

EMS RESEARCH
Obstacles of the Past, Opportunities in the Present, Models for the Future
By Elizabeth A. Criss, RN, MEd

“EMS still lacks meaningful data that demonstrates the effect of out-of-hospital care on illness and trauma.”

“If we enter these new practices without a plan for evaluating their outcomes, safety, and cost-effectiveness, we are doomed to developing a system that lags behind the standard of care.”

We have come a long way since the Emergency Medical Services Systems Act (EMSSA) of 1973¹ that formally organized EMS and standardized training for prehospital personnel. The goal now – as it was then – is to provide therapeutic interventions in the first 30 minutes of any emergency that will improve the final outcome for the patient. Today, in addition to providing emergency response, some of us participate in home health care or patient follow-up visits after hospitalization. In some parts of the United States, we may be the only health care available for an extended period of time due to terrain or population density. But despite this growth in size and responsibilities, EMS still lacks meaningful data that demonstrate the effect of out-of-hospital care on illness or trauma. It was not until 1991 (nearly 20 years after EMSSA) that a standardized data set for review and comparison of cardiac arrests was even established.² Now at least this one aspect of out-of-hospital care can be uniformly evaluated and patient outcomes adequately compared. This same type of information gathering exists for no other illness or injury, making system and treatment comparisons difficult and sometimes impossible.

Dr. Ron Stewart, one of the first and foremost EMS researchers, stated in a 1983 editorial that the time had come for our “initiative and innovative spirit” to solve the problems of EMS.³ He went on to say that “if our methods and techniques are not changed to conform to what is medically needed, EMS as we know it will fast fade from the medical scene.” Fifteen years have passed since Dr. Stewart published that challenge and we are only a little closer to answering the important questions that relate to system design, the effectiveness of trauma care or the impact of ALS in urban, suburban and especially rural environments.

The answers to these and other pressing questions come from research. The problem lies in the fact that some of the needed research requires us to activate an “innovative spirit” and adapt or develop new research methodologies. Presented here is a discussion on some of the problems encountered using current methodologies, opportunities that we have now and models for us to use in developing evaluations in the future.

Past Obstacles

For most people, “research” denotes a controlled environment where others carefully evaluate various components of a problem. In general, this is the traditional research model used in medicine. It can best be described as component-based, disease-specific and specialty-dominated.⁴ What this means is that (in the clinical model) research is generally conducted by experts on a specific disease process. They focus on a single treatment option and carefully control the environment to best understand results.

This clinical model, or component research, depends on the development of focused, directed questions that require collection of minimal data. Because the questions are so focused, researchers often collect data themselves or use minimal additional personnel. The research project often involves one medical specialty and is only conducted in a limited number of sites to control all the factors. Information gathered from the project is reliable and highly accurate. The desired outcome is easily defined. Given this description, it is not difficult to see how this does not translate well to the uncontrolled, multi-tasking EMS environment. Unfortunately, the use of this research model has led to inaccurate conclusions from studies conducted in the out-of-hospital environment.

An example of attempting to utilize component-based research is the “zero-time” IV study by O’Gorman et al.⁵ In this study, the authors wanted to know if starting an IV caused delays in patient transport. Their first step was to compare the success rates of IVs initiated in the field with those initiated en route to the hospital. Finding no difference in these groups, the authors concluded that in order to prevent additional time being added to a scene all IVs should be initiated en route. There is a problem with this “global” conclusion: No comparison was made of on-scene times for either group. So it is not possible to know if IVs were the cause of transport delays. By focusing on the component of IV initiation, the authors failed to account for additional patient-care activities that may cause delays. This study was widely accepted by many trauma surgeons who urged banning IVs outside the hospital.

Present Opportunities

Health care is on the verge of reform. The influx of managed care has necessitated that all of medicine re-evaluate the way patient care is provided. One of the ways EMS is meeting the challenges of a more fiscally responsible, customer service-oriented climate is by expanding its scope of services. While this may be good or bad, one thing is for certain: If we enter into these new practices without a plan for evaluating their outcomes, safety and cost-effectiveness, we are doomed to develop a system that lags behind the standard of care. We have an opportunity to develop unique, prospective research models that can provide us with the information necessary to defend our practice both medically and financially.

