

Research in EMS - Evidence-Based Medicine in EMS

Objectives

At the end of this lesson, the student should be able to:

1. Describe what evidenced-based medicine is.
2. Discuss why evidence -based-medicine is important.
3. Recognize how evidence-based medicine plays a role in prehospital care.

Case Study

You and your ambulance crew have responded to a motor vehicle accident on the highway. The accident involved a minivan and a delivery truck. The minivan was carrying one adult, one geriatric, and one pediatric patient, and in the delivery truck was only the driver, an adult male. The incident occurred when the delivery truck missed a stop sign while the driver was looking for an address and hit the minivan head on at about 15 mph. The door of the minivan, which had not been properly closed, was flung open and the adult in the minivan was ejected from the vehicle and landed on the concrete pavement.

Fortunately, the pediatric patient was in a rear-facing car seat that was properly secured. The geriatric patient, who was the driver, was wearing a seatbelt, and the airbags of the minivan did not deploy. The driver of the delivery truck was also wearing a seatbelt, but the vehicle was not equipped with airbags.

All patients were alert for their respective age groups. The pediatric patient seemed quite content with all the commotion and was happy to be examined by paramedics. The adult who was ejected from the vehicle was complaining of very painful arms as these had been extended to break the fall. There were abrasions and contusions on both hands of the ejected patient with no other injuries reported or detected. The geriatric patient was complaining of a painful back, but also stated that the pain is no better or worse than before the accident. The driver of the delivery vehicle complained of a painful shoulder from where the seatbelt restrained him.

There is another ambulance on scene along with the requisite fire crew. One of the crew members suggests that all the patients simply be immobilized on backboards as a precautionary measure, and transported to the closest medical facility while immobilized. A firefighter suggests that only the person who was ejected be immobilized on a back board. Over the course of the next few minutes, you receive several more suggestions for treatment of the patients, all which conflict on one or more levels.

You have all types of immobilization equipment at your disposal and know that not implementing spinal motion restriction can have its problems, but on the other hand, immobilizing someone unnecessarily to a backboard can also cause issues. Faced with a bit of a puzzle, as well as the threat of legal liability should you make an incorrect decision, you calmly reflect on your recent training for exactly this type of incident. The training you received is based on decades of clinical research, and has your medical director's agreement. This training combined with your own clinical expertise, quickly allows you to filter out the less optimal suggestions from your colleagues, and you give instructions to treat and transport all the patients per the latest evidence-based spinal motion restriction guidelines.

The one minute that it took you to make the decision that affects the lives of three adults and one child, as well as your professional integrity, was firmly backed up by the concept of evidence-based medicine (EBM).

Introduction

Evidence-based medicine (EBM), in short, is the reasonable use of the most current, best evidence when making treatment decisions about one's patients, while also considering patient values.¹ EBM is one of many different approaches which will be discussed in the objectives.

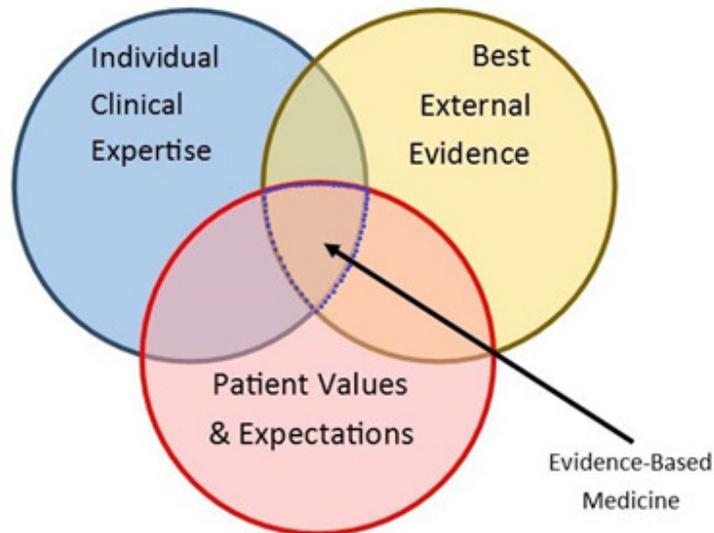


Figure 1 - Evidence-Based Medicine²

The term “evidence-based medicine” was originally introduced as “scientific medicine” in 1990 by Dr. Gordon Guyatt, a residency coordinator for internal medicine at McMaster University. Dr. Guyatt developed this concept from his mentor Dr. David Sackett who defined EBM as “the conscientious and judicious use of current best evidence from clinical research in the management of individual patients.”³ Scientific medicine was essentially a method of teaching that was presented at the patient’s bedside. EBM was not well accepted in the beginning, mostly as clinical decisions (whether correct or not), were not considered scientific. Dr. Guyatt renamed “scientific medicine” to “evidence-based medicine,” and the term was mentioned in the American College of Physicians (ACP) Journal Club editorial in 1991.⁴ The ACP Journal Club today helps physicians stay up-to-date with the most current EBM clinical information.⁵

