioning vehicle while transporting a patient, the on-duty supervisor must be notified immediately so patient care is not compromised or delayed.

4) The designated officer and/or on-duty supervisor shall determine whether it meets the criteria for a reportable incident based on this or other referenced System policies. If yes, they shall contact the EMS System Coordinator and/or System Medical Director or their designee. If patient care related, they shall also notify the receiving hospital EMS Coordinator (within the System) to assist in the investigation and report.

5) EMS agencies shall work with EMS System Coordinator or their designee to complete an investigation.

6) EMS agencies shall follow internal policies with respect to

   a) biohazard or hazmat incident with EMS personnel or equipment involved that causes hazard to patient or personnel.

   b) any incident that may be newsworthy.

7) Any System member may directly contact the Resource Hospital EMS System Coordinator and/or EMS System Medical Director if they question the timeliness or effectiveness of action at the EMS Agency/hospital and believe that failure to report or take appropriate action is placing patients and/or any element or member of the System at risk. The System shall not disclose the name of the complainant unless the complainant consents in writing to the disclosure.

8) **Medical Device Equipment Malfunction/Failure During Patient Care**

   a) Actions at Time of Malfunction:
   i) Attend to the medical needs of the patient, removing them from the area if necessary ii) Immediately remove the device from service. Preserve the device precisely as it was being used

at the time of the malfunction/failure, including attachments and/or disposable items. Do not change any settings or disconnect any attachments. Save all parts if an item breaks into pieces.

iii) Contact your immediate supervisor as soon as patient care is completed. If a death or injury occurred, immediately notify the EMS System Coordinator and/or the EMS Medical Director.

b) Documentation Requirements

i) Document objective, pertinent information regarding the patient's condition, description of the event and medical interventions taken in the Patient Care Report.

ii) DO NOT make any reference to the fact that Medical Device Failure Form was completed in the Patient Care Report. iii) DO NOT make any judgments or conclusion regarding the cause of the occurrence in the Patient Care Report.

iv) As soon as patient care is appropriately transferred to the receiving hospital, fill out a SOUTHERN FOX VALLEY INCIDENT FORM. Be as specific as possible, noting the following information:

(1) The name of the device.
(2) The manufacturer of the device, if known.
(3) The model number of the device.
(4) The lot and serial number of the device.
(5) The location in which the device was being used.
(6) The settings or modes operative at the time of the event.
(7) Patient information such as name, age, gender, estimated weight, presumptive diagnosis, status pre-event, status post-event, procedure being performed at the time of the event.
(8) If a pre-hospital worker was injured, list the name, age, gender, status pre-event, and status post-event.
(9) Narrative description of the event, including how the device contributed to the event.
(10) Description of the medical intervention(s) taken as a result of the event.
(11) Forward the completed "Medical Device Malfunction" form to your supervisor and simultaneously email a copy to the CDHEMSS System Coordinator.

c) Evaluation

i) The manufacturer's product specifications, the product's preventive maintenance records and repair records shall be available for review during the investigation.

ii) If the device is maintained under a service agreement, sequester the defective device and perform your investigation. Contact the manufacturer's representative or contracted agency to perform their inspection while maintaining the device within your jurisdiction. iii) A thorough inspection of the device shall be completed in accordance with the manufacturer's specifications, documented and presented to the Resource Hospital EMS Office. If deemed necessary, photographs shall be taken of the device.

iv) The Resource Hospital EMS Office will complete a thorough investigation of the occurrence, interviewing all crew members present at the time of the incident and the patient, if necessary.

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v) Within 24 hours of the occurrence, preliminary inspection report must be provided to the EMS Medical Director.
vi) Only upon notice from the EMS Medical Director shall the device be returned to service.

d) FDA Reporting
   i) Upon review of the incident, if there is suspicion that the medical device caused or contributed to a patient or healthcare worker's death or resulted in serious injury or illness, a report will be submitted to the FDA and/or product manufacturer by the EMS Agency, with assistance from the Resource Hospital EMS Office.
   ii) These reports are to be filed as soon as practical, but no later than 10 working days after the provider becomes aware of the information. A provider "becomes aware" when prehospital care providers or employees obtain such information about a reportable event.
   iii) Assistance in completing FDA form 3500 A will be provided to the EMS Agency by the EMS Resource Hospital EMS Staff.
   iv) If there is any dispute regarding the cause of the equipment failure or malfunction, a review panel (comprised of at least the crew members present at the time of the occurrence, the Fire Chief or his designee, the EMS Medical Director and if necessary, a biomedical engineer) will meet to review the details of the occurrence and make a determination if the medical device caused or contributed to a patient's death, serious illness or injury.
   v) Semiannual reports (FDA #3419) must be submitted by the EMS Agency with assistance from the Resource Hospital EMS Staff, to the FDA by January 1 for reports made July through December and by July 1 for reports made January through June of each year. If no reports are submitted to either the FDA or a manufacturer during these six month time periods, no semiannual report is required.

e) Record Keeping
   i) Provider Agencies must establish and maintain Medical Device Reporting (MDR) event files that contain information related to the adverse event, documentation of deliberations and decision-making processes, copies of forms and other information submitted to the FDA and others.
   ii) These records must be retained in an MDR event file for a period of two (2) years.
   iii) FDA employees are permitted to access, copy and verify the records in the MDR event file.

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