CHAPTER 8

Medical oversight of EMS systems

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Introduction

In the United States, and much of the rest of the world, medical direction of EMS is today widely endorsed and recognized as an essential component of any EMS system [1–4]. However, this has not always been the case. In the landmark 1966 white paper *Accidental Death and Disability, the Neglected Disease of Modern Society* [5], the role of physicians in prehospital care was envisioned as that of potentially staffing ambulances to provide direct patient care, similar to the role that physicians play today in other countries, particularly in Europe [6,7]. While there were a few efforts in the US in the late 1960s, in places such as Columbus, Ohio, to engage physicians in providing prehospital care, these efforts largely gave way to the use of "physician surrogates" who soon became known as paramedics [8]. These providers were initially trained and supervised by physicians to provide advanced prehospital care, especially to victims of sudden cardiac arrest or trauma. Within a few years, national standard curricula were developed by the US Department of Transportation, which standardized the training of paramedics and included requirements for physician oversight of the education of paramedics and the care they provide in the field.

Of note, the Emergency Medical Services Systems Act of 1973 made no reference to the need for medical direction [9]. When the EMS program at the Department of Health, Education, and Welfare (DHEW) subsequently developed the 15 essential components of an EMS system, they did not include medical direction as one of them. Despite these omissions, during the rapid development of EMS systems during the late 1960s and 1970s, medical direction of EMS became a *de facto* standard, especially for ALS providers. Although it was not considered one of the essential components, DHEW did eventually make medical direction for ALS a requirement for awarding grants. In 1988 the National Highway Traffic Safety Administration included medical direction as one of the ten essential components for state EMS technical assessments [10]. The EMS Agenda for the Future in 1996 identified the need for medical direction for all levels of EMS providers, a principle that was thereafter incorporated into the US Department of Transportation's national standard curricula for EMS providers, including those for EMTs. Medical direction remains a component of the National EMS Education Standards today.

Over the past 40 years, the role of the EMS medical director has evolved and has become more clearly defined through the efforts of the National Association of EMS Physicians, the American College of Emergency Physicians, federal agencies, and national organizations to encompass all aspects of an EMS system [1,3,4]. Peer-reviewed journals, including one dedicated solely to prehospital care, have enhanced the science behind the provision of care to patients in the out-of-hospital setting, including the roles [11] and effectiveness [12,13] of an EMS medical director. Additionally, the cognitive and skills requirements for EMS medical directors have been refined through the publication of textbooks on EMS medical direction, guidelines for EMS fellowships, and, more recently, the development of an American Board of Medical Specialties (ABMS) approved subspecialty in EMS.

The role of the EMS medical director over the past decade has continued to evolve and, more recently, may be accelerating. The events of September 11, 2001 have drawn many EMS medical directors into a much more active role in disaster planning and response. More recently, H1N1 and other emerging infectious diseases have required medical directors to address issues ranging from EMS provider safety and surge mitigation, to the storing and dispensing of medical countermeasures. Recent efforts to utilize EMS providers in communities to address a broader range of medical care and public health issues have engaged EMS medical directors in discussions and planning on how to safely and effectively provide oversight for these emerging EMS roles. EMS medical directors have traditionally felt responsible for the emergency care provided in their communities and, therefore, have taken a public health- and population-based approach to what they do. These new and expanded roles for EMS will necessitate a

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Barriers to effective medical direction of EMS

Over the past four decades, the medical knowledge base and skills set required for EMS medical directors have been increasingly well defined. There are, however, other skills that are essential to the success and longevity of an EMS medical director, including, among others, leadership, administrative, and political skills. By the very nature of their role, EMS medical directors must be able to develop a vision, articulate it, and then effect change. Every EMS system poses its own unique combination of challenges whether it is a state, local, air, ground, fire-based, third-service, private, volunteer, rural, urban, BLS, ALS, or critical care system. It is the task of the medical director to recognize these challenges and effectively manage them.

While the role of an EMS medical director may have been increasingly well defined and standardized at the national level, the authority and resources provided to an individual medical director by a given system or service most certainly have not. It is not uncommon to find a medical director with the title "medical advisor" and/or with limited authority. Many medical directors lack response vehicles, communications equipment, or staff support. The title, authority, compensation, and resources provided to a medical director should be defined in a formal contract or job description and must be appropriate for the service or system that they serve and be commensurate with their responsibility for the patient care that is provided (Box 8.2). A recent study suggests that EMS systems with engaged and compensated medical directors were more likely to have prehospital cardiovascular procedures in place [18]. Volunteer EMS providers are less likely to have recent contact with their medical director than their counterparts in hospital-based and county/municipal services [19].

Box 8.2 Authority and resources required by an EMS medical director

Authority to:

- Grant, suspend, or revoke the medical credentials of EMS providers (with due process)
- Approve medical equipment and protocols (including emergency medical dispatch)
- Conduct quality assurance and performance improvement (including emergency medical dispatch)
- Establish continuing medical education requirements to address local and quality improvement issues
- Supervise all patient care
- Provide input on operational and budget issues that affect patient care
- Advocate for EMS providers, patients, and the EMS system
- Designate base stations, trauma and specialty centers
- Serve as the medical liaison with the community, state, and national organizations

Resources

- Response vehicle
- Communications equipment
- Medical supplies and equipment
- Personal protective equipment
- Office space
- Support staff
- Compensation sufficient to fulfill the role
- Liability coverage for administrative acts and malpractice

Appropriate title

- Medical director and/or
- A rank, such as assistant or deputy chief

Indirect medical oversight

In most EMS systems, indirect medical oversight encompasses the majority of a medical director's activities and responsibilities. It is the process through which medical directors influence the practice of prehospital medicine in their communities [1]. Credentialing of EMS providers, quality assurance and performance improvement (QA/PI), and protocol development are all examples of how medical directors engage in indirect medical oversight.