From that point, many other people and organizations from a vast array of different medical and scientific backgrounds developed the concept of EBM. EBM aims to reduce the uncertainty of clinical decision-making at the bedside (or roadside as in the case of EMS), and to help providers make decisions based on clinical reasoning and not necessarily scientific data alone.⁶

This article will focus on only a small section of EBM, namely clinical decision-making in EMS.

Some of the more prominent cases of EBM and EMS include spinal motion restriction (SMR), bleeding control, sepsis, and cardiopulmonary resuscitation (CPR). Additionally, the following three clinical issues are also being developed using evidence-based guidelines (EBG): prehospital pain management for adults and children who have sustained traumatic injuries, prehospital treatment of pediatric seizures, and the use of air ambulances to transport injured patients from the scene.

Historically, many EMS protocols were based on the EMS pioneers' own clinical experience and often anecdotal evidence. Although well-intentioned, this led to dogmatic practices such as immobilizing anyone with even the remotest chance of a spinal injury on a spine board to giving all patients high-flow oxygen. Understanding EBM will allow prehospital care providers to better understand why protocols have done complete about-turns, and why it is important not to do something, simply because “That’s the way we always did it!”

What is Evidence-Based Medicine?

Evidence-based medicine (EBM) is simply about ensuring that any decisions made regarding a patient’s treatment are based on current and scientifically validated evidence. EBM is not dictated to EMS; it presents evidence based on questions that arise in the EMS field, and offers guidance based on research.⁷ EBM is not simply about referencing large studies, but needs to include critique, analysis, and in-depth discussion on how the study (or studies) applies to the case at hand. One might say that EBM is dynamic.

The five basic steps to EBM are: ask a question, find evidence to answer the question, analyze the evidence, make a clinical decision based on the evidence, and then evaluate the performance.⁸ The first step of asking a question or setting a hypothesis can be prompted by a need arising within a service. A need arising from within the service might be something such as which cardiac monitor to buy. Needs can also arise from external sources that are driving

guidelines such as SMR or sepsis management. The question should be clearly defined before embarking on any research. An example would be "Since we perform mostly inter-hospital transfers to and from cardiac facilities, which type of cardiac monitor would best suit these types of patients and fits within our budget?"

Once the question is asked, providers should then find the best evidence available that will help them support the answer. Both positive and negative evidence should be considered to eliminate any bias (if during the evidence gathering, one finds 20 negative articles for every positive article, that in itself is telling you something, so don't simply exclude the negatives). Given the example of purchasing a cardiac monitor for one's own service, it would be prudent to look at the history of patients transferred, and the type of procedures performed. Authoritative organizations including the American Heart Association, the American College of Emergency Physicians, cardiac monitor manufacturers, and the Food and Drug Administration will all offer guidelines, policies and give recommendations on how to treat and monitor a variety of cardiac conditions. Local requirements and standard operating procedures will also provide evidence in terms of patient care. Discussions with the hospitals that are serviced as well as allied agencies will also produce evidence to help make the decision on which monitor to purchase. The greater the quality of the source of evidence, the easier it will be to appraise.

The next step is to analyze or critically appraise the evidence. The evidence must be assessed for validity, clinical relevance, and how applicable it is to the circumstances around the question that has been asked.⁹ The quality and validity of the evidence needs to be considered during the analysis, and each piece should ideally be supported by more than one source. Providers conducting the research may be biased toward certain sources, and can tend to stop researching as soon as a source that supports this bias is found. Evidence should include sources that are both positive and negative. The appraisal can be performed within the service, by a panel, or by using any method as required.

An alternative method of using EBM effectively, in either on scene clinical decision-making or EMS research to solve higher level problems, is to use the "5 A's" process. This process gives one a different perspective to the five basic steps discussed above. The five A's are assess, ask, acquire, appraise, and apply.