There are many ways to evaluate expanded-service EMS. No matter the methodology, the goal should be to develop definable outcomes and cost of services so as to determine the overall effect on society. For example, one alternative is for all system or agency providers to take on expanded-service roles. In this model, the process would begin with an evaluation to determine current system effectiveness. Since cardiac arrest is the only illness for which uniform outcome measures exist, then it is reasonable to use that as the measure of effectiveness. An article by Spaite et al. describes three basic system types that can be used in building this model.⁶

The first system is one in which the rate of survival from cardiac arrest is known and monitored. These systems have done methodologically sound research, proven their benefit and published their findings. When this type of system implements expanded service it will be able to assess the effect on out-of-hospital cardiac arrest. The information will also make possible discussions on

the cost effectiveness of system changes, especially as they relate to overall morbidity and mortality.

The next system is not sure it makes a difference in cardiac arrest. There are anecdotal reports of success but the methodologically sound, peer-reviewed research has not been done. Before these systems consider entering expanded service, they should attempt to analyze their cardiac arrest survival rate, otherwise they may make a costly leap forward at the expense of part of their community.

The last type of system is one that knows they have little or no influence on cardiac arrest; cities such as New York, Chicago, and many rural environments are perfect examples. These systems have features that make it extremely unlikely they will ever positively affect a change in the cardiac arrest rate -- including geography, population density, climate, or resource limitations. Understanding these limitations, these systems could decide that entering expanded service is the most appropriate alternative to current attempts at providing emergency care. For them, providing alternative interventions may be a more cost-effective way to manage out-of-hospital care.

Another alternative for prospective analysis of expanded service involves adding the expanded service to only a single component of an already functioning system (i.e., nurse practitioner, physician's assistant). This could be thought of as using a modified component-based research model to evaluate a systems issue. The activities of this single component would not alter the emergency response functions of the remainder of the system, but would provide valuable information about cost-effectiveness and the long-term effects of the program on morbidity and mortality. Potential "negative" consequences from the program on the system's ability to resuscitate cardiac arrest would be minimal.

Certainly the prospective evaluations outlined here could prove challenging from an implementation perspective and a society standpoint. It could be necessary for a community to give up its current form of EMS in an effort to provide better care to a broader range of society. No matter what type of system is involved in the research, we should not hurry into expanded service EMS at the expense of a group of patients wherein we have proven our value.

Models for the Future

Since component-based research doesn't fit well into the uncontrolled, multi-tasking environment of EMS, we need to begin to develop models specifically for systems research.⁴ One good thing about this type of research is that other disciplines, such as engineering, behavioral science and epidemiology, have already designed models that we may be able to modify or replicate.

Systems research is multidisciplinary. It involves the evaluation of complex, interrelated questions that contain a variety of data elements. These data are diverse, numerous, and can be difficult to obtain with a high degree of accuracy or reliability. Unlike component research, systems research involves a large number of data collectors, and the research director is often not even involved in data collection. The outcome parameters are equally diverse and sometimes not easily defined.

Currently, there are only a limited number of studies that have utilized a systems-based research model. The most well-known example is the “chain of survival” concept adopted by the American Heart Association.⁷ To develop this concept, researchers gathered data on a variety of EMS systems and then evaluated how the various system components fit together and affected the outcome of cardiac arrest. In this model the authors focused on numerous questions, gathered data from different locations, and used different people (not at all like the component-based model used by many “systems” researchers). This multitasking endeavor was complex and challenging but has proven valuable in educating all levels of society on how to reduce mortality from out-of-hospital cardiac arrest.

Summary

EMS research is a work in progress. There are no easy answers and no easy methodologies – but nothing worthwhile is ever easy. For some issues, the window of opportunity for necessary research has closed. On others, the window is closing fast. And for some, the window has yet to be built. Our challenge is to intervene on those issues where the window is still open and carefully craft the windows of the future.

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7. Cummins RO, Ornato JP, Thies WH, et al. Improving survival from sudden cardiac arrest: The “chain of survival” concept: A statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. *Circulation* 1991; 83:1832-1847.

(Article 2)

**A Guide to the Research Process
By Elizabeth A. Criss, RN, MEd**

Every day, EMS managers and operations personnel are required to make decisions -- decisions about equipment, levels of performance and continuing education needs. The information for these decisions ultimately comes from the organized evaluation of data, also known as the research process.

Unfortunately, the idea of being involved in any type of research brings many EMS veterans to their knees. People tend to have a preconceived notion that research is difficult, time-consuming and, ultimately, not applicable to the everyday activities of EMS. However, if future decisions regarding EMS are to be based on fact – not presumption – the reality is that EMS must incorporate research into the evaluation of protocols, procedures, medications, and equipment. Simply put, research is vital to the practice of EMS and should be fostered and supported in all agencies and at all levels.

