The Journal of Trauma: Injury, Infection, and Critical Care: Volume 47(2)August 1999pp 225-232

Evidence-Based Medicine in Trauma Care: Whither Goest Thou?

Fabian, Timothy C. MD

Presidential Address at the 12th Scientific Assembly of the Eastern Association for the Surgery of Trauma, January 15, 1999, Orlando, Florida.

Address for reprints: Timothy C. Fabian, MD, Professor & Acting Chairman, Director of Trauma, Department of Surgery, University of Tennessee, 956 Court Avenue, #G228, Memphis, TN 38163; fax: 901-448-7689; email: tfabian@utmem1.utmem.edu.

(**Figure 6**) I believe that EAST has become a very credible academic organization in its relatively short lifespan. It is a dynamic organization, and a working organization. This is evident from the multiple projects initiated in recent years, including the management guidelines project, ultrasound course, trauma director's course, employment and fellowship directories, all of which are contained on one of the most effective websites of any academic organization (http://www.EAST.org). An analogy that I've come to in recent months is that in some ways EAST reminds me of the Millennium Falcon in the Star Wars trilogy. Han Solo and his comrades often took off at warp speed, but they were always fine-tuning the starship en route. It's akin to many of our projects. We tend to avoid waiting and planning something to death in committee. Sometimes, we may start a little quickly. But, at least when you've got something going, then you can fine-tune it. If you do little, there's not much to fine-tune.

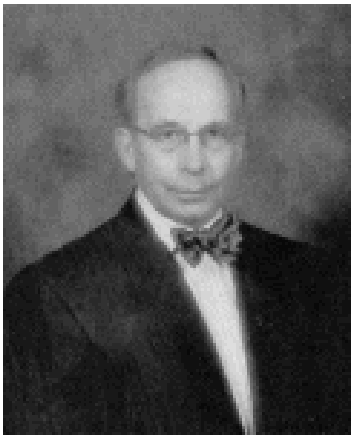

Figure 6. Dr. Timothy C. Fabian

Evidence-based medicine is one of the important areas today, and I think EAST has made an early, profound impact through the management guidelines project. We have the spaceship going, we are fine-tuning, and the project is going to improve. This talk will be set up as reflection upon a journey. We will begin looking at the past, move to the present, and, at the end, speculate where we're going in the future.

THE PAST

It is difficult to know where you are or where you're going without considering history. Pierre Charles Alexandre Louis was a Frenchman who published "Researches on the effects of blood-letting in some inflammatory diseases and on the influence of tartarised antimony and vesication in pneumonitis." **[1]** This was perhaps one of the earliest examples of evidence-based medicine in 1836. **[2]** Before that time, medicine was essentially trial and error. Let us consider some of his 160-year-old data. Bloodletting was a standard component of care in

multiple conditions. Louis analyzed 78 patients with pneumonia, and looked at the timing of bloodletting and the incidence of response in both patients who survived and those who died. He found that it did no good. In fact, when he did subset analysis, he found that there were some patients that appeared to be harmed by this approach.

Louis' method was termed "numerical analysis," which established controversy at the time. His mentor, Broussais, used 160,000 leeches a year for bleeding. Once again, this was a very common practice and an important part of most therapies at that time. It was part of the antiphlogistic doctrines, the anti-inflammatory doctrines. Practitioners believed in bleeding and low diet, or bleeding and starvation-a principle that has been adapted by the IRS today. But there was a commercial impact of the antiphlogistic doctrines. Before that time, France had been a net exporter of leeches, and then, because of Broussais' work, they were importing 30 million leeches a year from Hungary and Bohemia. **[2]** Criticisms from colleagues included "It's against tradition and individual experience." Does that sound a bit familiar? Similar arguments have been levelled against evidence-based medicine today. Mark Twain stated it well: "The man with a new idea is a crank until the idea succeeds." Many people do not like change, or new ideas. Change can upset mindsets and comfort zones. Pierre Louis certainly introduced important change. He also had an important impact on American medicine at the time, influencing prominent medical leaders in Boston, New York, and Philadelphia.

Let us now move along to a surgeon leading the way in evidence-based medicine. Ernest Amory Codman was a most interesting and important figure. He was an early experimenter with x-rays, which had been developed by Rontgen in the 19th century, but had no clinical application. At the turn of this century, Codman began x-ray experimentation. He and his friends had good and bad experiences; in his words, "There were many amazing, exciting, and tragic episodes in those days, for we all had burns, and some of us gave them. Many of my friends are now dead with x-ray cancer. It was fortunate for me that my interest in surgery was greater than Rontgen's discovery." **[3]**