Anyone in need of emergency medical services has the right to expect the highest quality evidence-based emergency medical care [20]. From the initial 9-1-1 call to the medical care rendered on scene and even at the hospital, medical directors have the opportunity to positively affect the emergency medical care that is provided to each patient. Each EMS system is unique, and the medical director is responsible for providing clinical leadership that is tailored to the community's needs.

The delivery of EMS is influenced by many factors including the health of the population, the availability of resources, and the proximity of acute care hospitals. Medical directors must have a nuanced understanding of system needs and resources and use that understanding to ensure the delivery of the highest quality prehospital emergency medical care possible within that community. This section discusses various elements of indirect medical oversight and highlights the corresponding responsibilities of the EMS medical director.

EMS provider education

The system medical director must understand and be able to articulate a comprehensive vision for EMS provider education. In most systems the educational requirements for the licensure of EMS providers will be established by the state. Over the past decade, states have increasingly been adopting the principles of the EMS Education Agenda for the Future: A Systems Approach [2], which espouses the use of national EMS education standards, national certification as a prerequisite for state licensure, and the accreditation of EMS education programs [2].

At the local level, the initial and ongoing educational requirements for EMS providers may be affected by the local system. System medical directors may require additional initial and ongoing provider education to address local needs and ongoing

reconsideration of the education and preparation of EMS providers, and perhaps medical directors, to take on these new roles and how to best ensure that EMS systems continue to function safely and effectively [14,15].

The evolution of the subspecialty of EMS

In the late 1960s and 1970s a relatively small group of dedicated physician mentors recognized the need for improvements in prehospital care to address major public health issues that were resulting in needless deaths. In cities such as Miami (Gene Nagal), Los Angeles (Michael Criley), Charlottesville (Richard Crampton), Baltimore (Peter Safer), Columbus (James Warren), and Seattle (Leonard Cobb and Michael Copass), they advocated for trained and supervised prehospital providers to care for patients with sudden cardiac arrest, trauma, and other life-threatening emergencies. These physicians were well recognized in their chosen specialties but, at the time, it is doubtful that they recognized that they were laying the foundation for what would eventually become a formal subspecialty in EMS.

Over the ensuing years, as systems were required by grants or state rules to appoint EMS medical directors, a number of physicians assumed the role. Some did so out of interest or a sense of community service, others perhaps because they were asked to take on responsibilities that no other physician was willing to assume. Many of these physicians served admirably, but moved on. However, as the decades went by, an increasing number of physicians became EMS medical directors because they were genuinely interested in prehospital care. Many were (and still are) former EMS providers who wanted to get back on the street and take on the responsibilities of an EMS medical director.

Over time these physicians came to view their medical director roles as the practice of EMS. A little over 100 physicians met in Hilton Head, South Carolina, in 1985 and subsequently formed the National Association of EMS Physicians. Several decades later, with the support of the American College of Emergency Physicians and other national specialty groups, they successfully petitioned the American Board of Emergency Medicine and the American Board of Medical Specialties to establish a subspecialty in EMS.

As with the specialty of emergency medicine, it is likely that the growth in the number of EMS subspecialists will not meet the demand for some time. There will continue to be challenges in recruiting EMS medical directors, particularly when a position is uncompensated and/or in a rural area. We should anticipate that EMS subspecialists will initially be employed by larger municipal systems, academic centers, state and regional systems, and national commercial providers. It is therefore likely that, for some time to come, we will continue to see physicians serving as local EMS medical directors who are not EMS subspecialty physicians.

State requirements for EMS medical direction

In the United States, the regulation of health care, including EMS, is by and large the responsibility of the states. While there may be national consensus on the need for medical direction, there is significant state-to-state variation on the legal requirements for it [16]. States generally require medical direction for ALS, but there is considerable variation in the requirement for medical direction at the BLS level. Additionally, the role of the medical director and his or her qualifications vary from state to state (Box 8.1 contains a list of generally accepted qualifications for an EMS medical director). There are some states in which the state EMS agency has limited or no statutory authority over BLS providers and, therefore, even if they wished to mandate medical direction at the BLS level, they lack the authority to do so. Some states are also challenged with insufficient numbers of physicians willing to take on the role of the EMS medical director, particularly in rural areas [17].

State laws and rules significantly affect the role of the medical director. Most states require a medical director to be engaged in education, credentialing, protocol development, and quality assurance. However, depending on the state, these functions may be performed variously at the local, county, regional, or state level. It is important for a medical director to be cognizant of the state laws and regulations for medical directors as well as the liability protections that may be provided through state law. Additionally, medical directors must be cognizant of federal laws and regulations that can affect their role and responsibilities.

Box 8.1 Generally accepted qualifications of an EMS medical director

- State licensure to practice medicine or osteopathy
- Board certification or preparedness in an appropriate specialty (emergency medicine desirable)
- Familiarity with state/local/regional EMS activities
- Training and/or experience in the clinical practice of EMS, EMS medical direction, and EMS research (EMS fellowship and EMS subspecialty certification desirable)
- Knowledge of all components of the EMS system and any relevant laws, regulations, policies, and plans including:
  - Emergency medical dispatch
  - Operations
  - Education and continuing medical education (CME)
  - Quality assurance and performance improvement
  - Mass casualty incident/disaster response
  - Labor relations, management, and fiscal oversight
  - Public health, wellness, and prevention
  - Occupational injury and illness
- Involvement in local/regional/state/national EMS organizations

Source: Adapted from Alonso-Serra 1998 [1].

