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Development of a Medical Operations Manual for the Pinellas County EMS System

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Establishing or revising prehospital EMS treatment protocols, a term we will consider inclusive of standing orders and standard medical operating procedures, provides a system with the opportunity to make significant changes in its field operations and medical control programs. The following paper will outline the philosophy and process used for a major protocol revision in the Pinellas County EMS system. This paper represents our review and comments in hopes of further improving the protocol revision process. This experience may be useful for other systems to consider in similar efforts.

Pinellas County EMS is a county-wide taxing authority and administrative resource to a metropolitan EMS system with seventeen first response ALS agencies and three ALS ambulance response agencies. This system directs the actions of approximately 385 paramedics and hundreds of additional EMT's under the control of a medical director and two associate medical directors retained by the EMS authority. In 1986, Pinellas County EMS responded to over 68,000 emergency calls.

Many problems in earlier editions of the Pinellas protocols were probably a result of the way in which the system had developed. Prior to the county-wide system, EMS providers functioned independently within their own districts. Approximately 30% of the County was then without ALS coverage. The quality of care varied considerably. Following successful passage of a referendum to create the county-wide EMS authority, an effort was made to provide a county-wide standard of care. The number of ALS provider agencies grew from twelve to twenty. Due to this rapid growth and persisting lack of a county-wide continuing education program, there was and still is considerable difficulty providing educational programs or materials in an appropriate fashion throughout the system. Consequently, previous protocols became instructional documents with directions on how to perform procedures, rather than becoming a set of concise clinical policy guidelines. For many paramedics, the protocols were their only encounter with medical control, aside from radio contact with the receiving emergency department physician.

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After their original implementation, the protocols expanded from time to time, but often at the sacrifice of clarity and consistency. For example, reprints were included that recommended drug dosages in conflict with the protocols to which they were attached.

Many of the paramedics had developed dissatisfaction with the protocol document. In March of 1986, the authors of this article, both field paramedics, made a formal proposal to the medical directors for an extensive revision effort. The proposal outlined rationale for a new style and format that would attempt to clarify objectives and remove many of its inconsistencies and ambiguities that had developed over the years. A draft set of reformatted protocols were submitted by the authors using the proposed format as illustration of how they might appear in final form. Shortly after that proposal was submitted, a protocol subcommittee was formed by the Pinellas Advanced Life Support (PALS) group. The protocol committee has delegates from many of the fire department first response agencies and ambulance companies, including several field paramedics.

The philosophies and format contained in the original proposal were presented to the committee. This was followed by considerable debate and modification, but the key elements of the proposal were retained.

PROTOCOL PHILOSOPHY

The protocol committee engaged in an rather extensive series of debates regarding the philosophy that would be most appropriate to the document. One of the first issues in these debates led to an agreement that protocols cannot and should not be viewed as a remedy for all medical control and training problems. The protocols should be considered as but one component of a prospective medical control program. Further, the protocols must make some realistic assumptions about the clinical expertise and competency of its field paramedics. Pinellas County EMS, probably not unlike most other agencies, has a wide spectrum of clinical competency amongst its field personnel. Without immediate means to upgrade those at the lower end of this spectrum, it was necessary to aim the degree of clinical latitude in the field towards a lowest common denominator. As training improves, this factor may be adjusted appropriately in future revisions.

The second major issue in these early protocol philoso-

phy debates lead to the conclusion that the protocols should not be teaching documents. They should instead be concise clinical guidelines which specify what procedures may be performed under given sets of circumstances. Training was a separate issue and needed its own solutions apart from what the protocols might offer. It was also recognized that a protocol can not be written for every possible combination or permutation of clinical circumstances. The trauma patient with a cardiac history and instances where one dysrhythmia converts to another are just some examples that do not fit in any one protocol. The clinical judgement of the paramedic must be used to successfully integrate and tailor care for specific patients. Physician consultation is encouraged, but we recognized that it isn't always practical or immediately available when a decision must be made.

The third major issue concerned the format in which each protocol should be presented. The debate established that each protocol subject would provide both adult and pediatric sequences. The adult sequence would be immediately followed by the pediatric sequence. Despite the redundancy in this approach, it seemed to be advantageous over the potentially complicated conditional statements in the original proposal that considered age and/or body size with a single treatment sequence. The format of both the adult and pediatric sequences were divided into two sections, fitting the way in which paramedics must operate in the field. Part I has actions authorized prior to physician contact and Part II consists of actions to anticipate or request with physician contact. This eliminated previous ambiguity over where such lines were drawn. However, considerable debate ensued over a proposed Part III section in which selected or alternative items from Part II may be carried out if physician contact was not possible or practical. This formatting was based in part on protocols published on the Hillsborough County EMS system (1). The Part III section was dismissed in favor of adopting a policy in which paramedics may initiate Part II orders independently, but must make explicit justification of those decisions in their run reports. Any run reports with paramedic initiated Part II orders or other protocol deviations will be flagged to receive special audit by medical control. This puts an additional emphasis on the need for quality documentation by field personnel and thorough audit procedures by medical control.