"Assess" is identifying the clinical problem.¹⁰

"Ask" involves using a formula called PICO to build up a good question. PICO stands for patient, intervention, comparison, and outcome. Patient quite simply is identifying your patient. Intervention will be a procedure, diagnosis, or prognosis that is being sought. Comparison gives you a control to compare against, and could also include a "gold standard." The outcome is what you would like to achieve and could include improved treatment, decreased morbidity/mortality, and so on. If one considers the case study, a question that may have been asked could be "With a geriatric patient involved in a low-risk motor vehicle accident, and the patient displaying no adverse neurological outcomes, could spinal motion restriction be beneficial or harmful?"¹¹

The "acquire" step takes the PICO formula used in the "ask" step and uses it to search for evidence. A good starting point to acquire evidence is to use only a few terms, and then expand the search if needed. Search terms for the case study might have been as simple as "geriatric and spinal." A search on PubMed.gov return three "best matches," and a total of 724 related articles (one can only imagine the time needed to go through that many articles in detail).¹²

The "appraise" step is just that, the collected evidence is appraised and evaluated to check for significance to the patient (or patients), strength of the evidence, and whether there are any factors (such as bias) that will disqualify the evidence.¹³

The last step, "apply," is the final discussion of the evidence and applying it to the respective patient or patients. The decisions made in the case study on which patients to immobilize and which patient' should not be immobilized, would be part of the "apply" step.¹⁴

The steps above talk about collecting evidence (or research). When conducting research, the research and review methods used are important. There are several techniques and concepts that the providers should understand when conducting research. These terms include qualitative, quantitative, observational studies, traditional review, systematic review, randomized controlled trials (RCT), and meta-analysis.¹⁵

Qualitative involves measuring something based on its quality, such as collecting data by observing or interviewing participants. Quantitative involves measuring something based on quantity, such as measuring the number of people who had adverse effects after spinal immobilization. The concepts of qualitative and quantitative are important, as many techniques are either one or the other.

Observational studies are classified as either cohort or case-control studies and are used to evaluate associations in medicine through observation and not intervention. Although observational studies have at times been touted as second rate, properly designed observational studies can rival the results of RCTs (discussed below). Cohort studies will follow a set of patients for a period of time, observing the outcome of either disease or recovery over time. The cohort study basically wants to see if a patient gets better or worse, and what, if anything, improved or deteriorated

the patient's situation.¹⁶ In the context of the case study, a cohort study might follow all patients who had SMR implemented, and see if they had any issues for several weeks after the initial incident.¹⁷

Case-control studies happen after the fact, and study the outcome results of a specific set of patients. For the purposes of SMR, all patients who had previously been secured to a spine board might be selected, and then the patients might be interviewed or have their medical records examined to come up with some results.¹⁸

A traditional (or narrative) review is often considered inaccurate and of poor quality as the author uses informal and subjective methods to write the review. It is also possible that the reviews contain bias and are selective in which studies are used in the review. Traditional reviews also do not explain how they were constructed or the methods used to select the studies.¹⁹

Systematic reviews differ from traditional reviews in that they are a form of research that selects evidence with the aim of answering a specific question. Systematic reviews are qualitative in nature. For example, is SMR necessary for every trauma patient? The process in which evidence is sought, selected, and critically appraised is made clear in the review. Systematic reviews have the advantage of comparing a wide range of findings as opposed to a much smaller selection in a traditional review. Systematic reviews are also useful in determining how consistent findings are across different studies. By adopting explicit methods, and following formal processes, bias is limited and accuracy and reliability are increased.²⁰

RCTs are quantitative studies in which participants are randomly placed into different groups, and that placement cannot be changed by either the participant or those conducting the study. Only one of the groups will receive the treatment being studied (also called the control). The random placement of participants allows researchers to see the effect the treatment has, without having people with any specific trait, such as being healthy or unhealthy. The RCT will reveal if a treatment has positive, neutral, or negative effects.²¹ RCTs are the gold standard when evaluating the effectiveness of interventions and can also be "double-blinded," in which neither the participants, nor those conducting the study know who is getting a control or a placebo. RCTs are expensive, time-consuming, and have ethical limitations. Part of an RCT is to alter variables within the trial, which could include altering medication or treatment given to a patient.

Meta-analysis is defined as "a quantitative, formal, epidemiological study design used to systematically assess previous research studies to derive conclusions about that body of research."²² Meta-analysis looks for common traits and truths between similar scientific studies. Meta-analysis has the advantage of being able to combine smaller, less significant research, into firm recommendations. For example, the three "best matches" discussed earlier in this objective, all mention that geriatric patients with spinal issues require special care.²³

Based on the discussion of the terms above, a knowledge of these is important when evaluating evidence and conducting research. It is only with this knowledge, as well a basic understanding of statistics, that EBM can be properly conducted and implemented.