QA/PI activities. These medical directors are frequently engaged in providing medical oversight for initial EMS provider training and, in such situations, may have the opportunity to address these needs prior to state licensure.

The medical director must have a strategy to ensure the retention of skills by EMS providers. An active continuing education program can address the challenges of knowledge and skills retention and ensure continued provider competency. Educational approaches are also essential to address QA issues such as deficiencies in 12-lead ECG interpretation or airway management, as well as the implementation of new protocols or the dissemination of the latest in evidence-based approaches to prehospital care.

Verification of competency and EMS provider credentialing

Other important components of indirect medical oversight include the verification of competency and credentialing. At its most basic level, competency equates with a provider's ability to safely and adequately perform patient care. Competency is predicated on the provider's ability to synthesize appropriate information, make effective medical decisions, and safely perform interventions. Credentialing is the process that grants an EMS provider the privilege to perform a prescribed role and specific skills within a service based on competency. A local credentialing process should include meetings with the medical director, chart reviews, field observation, and simulated patient encounters.

The medical director should establish criteria for initial and continued competency and conduct regularly scheduled provider reviews. The issue of competency is particularly important with certain low-frequency, high-impact patient care skills such as endotracheal intubation. Opportunities for intubations have been declining and it has been well established in the scientific literature that competency in the particular skill of endotracheal intubation is especially predicated upon frequent practice [21–24]. In the absence of a clear national standard for minimum intubations, medical directors must develop an effective plan for maintenance of this core skill. Literature suggests that intensive physician oversight is associated with increased intubating proficiency [25].

Finally, the medical director must have the authority to address the issue of EMS providers who are deemed to be incompetent or impaired to such an extent that they pose a threat to the public. To address this issue, the local credentialing process must enable a medical director to immediately suspend or limit the privileges of an EMS provider and to develop a plan for remediation, if that is deemed appropriate. In such circumstances, there should be a system of due process that is available to the provider.

System quality assurance and performance improvement

Quality assurance and performance improvement efforts comprise a large portion of indirect medical oversight responsibilities. Medical directors must actively monitor both provider and system performance to achieve and maintain a high standard of patient care. Quality assurance ensures that performance is as it should be. Performance improvement monitors processes and outcomes in an effort to augment and improve the overall quality of patient care [26].

When deficiencies are identified through the QA process, the program must provide the necessary changes to the system and/or retraining and remediation of the providers. QA is not a punitive process. Indeed, a well-structured QA plan prescribes corrective action, elucidates root causes, and educates providers.

Performance improvement is an effort to improve patient outcomes, which requires that EMS patient care records be linked with hospital outcomes. Recent advances that EMS systems have made in improving historically poor outcomes from sudden cardiac arrest are demonstrative of the positive effects of PI. Over the past decade, medical directors in a number of EMS systems have established comprehensive processes for monitoring sudden cardiac arrest outcomes while making incremental changes to improve the delivery of prearrival instructions for CPR and the quality of CPR on scene. With such PI efforts, outcomes particularly for witnessed ventricular fibrillation arrests have been reported to have risen significantly in a number of jurisdictions [27–32].

Quality assurance and performance improvement efforts may be performed in a number of ways. Retrospective activities include review of patient care reports, provider debriefings, incident reviews, and analysis of EMS data and outcomes. Concurrent activities generally include the monitoring of care in the field by the medical director, field training officers, or EMS supervisors, and through simulated patient encounters.

Electronic patient care reports are increasingly more available, giving medical directors unprecedented access to both the patient care reports and system data. Additionally, electronic summaries from monitors/defibrillators permit a detailed analysis of vital data, such as CPR compression density and depth and the timing of critical interventions. The widespread proliferation of waveform capnometry affords a similar level of patient care surveillance. Providers now can confirm endotracheal tube placement with near 100% accuracy and immediately recognize tube dislodgment or migration. Incorporating new technologies and using electronic patient care reporting establishes a vital link between patient care and the QA/PI processes.

System benchmarking is another useful tool in the QA/PI armamentarium. The ability to do benchmarking has markedly improved with the development and availability of electronic patient care reports and the establishment of the National EMS Information System (NEMSIS), which defines EMS data elements and is building a large repository of EMS data from all across the country. Benchmarking through NEMSIS, and other large databases such as CARES, enables medical directors to evaluate their systems against a template of system, clinical, and patient outcome data. In 2008 a position statement published by

the US Metropolitan Municipalities EMS Medical Directors called for the development and use of patient-centered measures of system performance. Potentially useful clinical benchmarks include the administration of aspirin for suspected cardiac chest pain, minimization of on-scene intervals for victims of penetrating trauma, and the use of non-invasive ventilation for respiratory failure [33,34].

Finally, QA and PI activities must include access to outcome data from hospitals. Patient outcomes are essential to understanding how prehospital interventions affect patient care. While prehospital data might indicate an increase in the return of spontaneous circulation, this is not the same as the percentage of patients who survive to hospital discharge and are neurologically intact. Patient care outcomes are affected by both prehospital and hospital care. The medical director must consider the entire continuum of care when evaluating the quality of care delivered to patients served by the EMS system.

