by Jack Start

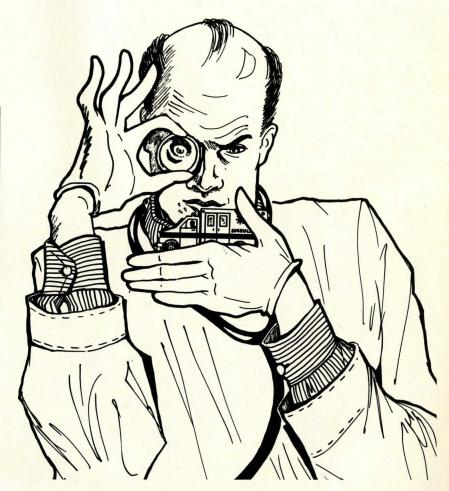
Organizing Quality Control in EMS

"I'm supposed to be the medical director, but the truth is I don't direct anything. I recommend, I advise, I coerce, I cajole, I get down on my knees...but I do not direct." The speaker was a board-certified emergency physician, who is the medical director of a large urban EMS system - in his case, a government "third-service" operation. His complaint was not unique. By the time I left the 1987 Scientific Assembly of the American College of Emergency Physicians (ACEP), I had heard at least 30 variations on the very same theme - medical directors without the power to direct.

The physician approached me as I gathered my notes from a panel discussion entitled, "EMS Quality Assurance: Is It Possible?" ACEP had given me the honor of sharing the panel with Drs. Richard Cales (Portland, Ore.), Mickey Eisenberg (Seattle, Wash.) and Ron Stewart (then of Pittsburgh, Pa.) — a virtual "Who's Who" of EMS physicians. The docs handled the "doctor stuff," while I focused on the organization and financing of medical quality control (QC) structures — the thrust of this article.

Jack Stout has been at the forefront of innovations in the design and implementation of EMS systems for the past dozen years. If you have a question, a problem, or a solution related to the public/private interace in prehospital care, address your letter to "Interface," JEMS, P.O. Box 1026, Solana Beach, CA 92075.

Like many other aspects of our



EMS industry, conventional wisdom regarding medical QC is hopelessly oversimplified. For example, in the early '70s a so-called ''model state statute'' for EMS regulation was supplied to the states and, with various modifications, adopted by many. Licensing provisions requiring vehicle inspections and personnel certification, usually based upon ''minimum standards,' furnished the core of these laws. Most of these statutes required

ALS providers to name a "medical director" as a condition of licensure. No one seemed to notice that, when push comes to shove, a medical director who serves at the pleasure of the organization he allegedly oversees may find himself in a difficult position, or in no position at all. It's the kind of provision that works best where it isn't needed — that is, in well-managed organizations already dedicated to quality. But what about the others?

One of our industry's best-known providers, a government "third service," recently terminated three medical directors in a two-year period. The question is raised: Were the medical directors fired because they weren't doing the job — or because they were? And even where there is no apparent controversy, how can the public be certain that the absence of controversy isn't merely the product of an absence of real oversight?

The problem is this: we must learn the distinction between external medical QC vs. internal medical QC. A good EMS system has both. We must also learn that truly effective external QC must be:

- completely independent from provider control;
- reasonably insulated from political interference;
- expert and current in clinical aspects of prehospital care;
- fully informed about system operations;
- · appropriately staffed; and

 adequately funded by a stable source of income.

In the course of designing and installing state of the art prehospital-care systems throughout the United States over the past 13 years, I have discovered a formula for building medical QC structures capable of meeting all six of the above-listed criteria. The formula has never failed. The aim of this article is to replace the conventional wisdom of EMS quality control with concepts that actually work.

"Internal" vs. "External" QC

At the heart of the formula is a critical distinction between "internal" vs. "external" medical quality control. The distinction is simple and profound: Internal QC operations are under the control or substantial influence of provider organizations. External QC operations are beyond the control or influence of provider organizations.

