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INCISIVE ANALYSIS OF EMS LEGAL TOPICS

Medical Error Reporting in EMS

(Editor's Note: This is part two of a three-part series.)

In the October 2011 issue of EMS Insider, we discussed the requirements for reporting Adverse Events to the U.S. Food and Drug Administration. However, reporting untoward or unexpected events which occur in the course of patient interaction or care to the FDA is only one aspect of Adverse Event reporting in EMS. EMS providers at all levels are also responsible for reporting medical errors which occur during the care of a patient to their employer and medical control authority.

It is a myth that only bad or poor EMTs and paramedics make mistakes. The reality is that even good EMTs and paramedics make mistakes, and often with surprisingly similar frequency. Does this mean that everyone in EMS is "bad" or "incompetent"? Not at all. The truth is, although we strive for perfection, and society expects it from its caregivers, statistically it is impossible to be "perfect" 100 % of the time.

Traditionally, EMS (and the health care system, in general) have employed a punitive model of quality assurance – correction of errors occurs through training, disciplinary action, or a combination of both. However, the correlation between disciplinary action and improved clinical performance in EMS has never been a proven.

What is a "medical error"?

What constitutes a "medical error" encompasses much more than the definition of an "adverse event" under FDA regulations. "Adverse events," for FDA purposes, are limited to unfavorable or unintended signs, symptoms or diseases temporally associated with a medicinal product, medical device, or biologic product.

On the other hand, a "medical error" can be defined as a mistake or system failure which results in improper care or patient injury, regardless of whether a medicinal product, medical device, or biologic product was involved, for example, if an unattended patient falls out of bed, or an EMS crew clears a patient's c-spine following a hasty assessment and later learns the patient is now a paraplegic.

The psychologist, James Reason, expanding on Danish researcher Jens Rasmussen's classification of human performance, identified three types of errors leading to Medical Errors, namely: Skill-based errors, rule-based mistakes and errors, and knowledge-based mistakes and errors.

Skill-based errors include both slips and lapses. Slips are errors which are committed at a skill-based level of performance, for example where an EMT incorrectly applies a splint. Lapses are memory failures or omissions that also occur at the skill-based level, such as where the EMT fails to assess pulse, motor and sensation following the application of the splint.

A rule is a pattern of behavior used to achieve a particular goal. Rule-based mistakes and errors occur where a rule is misapplied or a bad rule is chosen to achieve a given goal, resulting in a mistake or error, for example, where a paramedic, who should follow a specific procedure for administering medication, administers the wrong medication because they didn't follow proper procedure.

Knowledge-based mistakes or errors result when a decision for action is based on insufficient knowledge or a biased interpretation of relevant information. An example might be an EMS provider who fails to check a blood sugar on an "intoxicated" patient who turns out to be hypoglycemic.

A number of factors lead to the possible causes for errors:

Ineptitude—situations where all the proper knowledge and training are place, but the clinician fails to utilize them properly. The simple solution here is repetition and practice, which leads to proficiency;

Ignorance—situations where the clinician did not possess the knowledge to reasonably assess the situation in the first place, and as a result, acted with inappropriate judgment. The simple solution here is education, which can be tracked within the organization to help identify requirements for future continuing education;

Active failures—situations where an unsafe act is committed by the people in direct contact with the patient; and,

Latent Conditions (aka "system errors")—situations that are present in the health care system as a result of decisions made by designers, builders, procedure writers and management, leading to a cascading effect of errors which occur prior to the error in question, and contribute to it. Examples of Latent Conditions include poor scheduling or caregiver fatigue, environmental distrac-

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tions, improper equipment checking or maintenance, poorly designed equipment and faulty training.

Medical errors reporting Systems

Over the past 10 years, an increasing number of EMS services and systems have instituted mechanisms for reporting EMS medical errors and adverse events.