Field clinical supervision

Field clinical supervision by the medical director is sometimes viewed as a component of the QA/PI processes but, in fact, it is much more. Medical directors in the field have an opportunity not only to assess the performance of providers and the system, they have an opportunity to mentor, engage in hands-on patient care, and learn firsthand about the challenges faced by providers [1,7]. Medical directors who are active in the field uniformly report that the time that they spend on the street is not only productive, it is one of the most enjoyable aspects of their jobs [12].

Many medical directors today functioned as EMS providers at some time in the past. This is a benefit in preparing a medical director for field clinical supervision. Medical directors who lack that experience should invest some time in getting oriented to "life on the street." First and foremost, there are safety issues that must be considered as well as the many formal and informal rules and protocols that must be followed. Medical directors who understand these issues are able to insert themselves seamlessly into an incident and will garner significant credibility with EMS providers.

Medical directors can perform field clinical supervision by riding with supervisors, but there are limitations to this approach. It is preferable for a medical director to have an assigned response vehicle that enables him or her to respond from wherever he or she may be to mass casualty incidents or unusual occurrences, or to focus attention on particular incidents that are a priority in the QA/QI process. Medical directors who have assigned response vehicles should meet the same training and performance requirements as other members of the service who drive emergency vehicles. The vehicles must be appropriately equipped for emergency response and have communications equipment and medical supplies, including a defibrillator, and should ideally undergo the same state inspections and credentialing as other EMS vehicles. The medical director must have appropriate personal protective equipment (PPE).

Protocol development

The specifics of any region's EMS system will determine the role of the medical director in protocol development. Some systems function under state-wide protocols, and others use regional or local protocols. Regardless, medical directors must be leaders in protocol development and continuous review.

The evolution of EMS as a medical subspecialty parallels the growing evidence base for the practice of prehospital medicine that has been published over the past several decades. Historically, EMS protocols were extrapolated from in-hospital practice. Today, they are more often developed using scientific literature derived from prehospital studies, with input from EMS physicians and prehospital professionals. Medical directors must ensure that protocols are relevant and appropriate for the local system by taking available resources and community needs into consideration. In developing protocols, the medical director needs to be familiar with the existing scientific literature and the evolving evidence-based guidelines and model protocols that are available today.

Although protocols reflect the needs of any given EMS system, basic principles of treatment and transport destination should embrace the best available evidence. Protocol development is anything but a static process and medical directors must commit to regularly scheduled audits of prehospital practice and modify treatment protocols as appropriate. Finally, emergency medical dispatch protocols affect the first interaction between an EMS system and the citizens it serves. Physicians should be engaged in the implementation and quality review of dispatch protocols [35].

While prehospital protocols have historically varied from system to system, there is a growing trend toward more standardization. Since 2008 the National Highway Traffic Administration and the EMS for Children Program have collaborated with a working group composed of prehospital providers, physicians, and administrators [36]. The working group used the GRADE process to review current evidence with respect to field pain management and the air medical evacuation of trauma patients. It is anticipated that this project will form the foundation for a process to develop evidence-based guidelines in the future.

More recently, the Medical Directors Council of the National Association of State EMS Officials has been developing model protocols. Many agencies, both in the United States and abroad, post their protocols on the internet. The National Association of EMS Physicians addresses potentially controversial issues through its Standards and Clinical Practice Committee. Thus, there is an evolving set of resources available to assist medical directors in developing EMS protocols.

Designation and oversight of base stations

In most systems, direct medical oversight is delegated to "base stations." A base station is best defined as a hospital emergency department or health care facility that is designated to provide EMS personnel with direct medical oversight. In a centralized

approach, one physician and/or one base station provides that direction for the entire system. More typically, depending on the system, there is more than one designated base station. In fact, it is not uncommon for all receiving facilities to be designated as base stations.

The designation of a base station involves much more than tasking an available emergency department with medical oversight for providers in the field. Typically, depending on the system, the local, regional, or state medical director will establish criteria for the designation of base stations and a process to ensure that base stations continue to function at an acceptable level.

Designation and oversight of trauma and specialty centers

Regionalization of care from an EMS standpoint is the transport of patients to the hospital that is most appropriate for a patient's condition. This may entail bypassing hospitals that are not staffed or equipped to provide timely definitive care to the patient. A well-known phrase, "the right patient, to the right hospital, in the right time, with the right care," is used to describe this concept. Since the early 1980s, regionalization of trauma care has been advocated to reduce deaths and improve outcomes by transporting selected patients to trauma centers [37–39]. Since that time, the core principles learned in the development of trauma systems have been applied to the development of stroke, STEMI, and, more recently, cardiac arrest systems of care [40,41]. Box 8.3 contains examples of designated trauma and specialty centers. For further discussion, see Volume 2, Chapter 12.

As with base stations, an EMS medical director may need to establish criteria and a process for the designation of trauma and specialty centers and ensure that the designated centers continue to function at an acceptable level and maintain good risk-adjusted patient outcomes. Fortunately, there are national standards available to assist in that function. The American College of Surgeons, Committee on Trauma publishes standards for trauma centers and has a process that will verify that the trauma center meets those standards [42,43]. Similarly with stroke centers, the Brain Attack Coalition has published standards and the Joint Commission has a certification process for stroke centers. There are also standards for cardiac interventional centers for STEMI patients published by the American College of Cardiology and the American Heart Association as well as the Society for Cardiovascular Patient Care, which has an accreditation process for chest pain centers [44–46].