As a final preliminary step, the protocol committee reviewed the previous standing orders and those from other systems in its consideration of a table of contents. The items included in the new table of contents (Table 1) were separated into four sections - I. Administrative Protocols, II. Treatment Protocols, III. Procedure Manual, and IV. Drug Summaries.

The Administrative Protocols, Part I, cover issues such as transport destination protocols and on-scene medical command.

Treatment Protocols, Part II, include the working diagnosis and/or symptom based procedures for field care.

The Procedure Manual, Part III, was created to fill a limited need for instructional resources in this document. The introduction of the protocol document states the intent to avoid a role as an educational resource. Instead, the system would adopt texts listed in Table 2 as standard references. However, there are areas in which these standard resources conflict with each other, offer more than one method for a specific technique, or do not include procedures or policies for items the protocol committee wanted to include in the document. The procedure manual was designed to provide an educational reference for such cases. It includes discussions on local legal issues with clinical procedures for blood alcohol sampling, use of aerosolized bronchodilators, and clarification on titration of supplemental oxygen therapy with COPD patients and many other topics.

The Drug Summary section, Part IV, provides a concise description of each drug and how it is to be used specifically in the Pinellas system.

METHODS

Once these preliminaries were resolved, the work of writing drafts for each section were divided amongst the protocol subcommittee members. Each draft was to consider the standard resource texts, review of other specialized texts, recent articles in medical journals and similar protocols from other systems. In several cases, computerized searches of a medical literature data base (Medlars) was made to assist in getting the most contemporary information or to attempt to resolve controversies on specific items. The intent was to build a set of protocols based on published and referenced medical literature. The validity of the protocol then has a verifiable basis in the event of any litigation that might take issue with the protocols themselves. Further, it sets a valuable precedent that a protocol revision in this system must have a solid basis in published medical literature rather than just the opinions of the medical directors without external verification. It should compel the system to make careful review of the medical literature.

As each first draft was presented at protocol subcommittee meetings, it was subjected to very intense peer scrutiny. This process seemed to be a bit awkward at times for the person presenting the draft. However, it established an open attitude for constructive criticism. This was a crucial part of our protocol development process. After the first several drafts were reviewed, a consensus and understanding amongst the committee quickly developed that encouraged a very brief and concise format and allayed the apprehensions of those presenting the first drafts. The constructive feedback of the committee was used to write the second draft for each protocol.

To avoid frequent redundancies in each protocol with primary and secondary survey, ECG monitoring, IV lines,

DISCUSSION

The most effective part of our protocol development process was the open debate amongst the committee members. This must be done in an environment that encourages constructive criticism. It would seem advantageous in these sessions to present proposals and alternatives in treatment that are a bit unconventional or previously not considered to be a part of field EMS care. This encourages the debate to include serious consideration for a wider range of possibilities and potential innovations. For example, many of our committee members had initially rejected the idea of inhaled bronchodilators as an alternative to intravenous agents. Their skepticism seemed to be on the basis that it was very different from what we had done in the past and that medical director acceptance would be unlikely. However, the use of inhaled bronchodilators was finally accepted by the medical directors on the basis of our presentation of clinical rationale, supporting research literature and positive opinions from consulting specialty physicians.

The consultation of specialty physicians was extremely valuable. It must be recognized that any EMS medical director has very limited exposure to developments in all areas of critical care medicine, even under the best of circumstances. One of the best sources of information and critique are the specialists who deal with critical care problems in their particular area of expertise on a day to day basis. Based on our experience, the participation of specialty physicians should be sought in as many protocols as possible. We had sent each of the consulting specialty physicians the entire protocol package with a cover letter that explained what areas we would like them to address. It was important to send the entire package so that the items the specialists would consider could be put in proper context. Their responses to the committee were in the form of telephone conversations and notes written on copies of the document itself. In future efforts, each consulting specialist should be encouraged to present their findings to the committee in person. This would provide an opportunity to more thoroughly discuss the treatment options and controversies. The consulting specialists should also be asked to provide bibliographic citations whenever possible in support of any specific recommendations. The citations will give the protocol document a better medical/legal foundation in the event of any litigation. This was done to only a limited extent in these protocols. Further revisions should include a more complete bibliography.

