CHARTING THE PATH *of Clinical Progress*

Clinical progress in an EMS system requires either improving the system's compliance with its existing *system standard of care* or improving the system standard of care itself. Every well-structured EMS system incorporates features designed to ensure that street performance does, in fact, match the system standard of care, and that new technologies and beneficial clinical innovations are routinely incorporated in a timely and prudent manner. The following describes a generic process similar to those governing clinical progress in high-performance EMS systems.

The Quality Control Structure

Objective, expert, authoritative and physician-controlled *external* medical quality control is the absolute cornerstone of a sound prehospital system design. Ideally, a medical control board of some form is established by statute or ordinance to serve as the highest level of authority over every aspect of the EMS system that affects patient care. Often, this board consists of the medical directors (or their physician designees) of acute care receiving facilities throughout the medical trade area served by the EMS system.

Basic responsibilities of the medical control board include appointing a single medical director for the entire EMS system and establishing and updating the system standard of care. The medical director's authority extends over every system component affecting patient care (e.g., ambulance services, first-responder agencies, control center operations, on-line medical control, etc.). (See "Organizing and Funding Quality Control in EMS," March 1988 *JEMS* and "Medical Control and Medical Direction," December 1988 *JEMS*.)

Acting through its medical director, the medical control board establishes and periodically revises the system standard of care, and monitors and enforces compliance with that standard.

The system standard of care is the written body of standards and policies governing clinical aspects of the EMS system. As used in this context, it is a comprehensive term including:

Input standards, which include personnel certification requirements, in-service training requirements, equipment specifications, on-board inventory requirements and other requirements that the system must fulfill *before* receipt of a request for service.

An idea only becomes a suggestion when it's written down and submitted.

Performance standards, which include priority dispatching protocols and pre-arrival instructions, medical protocols, standing orders, response-time standards and other performance specifications describing how the system should behave *upon* receipt of a request for service.

Outcome standards, which include target survival rates for certain narrowly defined presenting problems or presumptive diagnoses, such as witnessed cardiac arrests involving patients whose medical histories meet defined criteria. Outcome standards are results the system intends to achieve by meeting its input and performance standards.

When the system's actual performance is not in compliance with its performance standards, corrective action usually requires modification of, or better adherence to, the system's input standards, or clarification of the performance standard in question. For example, repeated incidents of failure to properly immobilize a certain type of potential spinal cord injury may indicate a deficiency in pre-employment training, in the initial certification or recertification process, in the in-service training program, in the way in which the protocol itself is written, or some combination of these deficiencies.

Failure to comply with a performance standard may be a signal that input standards are lacking. Of course, where such chronic failure involves only a single crew or individual, correction may be limited to individualized remedial training or disciplinary action.

Outcome standards require an ability to conduct ongoing, valid clinical research, and are valuable tools for validating and improving performance standards. They may also indicate a pattern of failure to comply with existing input standards.

Until recently, outcome standards in EMS were focused almost exclusively on measures of mortality. In other sectors of the health-care industry, outcome standards also relate to measures of morbidity (e.g., rates of infection following specific types of surgery). As the EMS industry matures, outcome standards related to both morbidity and mortality will be increasingly used to define and improve the system standard of care, and to prove the worth of the EMS system itself.

Changing the Standard

While numerous workable variations also exist, the following process, depicted in Figure 1, can help to ensure the steady and orderly evolution of your system standard of care.

Progressive EMS systems are constantly looking for ways to improve compliance

with the existing system standard of care and for opportunities to advance the standard itself. The initial impetus for clinical progress can come from anyone who cares enough to become a reliable observer of the system in action and a student of clinical developments throughout our industry.

Whether an idea comes from a research paper in a professional journal, an advertisement, an informal conversation with a medic from another system, a personal experience in rendering patient care or as a result of a medical audit process—and regardless of whether the idea comes from a system status controller, an EMT, a paramedic, a manager, a physician or the medical director himself—an idea becomes a suggestion when it's written down and submitted as a standard of care suggestion. Until then, it is merely an idea.

To ensure that every potential opportunity for improvement receives careful consideration and to provide a record that may be useful in litigation, a formal process for initiating, reviewing and implementing improvements is employed. The first step in that process is submitting some form of standard of care suggestion to the medical director.