Box 8.3 Examples of designated trauma and specialty centers

Trauma – adult and pediatric
Stroke
Cardiac interventional (STEMI)
Cardiac arrest
Pediatric medical
Burn – adult and pediatric

To implement regionalization of emergency care, medical directors must start with the development of protocols and thoroughly educate EMS providers on criteria for the triage of patients to trauma and specialty centers. To ensure that trauma and specialty centers are continuing to function with good risk-adjusted outcomes, medical directors must require that designated centers provide patient care and outcome data as a condition of designation. In Arizona, for example, hospitals designated as "resuscitation centers" share patient outcome information with the referring EMS agency and there is now a CDC-sponsored CARES national registry for tracking the both prehospital and hospital outcomes of patients with cardiac arrests [47]. In Maryland and many other states, trauma centers are required to provide data to a trauma registry and the American College of Surgeons maintains a national trauma data bank. The American College of Cardiology has a STEMI registry and the American Stroke Association maintains a stroke registry into which hospitals may submit data. It is essential to ensure that the medical director has access to these registries and is able to link patients in the registries with prehospital reports.

The use of registries enables medical directors to benchmark system and hospital performance with risk-adjusted outcomes. These should be reviewed regularly by the medical director.

EMS provider safety and well-being

In most EMS systems the role of the EMS medical director does not include providing occupational medicine services. That said, medical directors must, nonetheless, prioritize EMS provider safety and well-being and advocate for these important issues. The medical directors' training and knowledge of EMS places them in a unique position to understand the health risks posed to EMS providers and then promote the development of a robust safety and well-being program for their providers.

The principal causes of work fatalities for EMS providers are transportation related; therefore, EMS medical directors should advocate for improvements in ambulance safety [48], including ambulance design, construction, and markings, as well as ensuring that there are policies that address occupant protection, driver screening and training, and the prudent use of lights and sirens. On-scene safety should also be addressed through the development of policies that are consistent with the Traffic Incident Management Systems program at the US Fire Administration, the Emergency Responder Safety Institute, and the US Department of Transportation.

Emergency medical services providers are also at risk for assaults, back, and other injuries [49]. Medical directors should work with administration to ensure that there are policies in place to minimize the likelihood of assaults and that ambulances and stretchers are designed to be as ergonomically friendly as possible [50–52]. Medical directors should advocate for EMS

providers to have access to appropriate PPE and be instructed in how to avoid exposures, especially to blood-borne and respiratory pathogens such as influenza and SARS.

Last but not least, the medical director should advocate for a wellness program, which is known to reduce injuries, absenteeism, and even deaths through the promotion of healthy lifestyles. Such a program should, at a minimum, include initial health screening, ongoing monitoring, weight control, physical fitness, and access to stress incident counselors when necessary.

EMS administrative issues – management and finance

Though not a primary role, EMS medical directors have a vested interest in the management and financing of EMS systems. They should therefore be knowledgeable and informed on these issues and be given the opportunity to provide input into management and budgetary decisions that potentially affect patient care. Budgetary advocacy may extend beyond the EMS service and include advocacy directed to the public, local and state governments, and the media. These activities are best done in conjunction with administration and, when appropriate, other stakeholder groups including labor organizations.

Box 8.4 State and federal laws that may affect an EMS medical director

- State EMS laws enforced by the state EMS office
- State and federal laws on controlled substances enforced by the US Drug Enforcement Administration and states
- Laws on Medicare reimbursement as well as fraud and abuse enforced by CMS and the Department of Justice
- Clinical Laboratory Improvement Amendment (CLIA) – requires either a certificate or waiver to use glucometers and perform other diagnostic tests – enforced by CMS and states
- Civil rights laws and laws related to the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act – addressing health information – enforced by the US Department of Health and Human Services
- Food, Drug, and Cosmetic Act – regulating medications and medical devices – enforced by the US Food and Drug Administration
- Occupational and Safety Act enforced by the Occupational Safety and Health Administration and states
- Various civil rights and antidiscrimination laws enforced by the US Equal Employment Opportunity Commission
- Airline Deregulation Act – preempts states (and locals) from regulating the rates, routes, or services of air medical services – enforced by the US Department of Transportation

Legal and regulatory issues

Both federal and state laws and regulations potentially affect the roles and responsibilities of an EMS medical director. At the state level, there may be state laws that place requirements or limits on EMS medical directors with respect to protocol development, EMS provider certification and licensure, quality assurance, reporting of suspected abuse, EMS worker safety, the registration and management of controlled substances, and others. The state may also impose educational requirements on the EMS medical directors themselves, including for continuing medical education.

There are several dozen federal laws and federal agencies that have a potential effect on or regulatory authority over EMS systems, and many of these can create responsibilities and pose challenges for the EMS medical director. Box 8.4 contains a list of federal and state laws that may affect an EMS medical director. A medical director should be familiar with all of these laws and know how they potentially affect his or her roles and responsibilities. Of particular concern to EMS medical directors are recent federal enforcement efforts related to controlled substances and reimbursement by Medicare.

In order to carry and administer controlled substances, EMS services must be registered with both the state and the US Drug Enforcement Administration (DEA). State laws related to controlled substances vary from state to state and this variation can, in turn, affect how federal rules are applied by the DEA in a particular state. Since it is common for an EMS agency's controlled substance registration to be held by the medical director, it is critical that the medical director be knowledgeable about these laws. In the past several years, the DEA has taken enforcement action against several EMS medical directors and some of these actions have resulted in large fines, the loss of medical licenses, and criminal charges.