The Importance of Evidenced-Based Medicine

EBM is an ongoing process that is supported by numerous large organizations. The National Prehospital Evidence-Based Guideline Model Process has been set up by the Federal Interagency Committee on EMS (FICEMS) and the National EMS Advisory Council (NEMSAC).²⁴

FICEMS is a committee that was established by Congress in 2005 to ensure the smooth running of federal agencies involved with EMS and 911 systems at all levels from local to state. FICEMS is a conglomeration of agencies including the Department of Defense, Department of Health and Human Services, Department of Homeland Security, Federal Communications Commission, and the Department of Transportation.²⁵

NEMSAC was set up in 2007 and consists of a council of EMS representatives and consumers to help guide the National Highway Traffic Safety Administration (NHTSA) on EMS. NEMSAC is simply a forum that puts considerable effort and expertise to provide advice on EMS programs. NEMSAC is not a regulatory council.²⁶

The National Prehospital Evidence-Based Guideline Model Process set up by FICEMS and NEMSAC was designed to create a model process for prehospital evidence-based guidelines (EBG) to be developed, implemented, and evaluated. The process contains a comprehensive and multidisciplinary eight-step approach for EBG for EMS. The process is based on the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) system which is the standard method for examining evidence quality and recommendation strengths. The model process follows the sequence of:²⁷

1. External Inputs

Existing guidelines and protocols (prehospital and evidence-based), EMS scope of practice, EMS educational

standards, and input from EMS researchers and professionals are all included in the process. Important aspects are not to always reinvent the wheel, and to also acknowledge that the way things have always been done, is not necessarily the right way.

2. **Guideline Initiation: EMS Evidence Accumulation and Evaluation**
Proposals for changes are accepted or created. Existing relevant evidence is identified. Systematic reviews are recommended or conducted. All involved parties will disclose any relevant affiliations or conflicts of interest.
3. **Evidence Appraisal and Establishment of Priorities for Guideline Development**
Appraise the quality of the evidence or the guidelines. Topics for further development of guidelines can be suggested during this phase. If any evidence is not selected, it is archived for possible future development.
4. **Guideline Development**
Outcome priorities are set, and the risks and benefits of interventions are determined. The strength of recommendation for each intervention is set. If no recommendations are set, an outline reasoning the lack of recommendations is created. The guideline is placed in an EMS context, and new guidelines are established, or endorsement guidelines are endorsed. Feedback is provided to the original source of the evidence.
5. **EMS Protocol Development (if new protocols are being developed)**
Establish EMS context and describe the clinical implications and strength of recommendations for the protocols.
6. **Disseminating of Guidelines/Protocols (for existing protocols)**
Provide a link to EMS Education Agenda for the Future and the National EMS Education Program Accreditation recommendations.
7. **Implementation**
Link to the national EMS provider for certification or recertification and EMS agency accreditation. Create evidence-based guidelines implementation tools (such as manuals and videos). Facilitate with national EMS organizations for the acceptance by medical direction authorities. Develop health informatics and software to support clinical decision software (this is a means of collecting, storing, and retrieving health-related data).
8. **Evaluation of Effectiveness, Outcomes, Clinical Research, Quality Improvement Evaluations**
Pilot testing and feasibility analysis for the evidence-based guidelines. Implement and monitor quality improvement benchmarks. Use National EMS Information System data to evaluate outcomes. Implement systems and outcomes research. Conduct clinical research on specific questions. Perform a cost-benefit analysis. Implement research on implementations, barriers, and facilitators.

After step eight is completed, the entire process loops back to step two which is the Guideline initiation. The process is continuous and extremely time- and resource -intensive.²⁸

Other major EBM stakeholders include the National Association of EMS Physicians (NAEMSP), National Highway Traffic Safety Administration, and the EMS for Children program, as well as the involvement of almost 60 other organizations. There is a major national investment in EBM.²⁹

In EMS, EBM addresses the issue of large variations in EMS practice, the challenges of implementing evidence in practice, and the lack of consistent measures to ensure quality EMS care. EBM aims to remedy these issues by producing consistent EMS patient guidelines, utilizing the wealth of current evidence to improve EMS quality, and lastly, to create standards to measure the quality of EMS care.³⁰

The American College of Emergency Physicians (ACEP) promotes high quality emergency care, and is an advocate for emergency physicians, patients, and the public. ACEP guides EMS in various ways including the release of policy statements. Two such policy statements include the management of patients with possible spinal injuries and managing massive hemorrhage. Both statements are backed by EBM, and mark a huge step forward in implementing EBM in EMS.³¹