Research can be thought of as eight organized steps designed to lead to a well-defined outcome. The first step is the formation of a hypothesis, and the last is the presentation of a final report. In between are six steps, each of which builds on the previous and toward the next. To be successful in the research process, it is important that each step is completed before moving on.

Idea Development

The first step in the process is identifying a problem or question. The source for a hypothesis could, for example, be recurrent problems with implementation of a new or existing protocol, documentation of the educational needs of the EMS agency or investigation of a manufacturer's claims about a piece of new equipment. Whatever the source, begin by writing down the idea as clearly and concisely as possible.

Now that a research topic has been identified, it's time to prepare a hypothesis for evaluation. Keep in mind that because the hypothesis forms the basis for the research, it should be a statement that can be proved or disproved using the resources within the EMS system or agency. For example, a hypothesis supporting a certain aspect of care in the treatment of penetrating chest wounds would be difficult to prove in an area with few such incidents.

While it is important to be as specific as possible when developing a hypothesis, there will be times during the succeeding steps when the hypothesis should, if necessary, be re-evaluated and revised.

Literature Review

The next step is to determine what other research has been done related to the topic. Discussions of current theories or new developments can be found in such EMS journals as *JEMS*, *Prehospital and Disaster Medicine*, *Annals of Emergency Medicine* and the *Journal of the American Medical Association*. Often, major publications can be accessed through an online computer search service. A librarian at a local university, medical school or public library can help construct a good literature search.

Additional sources for related material can be found by studying reference lists of existing articles, particularly review articles on the subject, or by searching a closely related topic. Although books

can become dated, they can be useful for finding background information or developing a historical perspective. During the literature search, it can sometimes be disheartening to find articles closely resembling the one being contemplated. However novice researchers need to realize that just because a question has been evaluated does not mean it is off-limits.

Each EMS system has operational guidelines and protocols that make it unique. Re-evaluating an existing research topic within the scope of one system is acceptable and can be beneficial, especially by providing valuable new information. Also, repeated research in one specific area can contribute to understanding and growth in all of EMS.

Once all the information gained from the literature is reviewed, it is time to review, re-evaluate and, if necessary, rewrite the hypothesis. The following questions should be asked during this period: Is the hypothesis still feasible? Is its focus too broad? Does it need to be narrowed? One common problem in research is taking on too much; the more focused the hypothesis, the greater the probability of success.

Project Design

Proper design of a project not only increases the probability of gaining useful results, but it will make the entire process much less time-consuming. If the literature review reveals several comparable studies, consideration should be given to adapting a similar project design, including outcome measures and patient-assessment techniques. Besides saving time, this enables the researcher to compare results from his study with the literature.

All research projects should be discussed with an experienced researcher, even one outside the field of medicine. Most projects involve multiple variables, and statisticians or experienced researchers can help identify possible stumbling blocks or simple evaluation techniques. The local medical control authority may be a starting point for assistance in project design, and community colleges or universities in the area will have statisticians on staff.

During the planning stage, it is also important to consider involving an Institution Review Board (IRB). IRBs review projects involving human subjects to check for patient safety and confidentiality. To find an IRB, check with a local medical center.

Planning should also include the type of study format to be used in the project. There are two general study formats commonly found in research.

A retrospective study reviews historical data and correlates observations, interventions and outcomes from these data. The information is gathered from existing run sheets or patient records. These studies are inexpensive and relatively quick to conduct, and the results can provide valuable information about system performance, patient demographics and efficacy of interventions. The weakness of a retrospective review, however, is that because data are gathered under uncontrolled circumstances, the conclusions are weak. Many researchers use this type of format to develop a historical basis for future research.

A prospective study involves the ongoing entry of patients into the research project. The patient-entry criteria are clearly defined, and the patients are followed to an established end point (e.g., admission or discharge from the hospital). While this type of project is more difficult to conduct, its conclusions are more reliable because specific, uniform data are gathered at specified intervals during the course of the patient's treatment or hospitalization. Furthermore, this type of study allows for alteration in treatment and subsequent observation of outcome for the specified patient population.

Regardless of which format is used, it is important to define the characteristics of the patient population used in the project. Be sure the criteria are clearly defined (e.g., age range and presenting symptoms). Examples and ideas for possible patient criteria can be found in the literature; using a patient population similar to those in related studies will assist in comparing results.

Another consideration is the size of the sample. The statistician or research adviser can help identify what sample size will provide adequate results. If the sample size is too small, the results may not prove or disprove the hypothesis, as it will be difficult to determine if the finding is a random occurrence or is truly significant. But remember, the more data you need, the longer the study will take to complete, and the more likely it is that the data collectors' interest will wane. Additionally, a bigger study sample and longer study will likely increase the cost.