Codman developed a revolutionary, but simple, concept, which he called "the end result idea." I would suggest to you that this was very good outcomes research and probably better than most of what is being done today. He said that every hospital should be responsible for following their patients, determining if the treatment was successful, and if it was not, deciding what went wrong. Although the approach was simplistic, perhaps we should revisit it. His practice was to develop 5-by-8 inch cards for every operation, and detail preoperative and postoperative care. The card was brought up a year later, and the patient was re-examined and evaluated for results relative to therapy. Codman thought the end result idea could be used to compare hospitals and surgeons. So the ideas of benchmarking today are not new; really, much of medicine is rediscovery, if you go back far enough. And he was certainly far ahead of his time. But Codman, like Pierre Louis before him, incited controversy. As mentioned, change is often not welcome and, of course, people were especially reluctant to scrutinize their own results and compare them with others. Status had been measured by seniority at that time. It would transform an artisan to an objective system. Codman began feeling a "sense of isolation," and "of being peculiar." **[3]**

He made some important contributions relative to the American College of Surgeons. In 1910, after attending the Royal College in Britain, he observed that an American College would be a good place to introduce his end results idea and to standardize hospitals. The College was established three years later, in 1913. He continued to believe that such an organization would be a good vehicle to analyze, and thus improve, patient care. Prompted by his stimulation, the American College of Surgeons (ACS) developed a committee called the Standardization of Hospitals in the late 1920s that ultimately became the Joint Commission for the Accreditation of Hospitals (JCAH) in 1957. So surgeons were leading the way to improve the quality of care in this country. In 1957, we were joined by the AMA, the American College of Physicians, and the American Hospital Association. The office remains in Chicago, where it began with the ACS. Codman was really the crystal around which the entire process developed. Although he was a leading force, Codman was never on the Board of Regents, nor was he president or vice president of the College. Tact was his short suit. He expressed the feeling that his epitaph might read "Ernest Amory Codman: killed by his colleagues." **[4]**

THE PRESENT

With the past as a backdrop to this discussion of evidence-based medicine, let's forge ahead and see where we are in the process. Many concepts for evidence-based medicine, and the first description, came out of

McMaster University in Hamilton, Ontario in the early 1990s: "Evidence-based medicine is the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients." **[5]**

I did a Medline search a few weeks ago simply to look at the number of articles on evidence-based medicine published from 1993 to 1998 (**Figure 1**). It appears to be taking hold in medical circles, although there remains a fair amount of skepticism and cynicism about the process. A similar literature search covering the last decade was also done to see what is happening with practice management guidelines (**Figure 2**). Management guidelines have been around a little bit longer, since 1987, and are often not evidence-based. The Figure showsa substantial increase in the last 5 years. Medicine specialties lead in the area. Surgery is trailing a little behind. Although we are a smaller specialty, we are similar to primary care in guideline interest. Thank goodness for OBGYN.

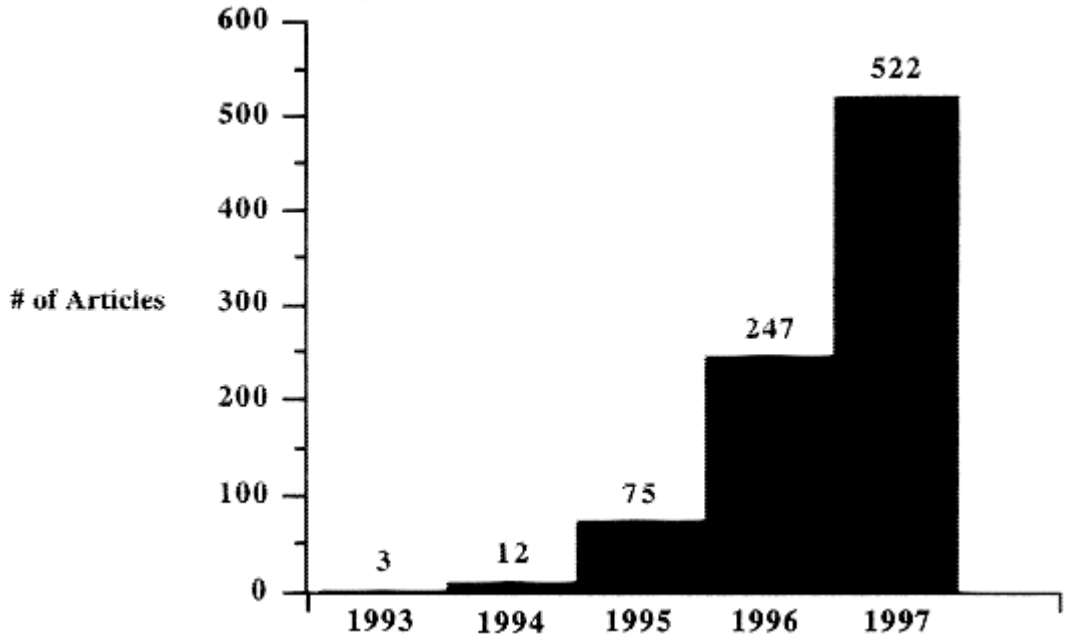

Figure 1. Results of Medline search for "evidence-based medicine" journal articles.