The American Heart Association's (AHA) 2015 guidelines were based on a massive systematic review of evidence. Two hundred fifty evidence reviewers from 30 different countries conducted a systematic review that resulted in the current EMS guidelines. Given the large amount of evidence, a system to prioritize review topics was implemented, which resulted in 166 reviews being conducted for the 2015 guidelines (compared to 274 in 2010). If one reviews the 2015 AHA guidelines closely, the level of detail and explanation of how the evidence was gathered and evaluated can be seen. This is an earmark of EBM, being able to explain how you arrived at a conclusion or recommendation.³²

"I suppose it is tempting, if the only tool you have is a hammer, to treat everything as if it were a nail." – Abraham Maslow, 1966. This quote applies to EBM. EBM is a tool and is not designed to solve every problem or answer every

question. EBM has its advantages and disadvantages. The advantages of EBM include the fact that outcomes are based on multiple, reliable sources, thus relying on a greater collective experience and expertise. Using EBM enhances critical thinking and appraisal skills, and teaches how to better ask questions. EBM also has the distinct advantage of being transparent in terms of how the evidence was gathered, and how a decision was reached. If a flaw has been discovered with EBM research, the research can simply be adjusted, and the entire process does not necessarily have to be repeated.

There are quite a few disadvantages to EBM, which supports the statement that EBM can't solve everything. EBM, like most studies, is expensive, time-consuming, and requires a level of expertise to conduct. If there is no evidence available, EBM may not be possible. During the evidence selection process, valid or useful papers may be excluded. EBM has a level of subjectivity to it, and evidence can be misinterpreted. Any evidence, regardless of how substantial it is, can be included. Because EBM is retrospective, in other words it is based on older studies, it is never entirely current. Due to the RCTs being the gold standard, EBM tends to prioritize these, even though RCTs has their own flaws. Lastly, EBM may not necessarily put the patients' interests and values first.³³

Clinical decisions should be evidence-based; however if EBM is not possible, there are alternatives. A question was posed to a group of physicians as to what these alternatives include, and they came back with the following (of which some are a little tongue-in-cheek): eminence-based medicine, vehemence-based medicine, eloquence-based medicine, providence-based medicine, diffidence-based medicine, nervousness-based medicine, and confidence-based medicine.³⁴

Eminence-based medicine follows the tenet that experience trumps evidence. Clinical experience has been defined as "making the same mistakes with increasing confidence over an impressive number of years."³⁵ Simply put, eminence-based medicine involves a senior practitioner making his or her own clinical decisions based almost exclusively on his or her own clinical experience. Vehemence-based medicine is when a practitioner insists that his or her approach is the most appropriate. Eloquence-based medicine is when a practitioner presents his or her solution in such an eloquent manner that it seems like the right choice even though there is no evidence to support it (basically good marketing).

Providence-based medicine unfortunately happens when a practitioner runs out of options and runs out of ideas on how to proceed, ultimately allowing nature to run its course. Diffidence-based medicine is when a doctor sees only a problem, does not look for a solution, and ends up doing nothing (incidentally this may be better than doing something harmful for the sake of doing something). Given the litigious society in which we live and work, nervousness-based medicine is when the threat of litigation causes practitioners to over-analyze and over-treat patients. Lastly, confidence-based medicine is limited to the surgeon's table, but could equally be extended to the domain of the prehospital care provider – sometimes, when there is no evidence and no support, one still must decide and often quickly.

Although some of the alternatives discussed had an element of humor, they all remained valid options, and the important takeaway is that providers should be aware that EBM does not always solve everything.

The American Heart Association has classes of recommendations and levels of evidence for clinical strategies, interventions, treatments, or diagnostic testing during care of patients. These classes and levels allow providers to assess the validity of evidence more quickly when working with EBM. There are five classes of recommendation: Class I (strong), Class IIa (moderate), Class IIb (weak), Class III (no benefit – moderate), and Class III (harm – strong).³⁶

Class I benefits greatly exceed the risks and is a recommended treatment that will be beneficial to the patient. Class IIa benefits also exceed the risks, and are considered reasonable treatment and can be beneficial. Class IIb benefits are either equal to or greater than the risks, and the usefulness of Class IIb is not quite clear.

Class III has either no benefits or is not recommended or Class III may in fact cause harm and should not be performed. When assessing evidence, providers should consider the classes of recommendations, and if possible seek more than one source of information.