It may be appropriate in many cases to have more than one specialist provide comments on the same protocol. An added benefit to specialty physician participation was the chance to educate them about our EMS agency, its protocols, and the professionalism we are striving for in our medical operations. Support amongst the attending physicians of the community is extremely valuable to any EMS system.

Another part of our protocol revision process utilized two computer information networks, CompuServe® and Mnematics Videotex®, to access medical special interest groups. These electronic communications networks include thousands of clinicians around the U.S. and abroad liked together via telephone modems and personal computers for the exchange of ideas and information. The networks also facilitate access to various medical data bases and on-line libraries. Several of the Pinellas County protocols and specific questions about treatment modalities were presented in these computerized medical forums. This feedback had provided the committee with excellent information from other specialists, emergency physicians and paramedics across the U.S and Canada. This resource should be used to a greater degree in future efforts. In lieu of face to face meetings, an on-line conference with several parties across the country or locally may be easily facilitated via the computer network.

The format of the protocols draw a line between what may be done with and without physician consultation. This line should be drawn on the basis of the difficulty in clinical decision making and risk/benefit ratio for each step. The overall clinical skill of the paramedics, their continuing education and medical control support programs should weigh heavily in deciding what the independent clinical decision making capability of a systems paramedics are. The fragmented nature of the Pinellas County EMS system, with eighteen ALS provider organizations and three private ambulance companies, makes skills evaluation, continuing education and medical control extremely difficult. Consequently, the lines where physician consultation is sought are set conservatively. However, as this system develops better evaluation, education and medical control programs, these lines may become a bit more liberal. There may be a possibility for individual paramedics or provider agencies within the system to obtain more clinical privileges based on favorable clinical evaluations and educational program participation. This could be an incentive used by a system to encourage higher levels of clinical performance, documentation and continuing education.

Considerable thought and debate led to the format and consensus in philosophy of the Medical Operations Manual. In the months since its implementation, some revisions have already been made. However, any substantial change to a protocol should undergo the full process academic scrutiny, debate and bibliographic research. There will be temptation to modify protocols in response to problems are not with the protocols, but are related to poor protocol orientation, continuing education or other medical control procedures. Disrupting the format and philosophy of the protocols not only weakens the document, but usually fails to solve the immediate problem. Protocols are only one of many parts of a medical control program with prospective, on-line, retrospective and feedback components.

A program to monitor the medical literature for potential

protocol innovations would be desirable and could form the basisfor an EMS research program.

SUMMARY

Protocols are a single component of a medical control program. They have a dramatic effect on the way in which care is delivered in the field. It is appropriate and beneficial to have selected field paramedics participate with their medical directors and specialty physicians in the protocol development and revision process. A major revision of the Pinellas County EMS protocols utilized paramedics as the primary authors of protocol drafts which where then subjected to specialty physician commentary. The EMS system medical directors were then presented a protocol draft supported by field paramedic input, medical literature references and the comments of consulting medical specialists. This established a valuable precedent in our system for future protocol revision efforts. Maintaining and improving the precedent of academic and clinical quality is an important responsibility of the protocol committee. By establishing a structured framework which includes the most current standards of field care, the system has a state of the art set of protocols that provide the system and its medical directors with considerable protection against litigation. This entire process may be useful to other prehospital EMS systems considering protocol development and revision issues.

REFEREE COMMENTARY

William Minix, M.D. (Associate Medical Director, Pinellas County EMS; Emergency Department, Palms of Pasadena Hospital) - The authors do an excellent job of describing development of the current M.O.M. (Medical Operations Manual) of the Pinellas County EMS System. Hopefully, this will aid other other systems in their efforts to standardize and improve their protocols.

In a larger perspective, this collaboration between paramedics and physicians to produce a unified and enlightened approach to pre-hospital management is reflective of a healthy recognition of the importance of the paramedics' unique perspective and facility in dealing with these most critical patient situations.

The professionalism of paramedics in this system is enhanced by the uniform and county-wide nature of these protocols as well as the rigorous approach of requiring multiple physician input and bibliographic citation, which will be expanded in subsequent revisions.

Finally, paramedics in this county are in a unique position to function in what is rapidly becoming a "state of the art" system. They are being called upon not only to assimilate innovations such as a trauma center, helicopter and new standing orders, but also to become an integral participant to "complete the feedback loop" by keeping medical control informed of how the standing orders are actually working in the field, how they can be better implemented, and how they can be improved.