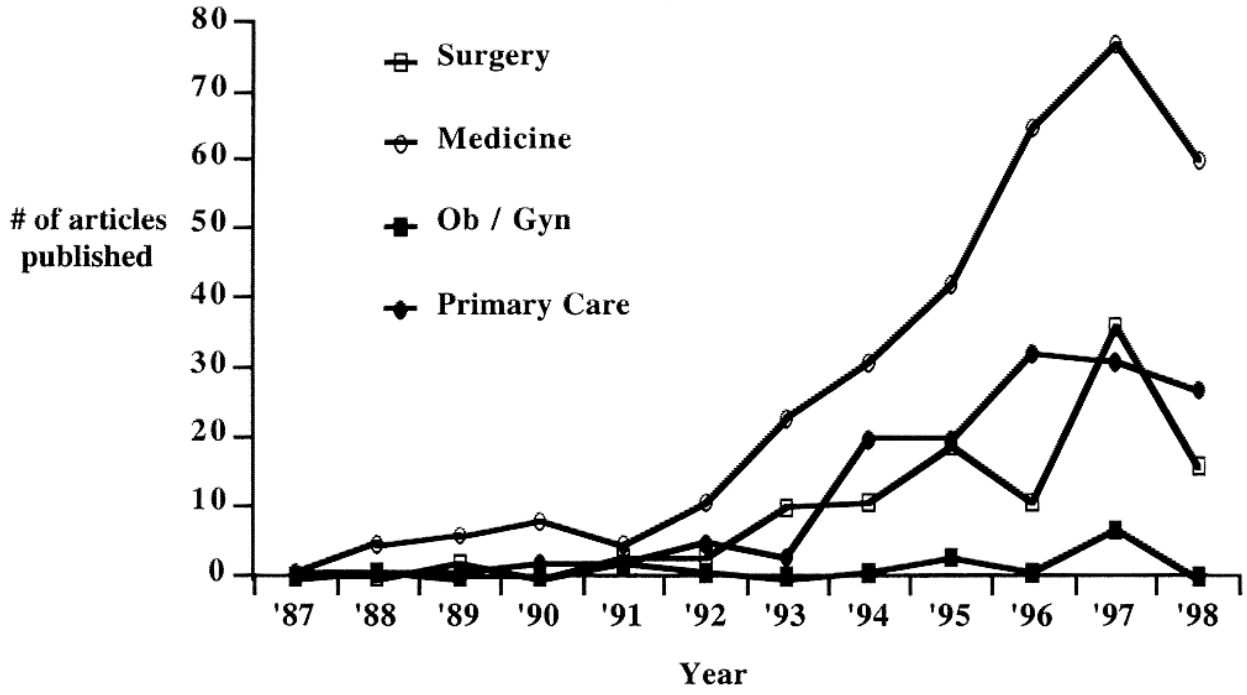

Figure 2. Results of Medline search for "practice management guidelines" journal articles.

Forces for Guidelines

There are multiple forces for the creation of guidelines:

- Decrease practice variation

- Slow the rate of rise of health-care costs

- Monitor inappropriate care

- Difficulty staying abreast of knowledge

Let's look at those forces, beginning with geographic variation. These are two articles published in the mid-1980s that have had a fairly profound impact over time. Wennberg found a 20-fold difference in carotid endarterectomies in 16 large communities in 4 states. **[6]** That was a little difficult to rationalize. Are some rates too low, are others too high, or is the proper answer somewhere between? It seems unlikely to be explained by variance in disease incidence. That report further noted that tonsillectomy rates in Vermont went from 8% to 70% in various areas and that hysterectomy rates in Maine had a variation of 20% to 70%. Another important study, which got the Federal Government's attention and from which we are feeling the effects today, was written by Chassin. **[7]** A variation of over 300% for half the procedures for Medicare in 13 metropolitan areas across the country was found. These large studies clearly demonstrate that there is wide practice variation across the United States.

What about variation at this meeting? We have talked about timing and fixation of fractures. There is certainly a large variation in that management. There was a nice paper from Ann Arbor addressing delayed aortic repair. There is currently a lot of variation with that treatment. If there is such variation, either it doesn't make a difference how you do something or some people are doing it better than others are. And I think the challenge is there for us to look at an evidence-based approach to evaluate those questions.

The data from Wennberg and Chassin were used in conjunction with the Freedom of Information Act, to require HCFA to release hospital-level mortalities from Medicare to help people make informed decisions. Well, an article subsequently came out in the New York Times that disclosed the fact that one hospital had an 87% mortality rate when it was predicted to be 22%. They didn't note the fact that this was a hospice that was caring for the terminally ill! So you have to be careful with data analysis, and clearly, doctors had better become involved in the process, because if we don't, others will.