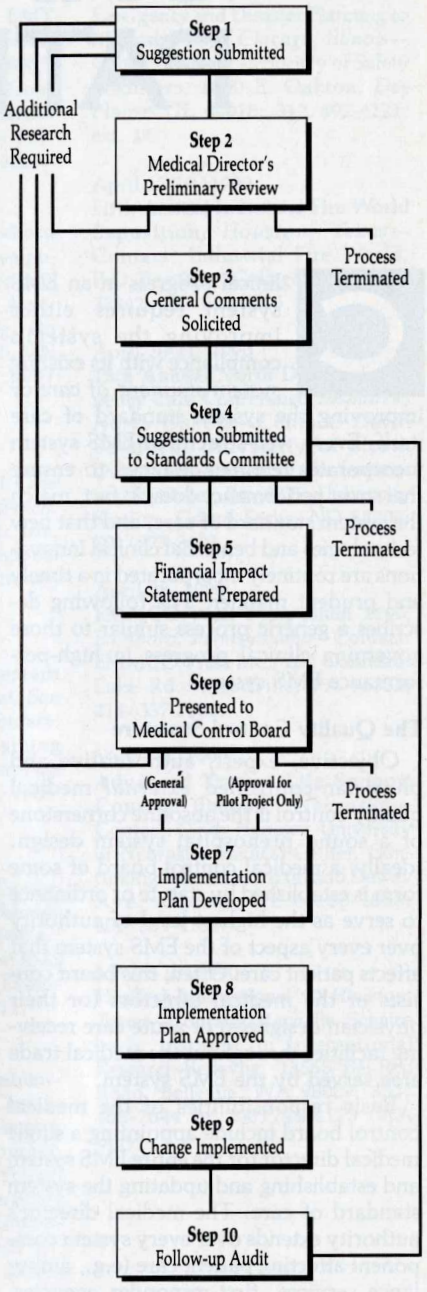
Step 1. Submit a Standard of Care Suggestion. A form may be helpful in expediting this process. In addition to the identity of the person making the suggestion, information requested may include a description of the current standard or practice and the change being suggested; the potential advantages of the change; the type of change (e.g., change to input standards, performance standards or both); the origin of the suggestion (e.g., recently published research, personal experience, local medical audit, experience of other system, etc.); a listing of other EMS systems currently using the suggested standard (with contact names, if available); a summary of related research, with references; and the objections likely to be raised in regard to the suggestion.

In addition to the original submission to the medical director, a copy of the suggestion should also be submitted to the various organizations that would be affected by the change, and a third copy should be retained by the person initiating the suggestion.

Step 2. Medical Director's Preliminary Review. Once a suggestion has been received by the medical director and, if necessary, expanded or clarified by its originator, the medical director will decide whether the concept has sufficient merit to warrant further consideration. If further consideration is justified, the process will continue. If not, the suggestion and the reason for its rejection will be documented and filed for later reference. A record of changes considered and rejected is just as important to long-term clinical progress as a record of the changes adopted.

Figure 1.

Process for Changing the System Standard of Care



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Step 3. Comments Obtained. Preliminary comments and recommendations regarding the suggestion should then be obtained in writing from the medical director and from the EMS system's executive director or business manager. Copies of the suggestion form, along with the preliminary comments of the medical director and business manager, are then sent for posting to each first-responder agency, the ambulance service provider, control center managers and the individual members of the medical control board. About 30 days should be allowed for submission of written comments by interested persons.

Step 4. Review and Comment by the Standards Committee. After the comments obtained during step 3 of the process have been received and compiled, the matter should be presented to the system's standards committee (or its equivalent) for review and comment. The standards committee, which is appointed by the medical director, usually consists of those particularly interested in clinical issues—e.g., paramedics, managers, quality control auditors, in-service training program coordinators, physicians and, in some systems, nurses.

All related documentation should be provided to the standards committee members at least 30 days in advance to the scheduled review, and the originator of the suggestion should always be invited to present the suggestion to the standards committee in person.

Before rendering a decision, the standards committee or the medical director may determine that additional information must be gathered. This information may include a more extensive review of the literature, inquiries regarding the use of the proposed standard in other EMS systems (by telephone, in writing, or by site-visit observation), demonstration by a product manufacturer and direct examination of a purchased sample product. Taking into consideration the standards committee's findings, the medical director must then decide whether the process shall be terminated or continued.

Step 5. Financial Impact Statement. If the suggestion merits further consideration, the next step is to compile a financial impact statement regarding the projected initial and ongoing marginal costs of implementing the proposed policy change.

The financial impact statement should be developed under the direction of the EMS system's business manager. Every provider organization whose financial obligations would be affected by the proposed policy change should be contacted and asked to supply a financial impact estimate with supporting documentation and rationale.

The method of cost analysis must, of course, depend to some extent on the nature of the policy change in question. However, every financial impact statement should include training, equipment, administrative and other costs, along with the effects of the policy change on fee structures and/or subsidy requirements.