Vaughn Whitehead, BA, REMT-P (Senior Paramedic, Hillsborough County EMS; Instructor, Hillsborough Community College) - EMS protocol development is an arduous but absolutely essential process for any prehospital EMS system. Having been involved with the protocols for Hillsborough County EMS since their inception in 1977, I am well aware of the plethora of problems inherent in their creation.

EMS is no longer the proverbial "babe in the woods," so reviewing protocols from other systems can prevent reinvention of the wheel.

Prior to the first words being written, the format and scope of the protocols must be determined. I believe it is a mistake for any protocol to attempt to address all situations. A certain amount of leeway must be left for discretionary treatment by the paramedic. Also, no protocol manual should attempt to be a training manual except when certain procedures need to be defined. A paramedic should not have to be reminded how to intubate by reading the protocols.

The use of committees for creating and review of each draft will provide a well rounded and error free document. Using few viewpoints will result in a protocol that will require rewriting in a very short time.

Since a treatment protocol manual is a medical/legal document, referencing is, for obvious reasons, mandatory.

It is obvious that Pinellas County has made an exemplary attempt to avoid the many pitfalls inherent in the production of medical protocols, and I commend you.

Francis E. Toscano, M.D. (Emergency Department, Morton Plant Hospital) - Paramedic protocols exist in nearly every city in the United States. Usually they are written by the medical director of the EMS system with input from physicians who specialize in emergency medicine, cardiology and trauma surgery. The protocols are then dictated to paramedics who are intimidated by the "expertise" of these authors and are forced to accept algorithms that can, at times, prove unworkable in the field.

The protocols described in this paper may prove to be far more practical, simply because they are written by paramedics who understand intimately the problems inherent in executing a complicated algorithm in the street.

The easy way to develop EMS protocols is to write the EMS directors of several major cities and request copies of their own protocols already in use. A few minor alterations here and there and, presto, you have new protocols. The method described by the authors of referring to the primary sources is far more painstaking but also far more valid. Their concern with litigation is a valid one. In today's legal climate, the county EMS system represents a very deep pocket waiting to be tapped by dissatisfied patients. The method by which these protocols were generated may help protect the County in some future litigation.

I congratulate the authors for reporting in detail their methods. Other EMS systems would be wise to follow suit. I now anxiously await the opportunity to view the results, the protocols themselves.

Mr. Gunderson's Response - I appreciate the time taken by the referees to review our paper. I think Dr. Minix brings up an important point regarding collaboration between paramedics and physicians. Their clinical and academic backgrounds can be very complimentary. I am glad to hear that the Pinellas system will be

expanding the input and bibliographic referencing with future revisions. It may be difficult to get very many of the field paramedics to participate in the feedback loop without a forum that incorporates their direct involvement. Typically, medical control interacts with the supervisory and training staff personnel in such matters. The field paramedics need to participate more. Through regular and frequent continuing education activities such as morbidity and mortality conferences, case reviews, and journal clubs, there will be opportunities for field personnel and their medical directors to interact and critique the protocols in light of their experience and new information they extract from the literature.

Mr. Whitehead's suggestion to review protocols from other systems is a good one, particularly to get ideas on which disorders to cover by a protocol and the format by which to present them. However, unless the protocols from other systems have a bibliography, I would be hesitant to use them because the clinical rationale behind them is not always so obvious. Even the new Pinellas protocols leave much to be desired for references. I hope that the Pinellas County protocol committee will work on improving the references and perhaps use them as a part of a continuing education process, perhaps through a directed reading program. I don't want to see systems fall into the trap described by Dr. Toscano of developing new protocols on the basis of other protocols with a few minor alterations. A system must consider the least common denominator factor in the clinical competency of its personnel, the rigor of its medical audit process, and the quality of its continuing education programs in determining the degree of autonomy and discretion allowed in the field. To do otherwise is not unlike taking someone else's prescription medications. It may not suit your system - it may even be toxic.

The remark by Dr. Toscano about the all too common feelings of intimidation in many paramedics by the expertise of physicians is true. That is another reason why I suggest more interaction between paramedics and physicians in academic activities such as journal clubs and case study conferences. Get field paramedics comfortable with their medical directors, being critical readers of research papers and questioning the clinical rationale behind their protocols. Medical directors would do themselves and their systems a great service by gearing continuing education programs more like residency programs than rote memorization exercises.

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