I would now like to turn to the information explosion. There are over 30 English language surgical journals that contain articles that may have some impact on how we manage trauma. In addition, there are at least eight specifically evidence-based medicine journals. Who can possibly keep up with all of these journals? Even the expert in an area has a difficult time keeping up with more than one or two topics. It has been estimated that among different groups of clinical physicians, the reading time for the average clinician is 30 minutes a week; for medical students, about an hour and a half; and for a PG-1, there is almost no time. We all remember what being a resident was like, we knew we were supposed to read, but we usually had little time to read. These reading times are real world. Groups such as EAST need to digest this information if it is going to be applied. Otherwise, it's just being wasted; hence, the necessity for evidence-based management guidelines. Although I am leery of quoting politicians, I don't think it has been put more succinctly than A1 Gore's statement on information management: "It's resembling the worst aspects of our agricultural policy which left grain rotting in thousands of storage bins while people were starving." Isn't that what is happening with the tremendous amount of important medical information that is contained in all of these journals? Most is simply not used. It builds up curriculum vitaes, but it doesn't go to medical care as often as it should. The following is an Equation thatis being used frequently in evidence-based medicine today: **Equation 1** That is, the usefulness of medical information is directly proportional to the relevance and validity and inversely proportional to the work involved.

$$\text{Usefulness of medical information} = \frac{(\text{Relevance})(\text{Validity})}{\text{Work}}$$

Equation 1

The clearest rationale for creating management guidelines is to improve the quality of care we are delivering to patients, which is precisely what Ernest Codman was trying to do at the turn of the century. There are also considerations of cost-effectiveness. We had better step up to the plate before we have them crammed down our throats by groups with less than altruistic interests. Others will-correction-are forming them today. There are commercial products being produced. They are by and large cost-cutting management tools, which are sometimes based on poorly validated data banks and superficial analyses. Most often, low quality evidence is used, and guidelines are based on black box-read "proprietary"-methodologies. There is significant money involved with these enterprises. Companies don't want you to know too much about proprietary, evidence-based approaches. It sounds oxymoronic.

One of the more successful groups of proprietary management guidelines is produced by Milliman and Robertson, Inc., a company from the San Diego area. Several hospitals and hospital groups in the country are using these today. They consist of seven volumes that range from inpatient surgical care to ambulatory surgery guidelines to worker's compensations. As I indicated, this is a commercial product. Purchase price is approximately $400 per volume or $3,000 for the entire collection. Managed care organizations are an important market for these guidelines. As order quantities increase to 200 copies, the cost per volume is reduced to $300. This is serious business.

A moment spent on nomenclature is appropriate. Clinical pathways are day-to-day outlines of how patient care should flow including diagnostic tests and preoperative and postoperative care from admission to discharge. They were first established by the nursing profession and have continued to gain popularity. The Southeastern and Southwestern Surgical Congresses are collaborating in establishing clinical pathways for elective general surgery operations. They have thus far developed approximately 20 pathways that are being published serially in The American Surgeon. They include pathways for breast surgery, gastrointestinal procedures, herniorrhaphy, and thyroid operations. That collaboration is a good example for our organization, and other organizations, to follow.

Management guidelines describe approaches for prevention, diagnosis, evaluation, or management. Protocols are formulas for application of guidelines. These are in the format of algorithms or decision analysis charts, which use an "if/then" format. This is an area that we need to develop in our EAST guidelines project to make them applicable and user-friendly. I am aware of three organizations besides EAST that have developed guidelines for trauma and critical care: the Society for Critical Care Medicine (SCCM), the Brain Trauma Foundation (BTF), and University Hospital Consortium (UHC). EAST owes the BTF a debt of gratitude for much of the methodology we have used. They began their project on guidelines for head injury management in the middle of this decade, and those guidelines are having a substantial impact on the care of brain-injured patients. SCCM has developed guidelines for IV sedation and analgesia, and for neuromuscular blockade. The UHC has guidelines for albumin, nonprotein colloid, and crystalloid solution utilization.

Guideline Development

Medical practice was first learned through an apprenticeship process. Young physicians followed established practitioners and learned from that experience. There was not always much science, mostly art. Textbooks have only been around for approximately 2 centuries. A lot of practice was and remains based around local customs, hearsay and dogma, and is so-called "eminence-based" medicine, if you will, which uses anecdotal evidence, clinical intuition, and personal experience as the basis for its approach. About 20 years ago, the pervasiveness of the process began dawning upon me. I went to medical school at Loyola, attended surgery residency at Ohio State, and moved to Emory for a trauma fellowship. Following training, I joined the faculty at the University of Tennessee, Memphis. Every place I went, there were certain things that were accepted with religious zeal. Drain, nasogastric tube, and chest tube management, principles of antibiotic use, and conduct of operations are some examples. I was struck by the observation that a lot of times, there certainly was wide variability, if not direct contradiction, in practice. It always takes a while to exorcise the misguided thoughts of the new faculty member. Those observations define the importance of establishing objective guidelines for practice.