The financial impact statement should also include a description of how these costs would be financed (both start-up and ongoing), a summary of the short-term and long-term impacts of the proposed policy

change on ambulance rates and/or subsidy requirements and the business manager's official comments regarding the proposed policy change.

Step 6. Presentation to the Medical Control Board. When the previous steps have been completed and the exact language of the proposed amendment to the system standard of care has been developed, the suggestion is ready for presentation to the medical control board. Following the medical director's presentation, the business manager should present the financial impact statement. The person initiating the suggestion should be offered an opportunity to address the medical control board.

All related documentation should be made available to the medical control board members at least 30 days in advance of the scheduled meeting. Unless additional information is required by the board before voting on the matter, it can then vote to determine whether the proposed policy change shall be adopted or rejected.

The policy change may be adopted for general implementation (i.e., systemwide) or on a pilot-project basis (i.e., short-term testing limited to selected personnel). The effective date of the policy change should be established by the medical director on approval of the implementation plan (see Step 7). If the policy change is adopted on a pilot-project basis, on completion of the pilot project, the results should be reviewed by the standards committee and the medical control board prior to deciding on general implementation.

Step 7. Development of the Implementation Plan. The EMS system structure should specifically assign responsibility for coordinating implementation of changes in the system standard of care to a single qualified organization. Once a change in the system standard of care has been approved by the medical control board, the designated organization should begin developing the implementation plan. It is the responsibility of that organization to coordinate development of the plan with all affected organizations. The implementation plan should include the following basic elements:

Rationale—This section should contain a concise statement explaining the current policy, the policy change and the rationale behind it.

Equipment/Supply Acquisition and Distribution—If the policy change requires the addition or replacement of equipment or supplies, this section should describe the items and quantities to be acquired (brand names, specifications, suppliers, etc.), the method and timing of acquisition and distribution, and the cost and means of disposing of equipment or supplies on hand that will be rendered obsolete by the policy change. When such costs are substantial, the implementation schedule may be timed to reduce inventory losses.

Prerequisite Training—This section describes the program of training to be completed by all affected personnel *prior* to the effective date of the policy change, including follow-up training of people who were unavailable during the initial training sessions and remedial training for those who initially fail to demonstrate competence. This section should also describe any related training to be required of new personnel for initial certification to work in the local system.

Behavioral objectives, instruction length and content, methods and materials, instructor qualifications, training sites and dates should be described. Depending on the nature of the policy change, the training involved may be as simple as a mailed and posted memorandum, with provision

for acknowledgement by individual personnel, or as formal as instruction sessions incorporating both didactic and practical components.

Evidence of Competence—When appropriate, the plan should also include a section describing the method whereby the effectiveness of the training program will be individually assessed. Depending on the nature of the change, such evidence may range from a brief written test administered at the end of training to written and practical testing administered under the medical director's supervision, possibly with follow-up testing to assess retention. If applicable, this section should also address the addition of related testing features prerequisite to certification of new personnel and for recertification purposes.

Implementation Schedule—This section should include a comprehensive schedule of the implementation process through the effective date of the policy change, and follow-up auditing when applicable.

Follow-up Auditing—For cases in which a new policy involves a substantial change in patient-care procedure, immediate follow-up auditing of a sampling of incidents in which patient care was (or should have been) affected by the policy change should be done. The purpose of this, of course, is to identify and correct flaws in the new policy or in its application as quickly as possible after implementation. This section should describe the follow-up auditing process to be employed, if any.

Step 8. Approval of the Implementation Plan. When completed, the draft implementation plan is then submitted to the medical director and, if appropriate, revised as directed. When approved by the medical director, the plan is ready for implementation.

Step 9. Implementation. When the implementation plan has been implemented to the satisfaction of the medical director, the change in the system standard of care becomes effective.

Step 10. Follow-up Auditing (Optional). As discussed under Step 7, follow-up auditing of a sampling of incidents that involve (or should involve) application of the new policy may be conducted. As a result of this process, corrective action may be required.

Conclusion

The above-described process is designed to promote consideration of potential improvements in the system standard of care, to ensure that clinical progress occurs in a timely and prudent manner, and to provide a documented record of your EMS system's clinical evolution. ■

This article was adapted from the book, High Performance EMS Systems (HPEMS) *by Jack L. Stout, to be published by Jems Publishing Company.*

Jack Stout has been at the forefront of innovations in the design and implementation of EMS systems for the past 12 years. If you have a question, problem or solution related to the public/private interface in prehospital care, address your letter to: ***Interface*****, P.O. Box 1026, Solana Beach, CA 92075.**