Data Collection

Data collection is the heart of the research process. Without it, there is no study and, if done poorly, the project will be unable to prove or disprove the original hypothesis. Data collection involves the determination of data points, selection of the research team and development of data collection tools.

Data Points

At this point, the researcher should re-review the hypothesis and decide what data points may provide valuable information in proving this hypothesis (e.g., age, gender and mechanism of injury). The data points should be reviewed with the research adviser or statistician. Keep in mind that once data collection has begun, additional points cannot be added.

The list of data points should also be reviewed to determine what the information source will be. For example, if a data point is final diagnosis, will that information come from the emergency department admission record, the EMS run report or both? If some of the data points do not have a readily available source, determine what will be required to gather that information. For example, will authorization to review autopsy records or obtain long-term follow-up data from the hospital be needed? If important data cannot be retrieved, the original hypothesis may have to be re-evaluated.

The Research Team

The next step is to determine who will gather the information. In a retrospective study, one person can usually complete the data collection; a single collector eliminates the variability that

can occur with multiple data collectors. In a prospective study, however, the individuals involved in the patient's care provide some of the data.

But whether one person or many people collect the data, it is important to meet with the potential data collector(s) and review the project's needs. Feedback on this step can lead to better designs for obtaining the necessary data.

If field personnel will be used for the data collection, keep in mind that their first task is to provide patient care. Therefore, information for the study must be easily documented. This is fairly easily accomplished if the information is part of the caregivers' normal routine; compliance with the research will increase if the field data collection is simple and does not interfere with patient care. Also, look into giving collectors some incentive, such as authorship on the publication, money or school credit.

Data Collection Tools

Once all the data points are established, it is time to design the necessary data collection tools. Remember, the easier the tool is to complete, the greater the compliance.

Suggestions from research team members should be incorporated into the form. Additionally, information to be gathered in the field should be limited to one page if at all possible. However, actual form design will depend on the types of data to be collected on team member input.

It is important to meet with everyone who will be collecting data to ensure that they receive the same training in using the form.

Project Protocol

Once the hypothesis has been formulated, the literature evaluated, the size and characteristics of the sample population determined, and the data collection tools developed, the researcher must define exactly how the data collection is to be conducted (i.e., a protocol or guideline must be developed for team members to follow). Suggestions for the protocol format include using a list, flow chart or diagram to demonstrate the steps in the research process. This should be limited to one page if possible, and team members should be encouraged to post it as a reminder.

Project Time Line

Every project needs a time frame, as even the most compulsive person overlooks seemingly minor details in the development and operation of a research project. Some target points in a research project include data for submitting the project idea to the agency, projected start date, dates for field data collection, date for an interim progress report, dates for data analysis and date for final written report. Because each project is unique – and as projects develop – other targets may be identified or added.

Analysis

Once all data have been gathered, the next step is statistical analysis. Before beginning, novice researchers should consult with experienced researchers and statisticians as to the exact

procedures they should use to examine their data. Again, sources from a local university, medical school or community college may be called on for assistance.

General information that is always useful includes tables of descriptive data on the population (e.g., patient age range, mean or gender). Many of the characteristics measured from the sample population can be initially described in a descriptive table format. In some studies, this may be the only type of statistic required.

However, in most cases, additional data analysis will be needed to determine if the initial hypothesis has been proved or disproved. To facilitate discussion with the statistician, a list of questions should be prepared that are to be answered from other data. The statistician may also provide insight into additional points to consider.

Once the sample is described, it can be determined whether the research data support the hypothesis. It is important to look at the results carefully and in the context of that particular EMS system only. It is all too easy to try to extrapolate research findings to other systems. However, field conditions vary so greatly that this type of broad generalization usually does not work.

Presentation of Results

Finally, it is time to write up the results of all this hard work. If all the preparation and data compilation were done correctly, the report writing should be relatively painless. Most reports follow a simple structure:

- 1) Introduction – Discuss problem identification, focus of evaluation and hypothesis.
- 2) Methods – Discuss the type of study, population characteristics, sample size, data points collected and collection and statistical methods.
- 3) Results – Include demographic data from the sample and findings from the statistical analysis, but be sure not to infer conclusions; only report results.
- 4) Discussion – Restate the hypothesis of the research, briefly review any pertinent historical data, review results and develop a discussion on the impact of these results on the EMS agency or system involved in the study. It is important to also include a discussion of the study's limitations (e.g., the retrospective format, or problems with patient identification or compliance with protocol).