A few methodologies are available. Expert consensus panels have been a popular approach. The Delphi method is a fairly sophisticated consensus approach. The NIH has held several consensus conferences. Several academic organizations commonly use that technique. Much of trauma care has evolved in that fashion. There are potential problems, however, including the influence and bias of a dominant member, group dynamics producing group think, polarization effects, and "consensus" because of lack of time or energy.

The attributes of management guidelines have been nicely outlined by Heffner. **[8]** They must be valid and reproducible in different locales. They need to be clinically applicable, emphasizing incorporation of algorithmic formulas. They need to be flexible and clear. Multidisciplinary development is key to impact and adoption. We cannot direct orthopedic surgeons on antibiotic prophylaxis for open fractures without their participation in the process. Emergency medicine physicians should participate in guidelines for obtaining cervical spine x-rays. Clinical pharmacists can be quite valuable in many areas of antibiotic or drug utilization. Nursing practitioners should be involved in areas that impact on patient care at the bedside. Guidelines should be physician-directed, non-threatening, developed from evidence-based outcomes, and integrated with performance improvement programs. They should have scheduled reviews and be updated as new evidence is reported. They must be "guidelines," not standards, and include boilerplate language. This is one of the things that scares many people, and is one of the common reasons not to establish them. "Gee, aren't they going to help us get sued?" I don't think so. But as guidelines, they are for the "average" patient, and we should include such language in our guideline processes so we don't open the door unnecessarily to lawsuits. They could be either inculpatory or exculpatory in lawsuits. This is not different from textbooks relative to medicolegal liability.

The Agency for Health Care Policy and Research (AHCPR) and the Cochrane Collaboration are two organizations that have provided important leadership regarding methodology and evidence-based approaches to guideline development. The AHCPR was established by the United States Legislature in 1989. The aforementioned practice variation studies were like a lightning rod that helped create the agency. The AHCPR developed 19 evidence-based guidelines, spending several million dollars in the process. They included a wide range of topics from decubitus ulcer to acute chest pain management. However, they ran into trouble a few years ago with a guideline on management of low back pain. A practitioner felt the government was overstepping its bounds, and was apparently offended because of a conflict with that practitioner's management. An influential member of Congress was contacted, and the AHCPR budget was sharply reduced.

The Agency no longer develops guidelines, but does provide evidence-based evaluations of medical literature, which can be used by other organizations for guideline development. They currently support 19 evidence-based practice centers across the country. The AHCPR also established the National Guidelines Clearinghouse on the Internet (http://www.guideline.gov) in the fall of 1998. This has been accomplished through a contract with the American Medical Association (AMA) and the American Association of Health Plans, and is intended to store practice guidelines for all specialties. The Cochrane Collaboration (http://www.cochrane.org) is an international collaboration that originated in, and remains based in, the United Kingdom. They maintain a registry of systematic reviews covering all aspects of medicine and have established a registry of all randomized controlled trials (RCTs). They have over 150,000 RCTs registered, an impressive volume of work; over 30,000 of these are not found on Medline. There is also a methodology of literature searches, which is underappreciated. They have established approximately 20 collaborative review groups as of this time. One is an injury study group that plans to establish protocols and guidelines, and has already developed guidelines for crystalloid and colloid use in shock.

Evidence-Based Outcome Evaluation

I believe the evidence-based outcome evaluation (EBOE) should be the engine driving the guideline process. This could be performed by statistical means with meta-analyses. That approach requires RCTs. Unfortunately, there are not many RCTs in most surgical fields, including trauma. Therefore, alternative evidence-based approaches are required. The approach that EAST has adopted is critical analysis through formal processes of data classification and assessment of confidence levels, which will be reviewed subsequently.

Major goals and challenges for the development of EBOEs are to eliminate bias as much as possible. They must be made widely available; using the Internet is the best way to accomplish that. There should be ongoing peer review, and new information should be added as it is produced. This is, once again, the advantage of the website over the cumbersome and slow process involved with print. This is something that EAST is challenged with. It is critical to our process. Although we are starting to do it, we need to have a very defined process so that we do not get behind the evidence.