Another issue of concern is the enforcement of federal laws regarding Medicare reimbursement by the Centers for Medicare and Medicaid Services (CMS). There are strict rules for the reimbursement of ambulance services provided to Medicare beneficiaries. Failure to observe these rules may result in fines as well as criminal sanctions. While medical directors may be only peripherally involved in billing activities of the service, one recent investigation resulted in the subpoena of the correspondences of the medical director to determine if he was complicit in the alleged improper billing practices of the service.

By law, the reimbursement for ambulance services by Medicare is limited to when ambulance transportation is provided and is medically necessary. CMS guidance defines medically necessary as meaning that transport by any other means is contraindicated. If the service bills for reimbursement at the ALS level, that level of care must be medically necessary as well. Medical necessity for an ALS reimbursement means that one or more ALS interventions were performed or that the condition of the patient warranted an assessment by an ALS provider, even if no ALS intervention was performed. The CMS rules for non-emergency transports are even more restrictive. Over the past several years, CMS has increased the number of audits of EMS services and several have included the participation of the US Department of Justice. Medical directors should be familiar with the CMS regulations on the coverage of ambulance services, which can be found in the Code of Federal Regulations (42 CFR 410.4).

Medical directors needing guidance should approach their state EMS offices, regional or state EMS medical directors, or

other experienced medical directors. Specific questions can be directed to the appropriate state or federal enforcement agency.

EMS research

Emergency medical services research is the foundation upon which the burgeoning EMS subspecialty was built, and has the potential to improve patient outcomes. Medical directors should have an understanding of how to design and conduct studies and educate EMS administrators and providers on the need for and benefits of prehospital care research [53]. While not all EMS systems will have the resources and ability to conduct rigorous and comprehensive randomized prospective studies, most have the capability to participate in some way, be it publishing anecdotal case reports or case series, or participating in a regional or national study.

Public health – public education, prevention, and response to catastrophic health events

Emergency medical services has been described as the intersection of public health, health care, and public safety. EMS medical directors should provide the leadership to engage EMS systems in public health activities that have the potential to improve EMS outcomes as well as the overall health and wellness of the community [4].

Over the past several decades, clear evidence has emerged that when EMS systems promote CPR training and AED use in the community, there are increases in the percentage of patients who survive prehospital sudden cardiac arrests [27–29]. Similarly, EMS systems should engage in injury prevention education that has the potential to reduce the frequency and severity of injuries. Examples include education on the use of seat belts and helmets, fall recognition and interventions in the elderly, distracted driving, fire prevention and fire alarms, and childhood drowning [54]. Public education on the signs and symptoms of acute stroke and STEMI and when to call 9-1-1 has been undertaken in an effort to reduce the time to definitive care.

Emergency medical services data are useful in identifying trends in death, illness, and injury in the community and should be used and incorporated into the local public health system's surveillance data to identify where there is a need for public health education, investigations, and potential interventions.

The EMS medical director needs to be prepared to monitor and support public health responses to major disease outbreaks such as pandemic influenza or SARS [55]. Outbreaks have the potential to affect not only the public, but EMS and health providers as well. EMS providers may be some of the first victims of an outbreak, as was the case with SARS in Canada and Taiwan [56,57]. Medical directors should work with their EMS systems to develop contingency plans to modify dispatch, on-scene, and transport protocols in the event that demands begin to exceed the availability of EMS and community health resources.

Since the events of September 11, 2001, EMS and public health officials have worked together at the local, state, and federal levels to improve our response to catastrophic health events, be they man-made or otherwise. These planning efforts have been directed toward integrating public health, EMS, and health care resources to improve the overall response and to mitigate the impact of the incident. Medical directors are key stakeholders in planning and responding to such incidents.

Direct medical oversight

Direct medical oversight refers to real-time physician-directed care. Direct medical oversight may be provided by a physician who is either physically or remotely present. The majority of modern direct medical oversight occurs in the provision of online medical direction via telephone, radio, and, at times, video consultation. As opposed to indirect medical oversight, there is immediate feedback to the quality assurance and improvement program and immediate impact on patient care. Online medical direction is provided remotely but, although the technology facilitating this interaction continues to improve, it does not replicate the physical presence of the medical director. While the bulk of direct medical oversight is performed remotely, the necessity and value of a physician's presence in the field cannot be overstressed [7].

As EMS systems developed and the need for physician "surrogates" was recognized in the 1970s, medical direction was pioneered by a dedicated cohort of physicians who trained and continuously supervised a group of paramedics who would themselves become trainers and supervisors [58]. These physicians had physical presence and medical authority with a close knowledge of the individual paramedic's training and skill level. Unfortunately, this level of physician involvement in both training and medical oversight proved extremely difficult to maintain. Many EMS systems developed without strong physician input or field presence [59,60]. EMS systems and the role of direct medical oversight within them evolved in ways as varied as the communities which they served. Some, but not all, jurisdictions would legislate for a medical director although often without fully delineating his or her role or level of training [16,61]. Regardless of the medical director's level of involvement, the constants remained: an expectation of competent and quality prehospital care, and of continuous and immediately available medical direction. The solution to limited physician interest and involvement, as well as the potentially crushing requirement of a constant presence for an ever-expanding service, moved direct medical oversight to the emergency department where the elements necessary for online medical direction could easily be established and were readily available.

Online medical direction

The most basic elements of an online medical direction program include an available physician and reliable communications, but there are a number of additional elements required to make that system functional. In the case of an EMS base station, the EMS

medical director delegates his or her responsibility for medical oversight to the online medical direction physician at the base station, and therefore must ensure that such direction is appropriate. The previous section on indirect medical oversight discussed the designation and oversight of base stations by the system medical director.