The reporting systems vary widely, in many cases taking into account such things as local culture and custom. Some of the systems allow anyone involved in EMS—practitioners, supervisors, medical command, physicians and nurses at receiving hospitals—to make anonymous reports, while others are limited to internal employees only. They provide immunity or amnesty from adverse employment or medical control action. However, there is generally no amnesty if the incident involves criminal activity, willfully inflicting harm on a patient, willful neglect or negligence to a patient, willful disregard for patient care policies and procedures, or untruthfulness about documentation or error reporting, or where the situation involves practitioner substance abuse. Some systems, actually award points for voluntary reporting of medical errors, with the points factoring into pay-raise and shift-bidding calculations.

The key to all of these systems is that they are non-punitive. The goal is the analysis of events, with an eye towards looking for dangerous practices and trends, finding the issues, and preventing them from occurring again.

National adverse event reporting in EMS…

One such reporting system, which originated in Pennsylvania, has served as the foundation and model for a national adverse event reporting system for EMS. Sponsored jointly by the North Central EMS Institute and the National EMS Management Association, EVENT—the EMS voluntary event notification Tool—is an anonymous, non-punitive and confidential system that has been developed to help improve the quality and reliability of the care provided to patients by emergency medical service personnel. The purpose of the Pennsylvania system and that of EVENT is to collect and utilize valuable information from anonymous reports to help improve the consistency and quality of the care in the EMS arena.

Information provided in these anonymous reports identifies needed changes in the systems and processes and does so without placing blame on the individual provider. Although there is no current requirement for services and practitioners to report medical errors to EVENT, the system has been designed to encourage and foster reporting on a national basis.

Developing a culture for reportings

Unlike FDA adverse event reporting, which is required by federal regulation, reporting medical errors which do not qualify as "adverse events" under FDA definitions is currently a product of local culture and policy.

Steve Whitehead, NREMT-P, wrote in a July 2007 article in *EMS Magazine*, organizations that are willing to forge a culture of openness, where individuals are encouraged to publicize their mistakes without fear of judgment or ridicule, may find that very culture their greatest weapon in creating quality patient care."[1]

Time and time again, evidence has shown that punitive action taken against those who make medical mistakes and errors does nothing to change the culture and patient outcomes. Developing and fostering a culture of openness which encourages and even rewards medical errors reporting is a "win-win" for the healthcare industry. After all, it is always better to record your own mistakes than for someone else to uncover them—which they inevitably will.

To encourage reporting, many states offer immunity, legal defenses and/or evidentiary exclusions for health care practitioners who voluntarily report medical errors. In the end, the ultimate goal is improving patient care and the delivery of health care, and movement away from punitive treatment of medical errors can go a long way towards such improvement and decreasing health care and legal costs associated with medical errors. □

References:

1. Whitehead S. Fallible Medicine: Responding to Errors in Emergency Care. *EMS Magazine*, July 2007.

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Public Safety Spectrum and Wireless Innovation Act Update

The Public Safety Spectrum and Wireless Innovation Act, known as S. 911, was excluded from the end-of-the-year legislation, to the disappointment of the bill's sponsor U.S. Senator John D. "Jay" Rockefeller IV.

In a statement, Rockefeller, who serves as the chair of the U.S. Senate committee on commerce, science and transportation, said, "I'm deeply disappointed that measures to create a first responder communications network were not included in the larger year-end package. Our police officers, firefighters and emergency personnel across America need to be able to rely on a nationwide, interoperable communications network when the unimaginable happens."

S. 911 would have provided public safety and first responders with an additional 10 MHz of spectrum to support a nationwide, interoperable wireless broadband network. It would also have authorized the Federal Communications Commission to hold auctions to provide funding to maintain such a network. In June 2011, the bill cleared the commerce committee by a vote of 21–4.

Although the effort was unsuccessful, Rockefeller vowed to push hard to work out a suitable compromise with the House. "Build out of a public safety communications network is in our national interest," he says. "We cannot afford further inaction." □