Bias is the chief enemy. It is difficult to totally eradicate. When you formulate a hypothesis for an experiment, that is bias in itself. But it is a necessary part of the scientific method. There are several biases that are not necessary, but which may be difficult to eliminate depending on the question asked and the experimental design required. There is allocation or selection bias, which has to do with assignment to group for question asked. The best designs, of course, are randomized, double-blinded comparisons. The investigator needs to be blinded, and very importantly, although few reports state this, the blinding must be maintained until all results are analyzed. It would seem this is intuitively obvious, but there are undoubtedly double-blinded trials where this does not happen. How often is the blind maintained during the study, but broken prior to complete analysis of outcomes?

There are statistical biases introduced by Type 1 or Type 2 errors, which can only be controlled for by large, sufficiently powered studies, or several smaller, consistent trials. Publication bias is also problematic. As we know, there is no journal of negative results; perhaps this phenomenon encourages investigators to torture data until it confesses. For the first couple of years after introduction of a new approach, reported data tends to be positive. A few years later, neutral or negative results tend to be more widely published, as they challenge what has now become accepted therapy.

Topic selection for performing an EBOE and subsequent development of a guideline is vital, but often underappreciated. A significant commitment of resources, manpower, and time is required to complete a guideline. Working diligently, the study groups for the EAST guidelines require 12 to 18 months to complete the process. Thus, significant planning for a list of topics is imperative. The methodology deserves to be much further refined. AHCPR suggests basing topic selection on incidence and cost. Other considerations for topic selection include areas of controversy or uncertainty, potential to reduce significant variation, availability of scientific data, and potential for rapid implementation. Judging by the 11 management guidelines that are currently on the website (http://www.EAST.org), we have done a fairly good job concerning topic selection. Perhaps we could have done better, but the ship is in the air.

I would like to quickly review the backbone of the EBOE: evidence assessment and levelling of confidence. Methodologies established by the Canadian and U.S. Preventive Task Forces have been used for evidence assessment (**Table 1**). Unfortunately there is not a great deal of class I data (RCTs). Furthermore, all RCTs are not equal. Many are underpowered or suffer from one or more previously described biases. To date, no objective system has been developed to quantify such shortcomings; such critiques are qualitative. Just because a study is class I does not automatically mean it is good. Vice-versa, some class III retrospective cohort or case-control studies can be quite helpful, especially for relatively uncommon but clinically important problems. Concerning evidence assessment, a word of caution is in order regarding completeness of literature searches. Regarding Medline sensitivity, Dickersin, an epidemiologist at Brown University, found that 50% is the standard when you are looking for all RCTs. **[9]** When you consider only Medline-indexed journals, the search process still misses one in four. There are approximately 16,000 journals, and only approximately 3,700 are on Medline. Efforts to improve literature searches should include improved terminology in reports (editors), improved indexing (National Library of Medicine), improved search strategies (trained personnel), and utilization of EMBASE (many European journals are not on Medline).

Evidence Assessment	Confidence Levels
Class I: Prospective RCTs	Level I: Justified based on scientific evidence, usually class I data
Class II: Prospective, nonrandomized, retrospective analyses, clear controls	Level II: Reasonably justified by scientific evidence and strongly supported by expert opinion, usually class I or II data
Class III: Retrospective, observational, expert opinion	Level III: Supported by available data, but scientific evidence is lacking

RCTs, randomized controlled trials.

Table 1. Evidence Assessment and Confidence Levels

Following completion of evidence assessment, confidence levels are established for conclusions based on the data analyzed. EAST has chosen a system of assignment of levels 1 to 3 (**Table 1**). Recommendations are based on clear scientific evidence, which is usually class I data. The Brain Trauma Foundations guidelines defined those as "standards," a term we wanted to avoid. Confidence level II is supported by less conclusive data, and level III is the lowest confidence level, supported by class III data and expert opinion. The Brain Trauma Foundation referred to the latter two as guidelines and options.

EAST Management Guideline Project

Now I want to take you through a time line of the guideline project (**Figure 3**). I think it is important for archival purposes to get it recorded here for the future. It began 5 years ago with a presidential address given by Mike Rhodes at the 7th Annual Meeting. **[10]** While Codman lead the way for outcome evaluation in surgery, I think Rhodes lead the way for this organization in developing evidence-based practice management guidelines. Following his challenge to the organization, a conference jointly sponsored by the Health Resources Service Administration and EAST was held in Baltimore, October 12 - 13, 1995. This joint meeting was one of the final projects for the Department of Trauma and Emergency Medical Services before it was phased out. Thanks to Chris Kaufman, who secured the grant of around $30,000 to support this guidelines conference, the basic methodology for guideline development was cast at that meeting. We largely followed AHCPR and Brain Trauma Foundation principles.