Eleven years ago I conducted our industry's first large-scale competitive procurement of primary ALS services — the Tulsa system. Back then, few EMS providers, public or private, had strong internal QC systems. In structuring ma-

jor procurements, we worked with the assumption that contractors' internal QC mechanisms were modest at best. Thus, we relied almost entirely upon external QC structures to establish clinical standards, monitor clinical performance and initiate future advancements in quality of care.

However, in recent years the quality and reliability of internal QC systems has advanced dramatically, especially among private contractors of primary emergency services. For example, in our most recent major procurement — Pinellas County, Florida — clinical capability, including the caliber of internal QC, was the primary factor in awarding the largest ALS contract in the history of our industry.

Today, external QC systems must be increasingly designed to capitalize upon and strengthen internal QC systems. There isn't space here to cover in depth the complex relationship between internal and external QC programs. But regardless of the quality and reliability of internal QC systems, the public and the medical community deserve to know that the quality of care being

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produced by their prehospital care system is externally monitored by an objective, independent, expert and informed *external* medical QC organization.

"On-line" vs. "Off-line" Control

Off-line medical control deals with such before- and after-the-fact matters as equipment specifications, training requirements, chart audits, written medical protocols, corrective action, and a whole lot more. In contrast, on-line medical control is a real-time, event-driven activity — i.e., medical direction of in-field activity by radio contact.

"Standing orders" should not be confused with "medical protocols." A "medical protocol" is merely a written description of how the EMS system should perform when confronted by a given presenting problem or presumptive diagnosis. "Standing orders" may or may not be included in a given medical protocol, depending upon whether authorization by radio contact is

called for prior to initiating specific procedures within the protocol.

If an advanced procedure is allowed without radio authorization, the procedure is said to be authorized by "standing orders." Either way, the procedure and its proper use should always be identified in the system's written medical protocols, to reduce as much as possible the need for (and dangers of) on-the-spot protocol development.

The structure and management of on-line medical control systems should be determined by the off-line QC system. That is, as an important component of the EMS system, the on-line control should be no less subject to off-line review and control than any other element of the prehospital care system. Surprisingly, in many EMS systems, on-line control is actually exempt from off-line authority. And in some EMS systems, the on-line control system is the off-line control system!

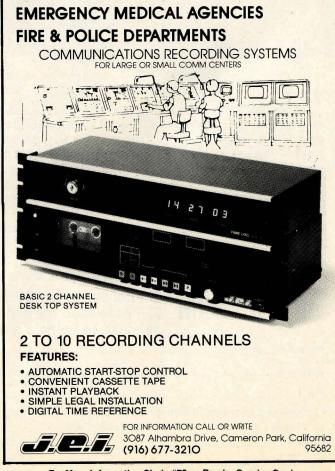
Today, there are three basic models for structuring on-line medical control: 1) centralized, in which all on-line medical direction

is provided by a single medical facility; 2) decentralized, in which on-line control is provided by a network of hospitals working under common operating procedures; and 3) laissez-faire, in which on-line control is provided by multiple facilities with limited or nonexistent operating procedures.

Of these three models, "laissez-faire" is by far the most common and by far the most dangerous. Under this model, physicians and sometimes even nurses at receiving facilities, regardless of their qualifications or knowledge of the prehospital care system, routinely direct patient care in the field. Usually, the only "rule" in such systems is that medics should contact the hospital to which they believe the patient should be delivered.

Experienced paramedics faced with such systems often, and understandably, engage in "doctor shopping." That is, coming on duty, they check to see where the "good docs" are working — those most knowledgeable of the system and its protocols — so that, in a critical





situation, they know where to call or where not to call.

Laissez-faire systems experience an unusually high frequency of communications-system failures as medics try to protect their patients from faulty orders: ''I'm sorry, Doctor...(crackle, hiss created by rubbing microphone on shirt)...your communication is garbled.'' The laissez-faire model places everyone at risk — especially the patient — and is a gold mine for plaintiffs' attorneys.

Either of the other two models of on-line control, i.e., centralized and decentralized, can work very well. The advantages of the centralized model are easier administration and less expensive communicationssystem requirements. Its disadvantages are reduced involvement and familiarity with the EMS system by the personnel of acute care facilities throughout the service area, and a tendency to evolve into "medical fiefdoms" - i.e., EMS systems ruled for years by a single physician personality who sometimes becomes so closely identified with the EMS system that even the appearance of objective oversight is abandoned.