The online medical direction physician should have experience in the emergency department managing the acutely ill or injured patient and, as the medical authority who answered the call, have a clear understanding of his or her responsibility to the patient and provider [62]. The physician must be familiar with local prehospital protocols as well as the design and operation of the entire EMS system, and be knowledgeable in the use of communications equipment and radio etiquette. He or she should have a thorough understanding of the quality assurance program and an ability to provide appropriate feedback to providers, the EMS medical director, and systems managers. These qualifications are typically obtained in the process of emergency medicine residency training and should be reinforced by the EMS system's medical director through a formal training program for physicians providing online medical direction.

The EMS system also depends on written policies, procedures, and protocols to develop and sustain an online medical direction program. There must be written policies that delineate the roles and responsibilities of physicians and prehospital providers. Evidence-based EMS protocols help to promote uniformity in care. Most systems have evolved from the practice of strict medical direction, which previously required base station contact for all patients. The safety and efficacy of "standing order" protocols have been demonstrated and a vast majority of EMS transports occur without online medical consultation [63,64]. At the same time, the benefits of online medical direction have not been clearly demonstrated outside limited instances of patient care refusals, with some potential in reducing emergency department overcrowding through transport destination decisions [65–70]. Indications for online medical directions in a given EMS system should be clearly delineated. Written procedures inform both parties as to when consultation is necessary, when it is expected, and how quality assurance issues such as protocol deviations and skills shortfalls should be addressed. EMS medical directors and other EMS system managers depend on base station physicians to provide feedback on provider and system performance.

Impact of communications technology on online medical direction

There has been significant discussion about the importance of communication between the base station physician and the EMS medical director with regard to quality assurance and performance improvement, although developing this relationship would be less effective without reliable and recordable communications between base stations and prehospital providers. The technologies enabling these communications are continuously evolving, and this will most certainly have a significant effect on how online medical direction is conducted. In the 1970s the federal government set aside a limited number of VHF channels for communicating by voice with the physician at the base station [71]. The potential usefulness of these frequencies was significantly reduced by the limited range of transmissions and frequent interference. Eventually, these channels were supplemented by eight UHF channels, which reduced interference, improved reliability, and enabled an increase in the use of analog ECG telemetry. The number of available UHF channels for base station use has recently been increased through the actions of the Federal Communications Commission and a process referred to as narrowbanding.

The rapid development of cellular phone networks has led to their increased use as a method of contacting base stations for medical orders and 12-lead ECG transmissions. Maintaining a recording of these radio or phone consultations is essential to the QA/PI process and must be a consideration in system design. While the discussion of online medical direction to this point has focused on the emergency department base station, there are jurisdictions that may rely on the medical director or directors for online medical direction. While this practice may provide significant benefit to the system, communications should be routed through a central communications center where a recording can be maintained for QA/PI purposes.

The advent of broadband wireless technologies and the widespread utilization of smartphones by the lay and medical communities are naturally causing increased interest in advancing telemedicine applications in EMS. Telemedicine has been used by EMS since the 1970s when analog ECG telemetry was employed to send rhythm strips to the emergency department for physician confirmation. Today, the use of ECG telemetry has become much less common and has recently been supplanted by the transmission of 12-lead ECGs for prehospital cardiac catheterization lab activation. Cellular telephones equipped with cameras are often used to photograph crash scenes by patients and prehospital providers. Smartphones with photo and video capabilities and ubiquitous data connections present a simple and fast method of transmitting images of 12-lead ECGs, scene surveys, and patient assessments. The ease of increased connectivity must be tempered by the need to preserve the medical record while maintaining patient confidentiality and standards consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Telepresence is the next anticipated advancement for online medical direction and has been tested in a few areas of the United States. While initial successes have been noted in assisting with destination determinations in trauma and improved success rates with video-assisted intubation, budgetary constraints have been confounding factors [72]. Technologies have been developed which allow for recorded video and audio streaming as well as real-time transmission of physiological data, pulse, respiratory rate, temperature, invasive and noninvasive blood pressure, capnography, and ECG telemetry. This has broad implications for the future of prehospital care and

following a structural collapse, for example, may benefit from a physician response to the scene to perform an amputation that facilitates the timely extraction of the patient. Although prehospital amputation is exceedingly rare [81], preparation for that possibility is recommended.

The potential benefit of an on-scene EMS physician is not limited to the procedures they may be able to perform. A physician's assessment and diagnostic skills may be useful in differentiating conditions that could affect both out-of-hospital care and the decision on hospital destination. On-scene physicians can also be beneficial in recognizing and treating potentially life-threatening conditions with prolonged scene times, such as a crush syndrome during a complicated extrication [82]. The use of physicians in prehospital air transport has been associated with decreased mortality for patients with traumatic injuries [83].

Contrasting European prehospital care with that in the United States

Europe has had a long-standing experience of physicians in the prehospital setting [7]. In Denmark, for example, physicians respond to the homes of patients, initiate treatment, and often are able to avoid transporting patients to the hospital [84]. By treating these patients in their own homes, Danish prehospital physicians are able to eliminate the need to transport every patient who requests medical assistance, as is common in the United States. In Europe, physicians are more likely to be a part of helicopter-based EMS systems [85]. Furthermore, some helicopter-based EMS systems in Australia provide physicians on every mission [86]. In some regions of Germany, ALS units are staffed by physicians [87] as part of routine prehospital care. In France, physicians respond to calls for medical service in the out-of-hospital setting [6], often separate from the ambulance services response system. By contrast, physicians in the US who respond to 9-1-1 calls generally do so as an integral part of the EMS system.