Other Points to Consider

Once a study is complete, it is a good idea to keep an active file containing anecdotes from participants or subjects as well as any obvious biases that may have developed despite a careful project protocol. These will be useful for the final report and in the development of the next research project.

Researchers are also reminded to provide feedback about the study to the research team members. There is nothing worse than working on a project only to never hear about its outcome. The team members comprise an important part of the project and should be informed of the final results.

Conclusion

Research is necessary for EMS to grow and evolve, and involvement in the process is important for all EMS personnel. Developing projects within an agency to evaluate system performance is just as important to EMS as is evaluating prehospital use of thrombolytic therapy. Growing to a comfort level with this process takes time, but if people stay with it, work with it and – most of all – enjoy it, the results will be worth it.

Recommended Reading

Stapezynski JS, Paris DM: “Conducting prehospital research.” In Roush WR (Ed). *Principles of EMS Systems: A Comprehensive Text for Physicians*. Dallas; American College of Emergency Physicians, 1990.

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Reading Smart: Discovering What the Data Do and Don't Say By Elizabeth A. Criss, RN, MEd

When a commercial says “four out of five” people agree, what does that mean? The advertiser is hoping you think it means 80 percent of all people support that particular product or idea. But couldn't it also mean something else? For instance, what if they had only asked five people for their opinions or mailed out only 10 surveys and received five responses – four people for, one against. There are many other possible combinations that could produce these numbers and still not represent 80 percent of the population. Is this wrong? It's hard to say. The best response is probably that results, like beauty, are in the eyes of the beholder.

That's all well and good for TV commercials, but this same “data torturing” can occur in medical research. Raw data generated by a project really doesn't mean anything until it's analyzed, and the tools used to analyze this information and the way data is compared determine what conclusions can be drawn. That can leave a lot of room for interpretation.

Let's say you're interested in finding the latest research on the pneumatic anti-shock garment (PASG). Flipping through the journals, you find a study evaluating the effect of PASGs on nontrauma patients. The abstract states this is a prospective study done on 300 patients during a 12-month period. The findings of the study indicate that PASGs are of little value in the treatment of nontrauma patients in the prehospital environment.

Intrigued by these findings, you read the article. The results section describes the 300 patients. You note that the study divided the patients into two groups: blood pressure (BP) > 60 mmHg and BP ≤ 60 mmHg. To assist in understanding the results, the authors include Tables 1 through 3.

Moving on to the discussion, you note the authors' conclusion: “For the majority of nontraumatic patients, the PASG is not beneficial and possibly increases mortality.” To support their

conclusion, there is a more lengthy and detailed explanation than you found in the abstract. Looking back over the information in Tables 1 and 2, you believe this to be a reasonable conclusion.

But what about Table 3? Didn't it demonstrate that PASG use in these patients reduced mortality? It did, but the authors' conclusions are still valid. It's important to note that the authors said "in the majority of "patients," not that the results applied to all patients. So, why didn't the authors make more reference to the group in Table 3?

Table 3 highlights a subgroup, patients, with a BP of ≤ 60 mmHg that was positively affected by PASG use. Sometimes groups like this are left out due to the small number of patients in the subgroup; a small sample size does not allow the authors to calculate meaningful statistics or draw any significant conclusions. Without statistics, the most the authors can do is discuss the result as a possible trend. Nevertheless, the authors should at least mention this group as a potential area for future research. Another possibility for leaving subgroups out of a discussion is that they did not support the author's original hypothesis. Although not entirely ethical, this has been done.

The point of all this is that it is important to understand that data can be manipulated. Researchers will sometimes drop patients who don't fit the desired hypothesis or support a certain position. It is important for you, the reader, to scrutinize the literature and account for all the patients. If the authors say "majority," instead of "all," find out where the rest of the population went. Be suspicious. Ask yourself if these patients were deliberately left out, or if the sample was just too small to be meaningful.

Most of the research published today is well-controlled and scrutinized by professional review panels. However, it doesn't hurt to become critical reader and ask questions.

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Table 1

All Study Participants

	Number of Patients	Number of Deaths	Percent Mortality
PASG	165	50	30.3
No PASG	135	30	22.3

Table 2

Patients with BP>60 mmHg

	Number of Patients	Number of Deaths	Percent Mortality
PASG	115	44	38.3
No PASG	102	22	21.6

Table 3Patients with BP \leq 60 mmHg

	Number of Patients	Number of Deaths	Percent Mortality
PASG	50	6	12
No PASG	33	8	24.2