Accompanying the classes of recommendations are levels or quality of evidence. These levels are Level A, Level B-R, Level B-NR, Level C-LD, and Level C-EO. Level A consists of high-quality evidence that is obtained from more than one RCT. Level A will also include analysis of high-quality RCTs and at least one of those RCTs will have been verified by other high-quality registry studies.

The Level B level of evidence includes evidence from randomized trials (Level B-R) or from nonrandomized trials (Level B-NR). Level B-R consists of moderate quality evidence from at least one RCT, as well as analysis of other moderate-quality RCTs. Level B-NR includes only evidence from properly built and performed nonrandomized, observational, or registry studies. Level B-NR also includes analyses of the included studies. Neither Level B-R nor Level B-NR contain any RCTs that have been corroborated by high-quality registry studies.

Level C-LD (limited design) is based on either observational or randomized studies that are either randomized or non-

randomized. The studies that are included in Level C-LD have limitations in terms of design and execution. As with the previous levels, Level C-LD will include meta-analysis of the included studies.

Lastly, Level C-EO (expert opinion), includes only the consensus of experts based on their clinical experience.

Providers may be tempted to only seek out Class I, Level A evidence, but need to understand that the classes of recommendation and levels of evidence are determined independently of one another. An important aspect of EBM is clinical experience, and not every question asked can have a clinical trial behind it. If multiple experts reach consensus on a treatment, it might well receive a Class I recommendation, even though the level of evidence is only Level C-EO.

The ACEP also has criteria for clinical findings and strength of recommendations. The recommendations are Level A, Level B, or Level C. Level A has a high level of clinical certainty (such as from Class I or Class II). Level B recommendations reflect a moderate degree of clinical certainty (such as Class II or studies that address the issue at hand directly).³⁷ Level C recommendations are for other patient management strategies that are based on Class III studies or on panel consensus if there is no literature. ACEP highlights that recommendations that originate from a highly rated body of evidence should not necessarily receive the same level of rating of the individual studies used – this is because there are numerous factors when selecting and interpreting evidence that may diminish the quality of the recommendations.³⁸

Providers are often not aware that the patient care report can have a significant impact on EBM. Recording patient care information in a clear, concise, consistent, and regular manner can provide studies with the information they need to draw conclusions. These conclusions will ultimately provide feedback into policies or recommendations that will be used by EMS services.³⁹

Policies that are derived from EBM become local protocol through a rather lengthy process. EMS, among other sources (such as RCTs), will feed information into one or more studies, and that information will ultimately be turned into a policy statement that is backed by national organizations such as ACEP. Ultimately, those policies will exert an influence on local organizations and eventually become local protocol.⁴⁰

EBM is not without criticism. Some feel that EBM takes clinical decision-making (which is made up of years of experience, training, and intuition) and tries to turn it into an algorithm which does not necessarily suit all patients. EBM is supposed to incorporate the best evidence, however not everyone understands what “best evidence” is, and various entities may be able to manipulate “best evidence” to their own advantage. There have been cases, such as insulin for diabetic acidosis, and penicillin for bacterial endocarditis that were implemented based on single studies, and have had dramatically positive outcomes to patient health. EBM would effectively have not allowed a treatment based on a single study. EBM also does not consider things such as the patient’s socio-economic status, which can have significant influence on long-term care (such as a patient living in a poor, remote area with limited access to healthcare infrastructure).⁴¹

Evidenced-Based Medicine and Prehospital Care

There are dozens, if not hundreds of sources of medical research, which together result in the publication of over two million research papers each year.⁴² Of these articles, only a small amount will become relevant to prehospital care patients. As more clinical data is collected and analyzed, more recommendations and proposals will come to light, and some of these will end up as EMS guidelines and protocols.

As was mentioned in the previous objective, EMS continually supplies EBM with data in the form of patient care reports. The level of care that EMS providers give their patients will also impact many studies that occur once a patient reaches hospital. Although it is not always apparent, EMS personnel are major contributors to EBM.