Special situations requiring on-scene care by EMS physicians

There are several special situations in which EMS physicians may be called upon to render care in the field. Urban search and rescue teams, for example, specialize in locating and extracting trapped patients following structure collapses. Physicians on these teams provide on-scene care to entrapped victims, in addition to providing medical support for the members of the team itself [88]. These physicians must be proficient in treating patients with various types of trauma and crush syndrome, as well as confined space medicine and occupational medicine [89,90].

Emergency medical services physicians may also be requested to deliver direct patient care at mass gathering events [91]. The provision of care by physicians at these events has been demonstrated to reduce the need for patient transports, thus potentially reducing their effect on local EMS and emergency department resources [92].These findings suggest that EMS physicians can improve system efficiency by providing direct care at mass gathering events.

Finally, during large disasters or mass casualty incidents, it may be necessary for EMS physicians to provide direct patient care. During such events, EMS physicians can augment the care being provided by overwhelmed field providers. EMS physicians may be helpful in performing other functions during a disaster response, such as providing triage and establishing field treatment facilities to reduce the surge burden on receiving facilities. In all these circumstances where EMS physicians operate in the field, it is crucial that responding EMS physicians operate within the incident command system structure, and avoid "freelancing."

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potential expansion of role of paramedics in the field. Telepresence would simulate the physical presence of the medical director or base station physician in the field, demonstrating a significant contribution to QA/PI programs.

On-scene medical direction

Despite these advances, the value of having the EMS medical director in the field cannot be overstated [7]. As with our pioneer EMS medical directors, these interactions in the clinical environment provide opportunities for education and evaluation that cannot be simulated or provided remotely. Frequent physical presence of EMS medical directors on scene improves their understanding of the environment and allows them to develop a rapport with providers that ultimately facilitates educational and QA/PI activities.

The superiority of bedside teaching has clearly been identified in medical literature [72–74]. All physicians have experienced the benefits of bedside teaching and should take a similar approach with prehospital providers [75]. Familiarity, and the expectation that the EMS medical director is often on scene, will put the provider at ease and is a behavior that needs to be trained. Introductions to the patient, when possible, and to other individuals on the scene are recommended. While the EMS medical director is certainly responsible for the care of the patient, his or her primary role is to evaluate whether providers will come to a diagnosis and develop a treatment plan, assisting them with their assessment through Socratic questioning only if it becomes necessary. Similarly, treatment plans should be carried out by the prehospital providers, with positive or corrective feedback provided when necessary. There are also benefits to serving as a role model when teaching physical assessment and skills. The EMS medical director should step in when those rare instances of particularly difficult procedures occur or if additional support is needed, but only as a last resort. The EMS medical director should be provided with the appropriate tools and protections to facilitate this activity.

Direct patient care in the field

Although most of the on-scene responsibilities of the EMS medical director will involve the direct medical oversight of EMS personnel, there are instances in which it may be both appropriate and necessary for the medical director to provide direct medical care. Medical directors must be aware of the various potential scenarios in which their expertise in providing direct patient care is needed. These scenarios may present themselves without warning, so it is imperative that guidelines be developed that address this possibility and support optimal patient outcomes. While these scenarios may be relatively rare, contemporary EMS systems will incorporate the skills and experience of the medical director in direct patient care when necessary.

The on-scene medical director should consider providing direct patient care after unsuccessful attempts of a critical procedure by an EMS provider. Airway management, especially, has been shown to be a skill that is commonly challenging in the prehospital environment [76–78]. Endotracheal intubation is performed relatively infrequently compared to other prehospital procedures [77]. These findings provide support for strategies that involve having higher trained and more experienced providers assume care when field providers are unable to achieve success. If on scene, the medical director has the ethical and possibly legal responsibility to assume the task of performing such skills. The number of attempts that should be allowed before the physician takes a more active role must be dictated by the individual patient, field provider experience, time criticality of the procedure, and other factors that may contribute to the challenges being encountered.

Skills that are beyond the scope of an EMS provider may also need to be performed by an on-scene EMS physician. For example, if BLS providers are caring for a patient who requires an ALS skill such as the administration of an IV drug, an on-scene EMS physician should consider performing these procedures if waiting for the arrival of an ALS provider would be potentially detrimental to the patient. A patient in the care of a BLS crew with unstable tachycardia who requires immediate cardioversion should have this procedure performed by an EMS physician who is already on scene, rather than wait for the arrival of an ALS provider.

There are also medical procedures that are beyond the scope of an EMS provider of any level. Patients with circumferential chest burns, for instance, who are developing worsening respiratory distress may need to undergo field escharotomy [79]. The EMS physician should exercise judgment when deciding when to perform these extraordinary procedures. If a patient's condition is deteriorating rapidly, and waiting for transportation to an emergency department would put that patient at an undue risk, then the EMS physician should consider performing the necessary procedure. The use of extracorporeal membrane oxygen support may require direct physician care during transport between facilities [80].

Box 8.5 lists interventions that may be beyond an EMS provider's scope of practice and may need to be performed by an on-scene EMS physician. EMS medical directors should develop protocols for their individual systems that establish when an EMS physician should be dispatched to scenarios that would benefit from physician intervention. A prolonged entrapment

Box 8.5 Potential interventions by EMS physicians that are typically not in the scope of practice of EMS providers

- Amputation
- Escharotomy
- Administration of drugs outside existing prehospital protocols
- Administration of blood products
- Tube thoracostomy
- Venous cutdown
- Pericardiocentesis

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