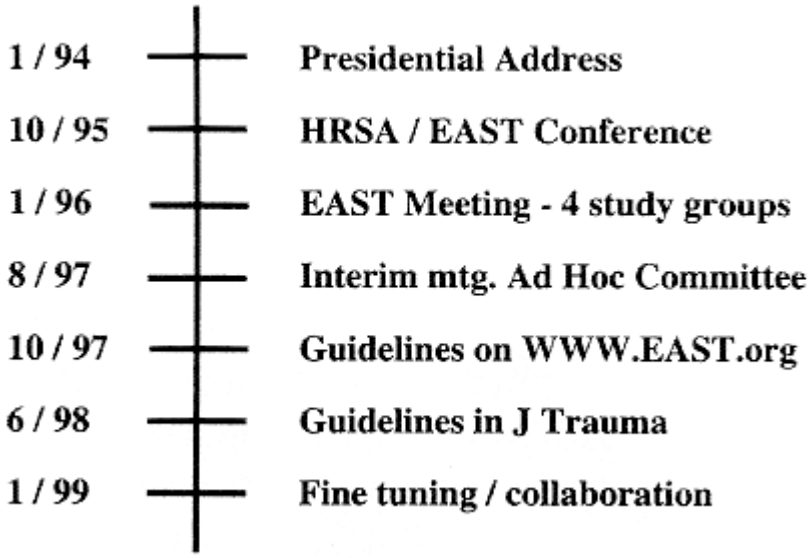

Figure 3. Timeline of EAST Management Guidelines Project.

At the annual meeting a couple of months later, study groups were established and four topics were selected: 1) blunt cardiac injury; 2) cervical spine evaluation; 3) penetrating colon injury; 4) deep venous thrombosis prophylaxis. I was made the chairman of the penetrating colon study group, which was probably not a good idea. The chairman has a significant influence on leveling of confidence. You shouldn't put the fox in the henhouse. That introduces potential bias, the hated enemy. But the organization lives and learns, and fine-tunes in flight. We began the process of convening for an interim meeting in August 1997, and held a second in September 1998. Lehigh Valley Hospital in Allentown, Pennsylvania has generously provided approximately $50,000 in grant funding to support those meetings. The interim conferences permit study group members to discuss the projects and further develop the guidelines and the methodology through criticism, consensus, and camaraderie. Those meetings have been valuable components to the process. At this time, I would like to thank Judy Schultz, who is the Administrative Director for Trauma Services at Lehigh Valley. She has really done a yeoman's job in organizing these as well as multiple other aspects of the project.

The development process is obviously important, but without dissemination, there is no impact. I believe our website has been very effective. It was initiated in the fall of 1997 and has become progressively active (**Figure 4**). The website has had significant impact on this organization. It has provided visibility not only in the United States; 10% of the hits are international. The Practice Guidelines are an important component of these hits. As webmaster for EAST, Mike McGonigal has done a phenomenal job, and richly deserves our collective thanks.