For decades SMR was a standard precaution for any patient that might have the slightest chance of a spinal injury. There was little scientific evidence to support SMR, and only a few cases showed that it had positive neurological outcomes on a patient. A big emphasis was that if a certain type of mechanism of injury (MOI) was encountered by the patient, such as a motor vehicle accident or gunshot wound, then the patient should be immobilized regardless of any findings on the patient’s physical assessment. Today EBM has been used to limit unnecessary SMR, and has contributed to giving providers easier to use criteria for deciding whether to use SMR. Additionally, providers are also able to give their own clinical reasoning on using SMR. As evidence is accumulated over time, it is now being suggested that SMR can in fact harm patients in several different circumstances.⁴³

There have been several major EBM recommendations that significantly affect EMS implementation of spinal motion restriction, massive hemorrhage, and CPR. EMS protocols for SMR have been influenced by the Canadian C-spine Rule (CCR) and the National Emergency X-Radiography Utilization Study (NEXUS). Both studies had the aim of helping physicians decide if unnecessary cervical spine imaging could be avoided. If a patient did not require imaging, then the patient did not require SMR.⁴⁴

The NEXUS study was observational, and observed 34,069 patients ranging in age from one to 101 years, and involved 21 US trauma centers. The CCR study was a prospective, cohort study that sample 8,924 adults with blunt trauma to the head or neck, all of whom had stable vital signs and were fully conscious.⁴⁵

NEXUS had a sensitivity (the ability to test and correctly identify) of 99.6 percent for ruling out cervical spine injuries and detected 99 percent of all cervical spine injuries. Additional studies have since shown a sensitivity ranging from 83 to 100 percent of spinal injuries (with most studies finding more than 90 percent). Overall, the NEXUS criteria could eliminate unnecessary imaging by 12.6 percent, which translates to massive healthcare savings.⁴⁶

The CCR was found to be very sensitive for detecting cervical spine injuries, and detected 99 to 100 percent of cervical spine injuries. Studies conducted since the original study, have all shown a sensitivity of 90 to 100 percent. The CCR reduces the need for unnecessary imaging by more than 40 percent.⁴⁷

A trial involving a head to head comparison between NEXUS and the CCR, showed that the CCR had a greater sensitivity (99.4 percent) compared to NEXUS (90.7 percent). Although the CCR is more complicated than the NEXUS criteria, it is more sensitive, and can even be used to clear patients that cannot be cleared using NEXUS.⁴⁸

Throughout the article it has been highlighted that providers need to understand the limitations of studies. The CCR applies to adults (who must also be younger than 65 years) whereas NEXUS applies to any patient older than one year. Subsequent literature suggests that caution be applied when using NEXUS on patients older than 65 years (where the sensitivity reduces to 66 to 84 percent).⁴⁹ If an EMS service happened to be serving a retired population with the average age greater than 65, EBM or not, the CCR would not be a good choice.

A result of the SMR EBM is that EMS no longer routinely immobilizes patients on spine boards or with cervical collars, as the evidence further suggests that SMR can cause a host of other problems such as respiratory compromise, pressure sores, and even raised intracranial pressure.

The 2015 AHA guidelines brought with them some important recommendations for EMS. Such recommendations included the C-A-B (circulation – airway - breathing) sequence (as opposed to the A-B-C sequence), that chest compressions are not delayed, that there should be 30 compressions before two rescue breaths, and an increase in the chest compression rate to 100 to 120 compressions per minute (with no less than 100 compressions per minute).⁵⁰

These recommendations came out of systematic reviews. The AHA guidelines briefly outlined two important additions to the 2015 review process, namely the use of GRADE (the evidence review system) and the use of a custom-built, web-based collaboration platform that allowed reviewers from across the world to collaborate in a single place. This platform was named Systematic Evidence Evaluation and Review System (SEERS).⁵¹

The SEERS system ensured a great deal of consistency when the evidence was captured, which made the evaluation of the data much easier. The systematic review process used by the AHA was broken down into five main categories. These five categories are question development – systematic review question development (done in PICO format) (assess), search strategy development (ask), evidence reviewer article selection (acquire), evidence review using GRADE (appraise), and development of the 2015 International Consensus on CPR and ECC Science with Treatment Recommendations (apply).⁵²

The AHA 2015 guidelines first assessed the 274 PICO questions asked in 2010 and expanded this to a list of 336 questions for systematic review in 2015. After prioritization, only 165 questions underwent systematic review for 2015. Developing the 2015 AHA guidelines was a huge undertaking, but was essentially based on a few basic principles of EBM. This is a classic example of how EBM has influenced prehospital emergency care.⁵³

Out-of-hospital severe hemorrhage control is another area that has been influenced by EBM. The Emergency Care Research Institute (ECRI) partnered with both private and public organizations with the intent of performing a systematic review of several topics relating to hemorrhage control. ECRI essentially followed the 5 A's process and also used the GRADE principles (as used for the 2015 AHA guidelines) to determine the overall strength of the evidence base. The key questions that were asked were mainly comparisons of different hemorrhage control techniques (such as tourniquet to external pressure), comparisons of different hemorrhage control adjuncts, and how long tourniquets should be used for.