The advantages of the decentralized model are increased involvement and familiarity with the EMS system and its people by healthcare professionals throughout the community, and an automatic antidote to the "medical fiefdom." Its disadvantages are more complex administration and more expensive communications-system requirements.

Regardless of whether the centralized or decentralized model is employed, physicians wishing to participate in on-line medical control should be specially trained and certified on EMS system protocols and communications procedures, and their performance should be subject to the same level of off-line review and evaluation as that of ambulance crews, first responders, and control-center personnel.

Whose Patients Are These, Anyway?

To establish a truly effective offline medical QC structure, one must first recognize that EMS patients are hospital patients, and that the prehospital care system is only an extension of hospital-based physicians. Emergency physicians receive our patients, examine our patients, evaluate our work, and sometimes correct it. They are in a unique position to assess our performance. The patients we bring them are their patients, not ours.

In every EMS system I have worked to develop, responsibility and authority for off-line medical QC have been somehow legally vested in a "medical control board" made up of physicians from acutecare receiving facilities throughout the community. In every case, the legally constructed powers and duties of the medical control board extend over all aspects of the prehospital care system affecting patient care.

For example, the following list of duties is taken from actual contracts and ordinances governing off-line medical QC services:

General Scope of Work — As provided for by City/County ordinance, the Medical Control Board shall develop standards governing every



aspect of the EMS System affecting patient care, and shall monitor compliance with those standards by the various individuals and organizations involved in the delivery of EMS throughout the City/County, and shall recruit and retain the EMS system Medical Director, who shall serve at the pleasure of the Medical Control Board. Such standards shall include:

- 1. Medical protocols;
- 2. Priority dispatching protocols, telephone protocols, and prearrival instruction protocols as appropriate for ambulance services, first responders and wheelchair transport services.
- 3. Transport protocols (air and ground);
- 4. Equipment and supply standards for ambulances, first responder units and wheelchair transport units:
- 5. Standards for training, testing, and certification of ambulance crews, first responders, wheelchair transport crews,

- dispatch personnel, and on-line medical control personnel;
- 6. Protocols governing on-scene control of patient care;
- 7. Procedures for the conduct of medical audits:
- 8. Communications-equipment standards for facilities engaging in on-line medical control;
- 9. Standards of due process governing the suspension or revocation of an EMS license, permit, or certification; and,
- 10. Such other standards as may be necessary to ensure reliable patient care.

Long Term Responsibilities - The Medical Control Board's ongoing responsibilities shall include the following:

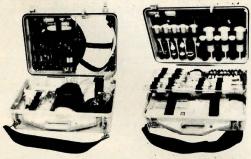
1. Annual Review and Revision of Protocols. The Medical Director shall annually complete a comprehensive review of all written protocols of the EMS system, including medical protocols and transport protocols. Such review shall take into consideration the results of medical audits conducted throughout the year, a review of the EMS literature regarding new

findings which might impact protocol revision, and input from field personnel and interested physicians. It shall be permissible for selected protocols to be reviewed each month during the year so that all protocols will have been subjected to formal review during each 12-month period. Prior to implementation of any protocol change, the Medical Director shall require completion by all affected personnel of an approved in-service training module regarding that change, including testing procedures if appropriate.

2. Personnel Certification Program. The Medical Control Board shall develop, implement, and periodically revise as appropriate a local personnel certification program for the following types of personnel: first responders, ambulance personnel, control center personnel, and online medical control physicians.

3. Equipment Inspections. Using an inspection checklist and documentation form approved by the Medical Control Board, the Medical Director or his designee shall periodically inspect the on-board

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medical equipment on all EMS first response vehicles and ambulances operating within the City/County.