The searches revealed 1,599 citations, of which 1,116 were excluded for various reasons. The remaining 483 citations went forward for abstract screening. After the abstract screening, only 283 full articles were retrieved. Of the 283 full articles that were reviewed, 23 were clinical studies (16 of tourniquet use and seven of hemostatic dressing use), nine studies were with human volunteers, three were simulation studies, and 39 consisted of animal model studies.

The study that resulted in the hemorrhage control guidelines mentioned several limitations of the evidence base as well as gaps in the research. The limitations included an acknowledgement that emergency trauma incidents don't easily lend themselves to randomized trials or to allow definitive answers to be obtained. This limitation highlights the

importance of the term “best available evidence.”

The main gap in the research was that civilian use of tourniquets and hemostatic agents are limited, and the few studies that were available, did not have relevant outcomes. This obviously had an impact on the study, and possibly created a reliance on data in a military context.

The conclusion of the study, which has dramatically influenced EMS, is that tourniquets save lives (whereas previously, tourniquets were considered dangerous), and the adverse effects from using tourniquets were manageable, and could be limited through proper training. Hemostatic dressings do not have much data supporting their use in humans. Future studies will need to ask the question if tourniquet use in the civilian setting is as applicable as it is in the military setting. The result of the EBM and hemorrhage control is that civilian EMS and law enforcement religiously carry tourniquets.⁵⁴

Sepsis is another area in prehospital emergency care that has been analyzed by EBM. The Prehospital Early Sepsis Detection score is an evidence-based early identification tool that is based on retrospective research that was collected between 2004 and 2006. The research included patients older than 18 years who were transported by EMS to a major academic center, and who received an ICD-9-CM diagnostic code for sepsis. The study measured physiological variables such as mean arterial pressure (MAP), heart rate (HR), respiratory rate (RR), and shock index (SI). SI is calculated by dividing the heart rate by the systolic blood pressure with normal being around 0.5, and shock around 1.0.⁵⁵ Patients were also assessed for a fever of greater than 38°C (100.4°F). The resultant sepsis score would indicate the likelihood of a patient to have hyperlactatemia (high levels of blood lactate) which is a good indicator for indicating patient mortality within 28 days.⁵⁶

A later retrospective analysis of adults in a cohort, emergency department setting studied 2,524 patients. The study found that an increased SI of 0.7 or more were three times more likely to present with hyperlactatemia than those with a normal SI. The study basically confirmed the findings that SI is a good indicator for sepsis.⁵⁷

A cohort study of sepsis in Seattle revealed that 40 percent of patients with severe sepsis arrive at the hospital via EMS. The transport of these patients usually exceeded 45 minutes. The study also highlighted that the rate of sepsis was greater than the rate of acute myocardial infarction or stroke. A different study showed that for every hour that antibiotic administration is delayed after sepsis induced hypotension, survival drops by 7.6 percent. Yet another study showed that any volume of prehospital fluid administration (even just inserting a catheter), reduced the chance of in-hospital mortality. These sepsis studies tell EMS the same thing, that early goal-directed therapy which includes the administration of fluids and antibiotics and strict management of hemodynamic status – can all reduce patient morbidity and mortality.⁵⁸

SMR, CPR, hemorrhage control, and sepsis are only a few of the areas that originate from EBM. As data collection and analysis of patient care and patient outcomes becomes more detailed and frequent, more evidence will become available, and more aspects of EMS will be the result of EBM.

Case Study Conclusion

The case study presented the provider with several patients with potential spinal injuries. Spinal injuries have been the victim of dogma for years if not decades, and EBM is only now showing the way toward correct spinal clearance techniques and appropriate care for those with potential spinal injuries.

By having knowledge of the latest treatment protocols, and even how those protocols came about, providers should be able to systematically work through even the most grueling and complex of scenarios, including mass casualty situations.

In the case study, the provider simply had to know that unnecessary SMR can be harmful, and needed to know which rules to apply to safely clear the patients' respective cervical spines. In the case study, if a patient did qualify for SMR, the provider would still need to know how to apply SMR to reduce the complications associated with it. Reducing the complications could also involve techniques that were developed using EBM.

Conclusion

EBM is not that much of a mystery. Although research can be extremely complicated, especially when it comes down to statistical analysis of the data, a basic understanding of the different types of studies that are conducted will help providers understand why certain protocols exist. Additionally, understanding the steps of EBM, and how providers contribute to these studies through their daily actions, can also greatly contribute to future EMS protocols.

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