4. Medical Audit Process. The Medical Director shall conduct or cause to be conducted medical audits of EMS system performance in regard to specific cases as follows:

- a) Whenever an audit is requested by a physician involved with an incident, or by a patient's personal physician;
- b) Whenever a paramedic certified by the City/County requests that an audit be conducted of a case in which that paramedic was involved;
- c) Whenever an audit is requested by a member or board member of the Medical Control Board;
- d) Whenever an audit is requested by the EMS Authority;
- e) Whenever the Medical Director has determined that an audit is in order.
- 6. Due Process Requirements. Subject to approval by the City/County Attorney, the Medical Control Board shall develop and adopt standards of due process prerequisite to

the issuance of a recommendation by the Medical Director for the suspension, revocation, refusal to renew, or refusal to initially issue a personnel certificate or vehicle permit.

7. Annual Report. The Medical Director shall annually present to the Board of the EMS Authority a written and oral report concerning the clinical performance of the EMS System, its deficiencies, its progress, and its future.

Extent of Authority

As you can see, the power of the medical control board is extensive. At the local level, such authority comes from and ultimately rests with the elected officials whose ordinances and contracts originally create the EMS system structure. Thus, all such regulatory bodies are, in a sense, "advisory" to elected officials. This does not mean that the city council or county commission must approve every decision by the medical control board. The following language, in ordinances and contracts, handles the problem:

Option to Review and Revise. The City Council/County Commission may require a public hearing regarding any standard proposed or adopted by the Medical Control Board, and thereto may amend, alter or revoke any standard, rule or regulation of the Medical Control Board, before or after its adoption. The collective protocols and standards adopted by the Medical Control Board shall constitute the "Rules and Regulations" which govern the operation of the EMS System.

Creating the Medical Control Board

The process for creating the medical control board, and even its official name, differed in various communities. Depending upon applicable state statutes as well as local history and preferences, a specific regulatory structure was necessarily tailored to fit each situation.

The following language is taken from actual contracts and ordinances developed by our firm to set up medical control structures:

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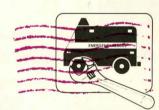
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A. Establish Foundation. There is hereby established an Emergency Physicians Foundation whose membership shall consist of the physician directors, or their physician designees, of the emergency departments of those acute care receiving hospitals which choose to participate in the Foundation.

B. Foundation Directors. The membership of the Foundation shall periodically, in accordance with the Foundation's bylaws, elect from among its membership six physicians engaged in the full-time practice of emergency medicine to serve on the Foundation's seven-person board of directors. The seventh member of the board shall be a licensed physician appointed by the County Medical Society and shall serve at its pleasure. The board of directors shall elect its officers, select the EMS system's Medical Director, and generally conduct the business of the Foundation.

C. Medical Control Board. The

Foundation's board of directors shall also serve as the Medical Control Board of the City/County EMS System.

Funding External Medical Quality Control

A number of the ALS systems we helped to create operate with little or no local tax subsidy. Thus, we were forced to develop a mechanism for funding the costs of external OC independent of local tax support. Looking to other industries for ideas, we noticed that the costs of regulation in many industries are actually included within user fees. For example, in many states, construction permit fees paid by contractors cover the costs of govern mental inspection. Thus, the costs of regulation are included within contractors' prices.

Borrowing the concept, we have incorporated within EMS ordinances a special per-transport "franchise fee" to finance the cost of medical QC. For example, Section 6.31 of the EMS ordinance we developed for the City of Fort Worth, Texas reads as follows: "A

fee of three dollars per ambulance run shall be charged and collected by the operator (i.e., provider), which sum shall be paid to the Emergency Physicians Advisory Board (i.e., Fort Worth's medical control board) to defray the costs of medical regulation of the [EMS] system."

In Forth Worth, this "franchise fee" raises approximately \$100,000 annually for medical QC purposes. In the newer and larger Pinellas County, Florida system, a similar provision will soon raise approximately \$250,000 annually for medical QC and EMS research.

Conclusion

I do not deny a strong personal commitment to placing medical control of EMS systems under the firm control of the very physicians whose patients we serve. While specifics must be tailored to fit applicable state statutes and local preferences, the objective of broadbased physician control over the prehospital care system can and should be achieved in every community.