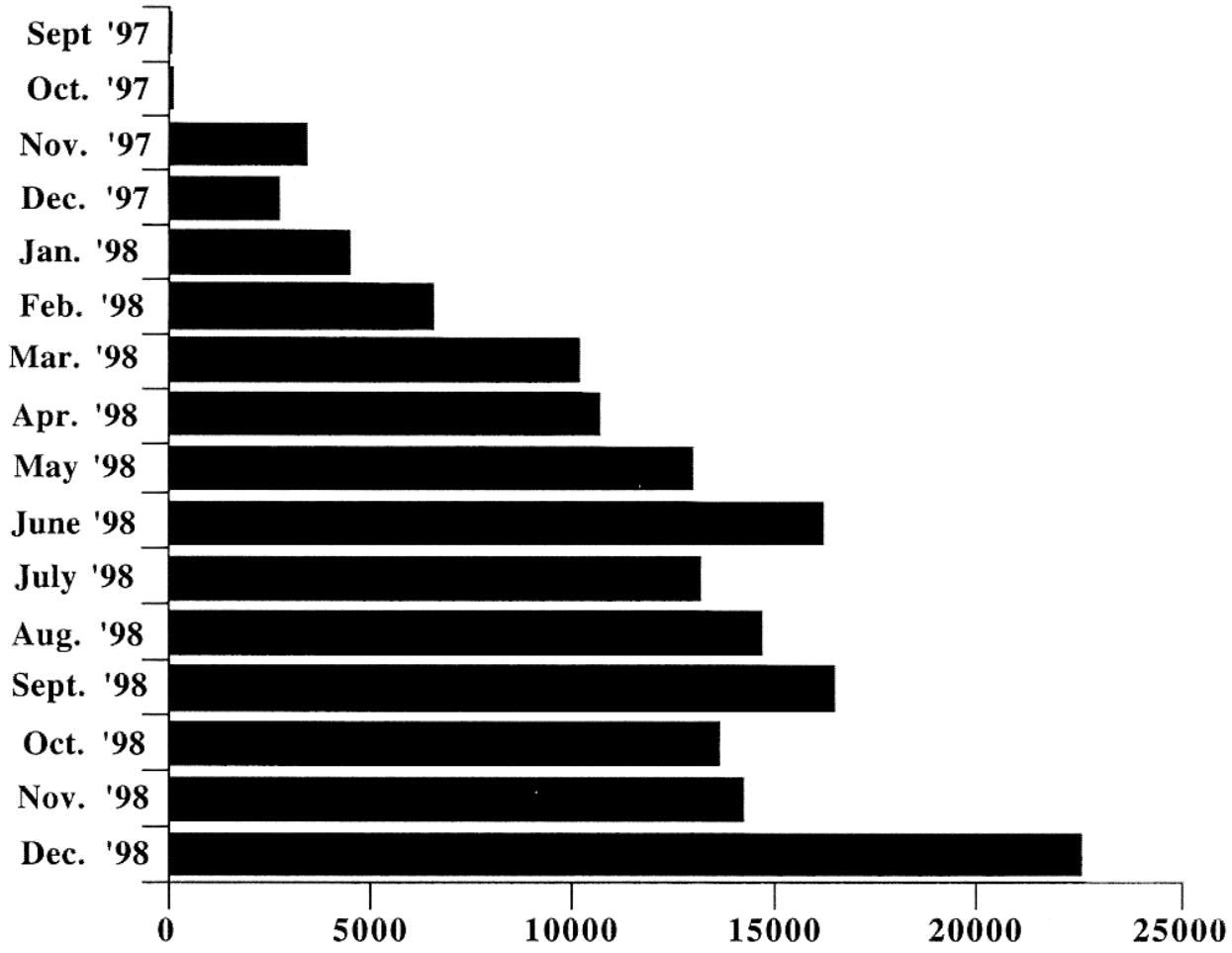

Figure 4. EAST website hits.

The next important occurrence in the timeline was getting guidelines in print. The first four guidelines were submitted in abbreviated format and published last June in the Journal of Trauma. It is vital that the guidelines be presented through multiple forums and media. We will continue to attempt publishing abridged guidelines in the Journal of Trauma.

Where are we now at this annual meeting? We need to fine-tune, and we need to collaborate. Relative to fine-tuning, Mike Pasquale and his Committee on Management Guidelines have done a great job in recently developing a primer that will be produced at the website. This primer succinctly describes our methodology so all of the study groups are doing it the same way, and others can follow and critique the process. Consistent products are crucial for success. We will fine-tune the primer as we go, too, but it is an excellent first go-around. I would encourage all of you to review this to fully understand the process and to provide comments and criticisms so we can do better in the future. The primer describes the 10 fundamental steps in the process of guideline development (**Table 2**). Asterisks were placed on areas that deserve special attention and have been somewhat overlooked up to now. It is quite important to list the goals and specific questions up front; otherwise, the process starts diffusing from the word go. We also need to refine the grading of scientific evidence. Again, not all prospective trials are the same. Implementation certainly must be worked on, and algorithms developed to facilitate application. Finally, evaluation and revision processes must be firmly established to ensure the validity of the process for the future.

Step 1	Topic selection
Step 2	Selection of panel
Step 3	Clarification of guideline purpose and scope
*Step 4	Listing of goals and specific questions
*Step 5	Grading of scientific evidence
Step 6	Establishing recommendations
Step 7	Drafting the document (standardized)
Step 8	Presentation
*Step 9	Implementation
*Step 10	Evaluation and revision

* Denote areas that deserve special attention.

Table 2. Steps for Development of EAST Management Guidelines

Future

We have looked at some history and considered recent developments. For the final few minutes, I want to speculate on the future. The future consists of collaboration and research. How do we get there? Let's begin by looking at the application of EBOEs (**Figure 5**). Following the process of EBOE as illustrated in the primer (**Table 1**), there will be level I, II, or III assessments/recommendations. Level I and most level II assessments would lead to firmly established guidelines, whereas level III, and some level II, assessments would direct the appropriate questions for future research, especially multi-institutional trials. Collaboration is definitely the key to impacting that for which we developed the guideline project: optimal care for trauma patients. EAST has lead the way, but we also need to work closely with the Western Trauma Association (WTA), the American Association for the Surgery of Trauma (AAST), and importantly, the ACS through the Committee on Trauma. Through collaboration, we can improve the guideline process, we can maximize utilization, and we can conduct sophisticated clinical trials with major funding. To that end, collaboration has begun. The AAST provided $10,000 to sponsor conferences in July 1997 and August 1998 to get the academic groups together and begin a dialogue. The methodology and process have been discussed. An important outcome is establishment by the AAST of an Evidence-Based Outcomes Committee. That group is forming an editorial board to critique EAST guidelines. External peer review is imperative.

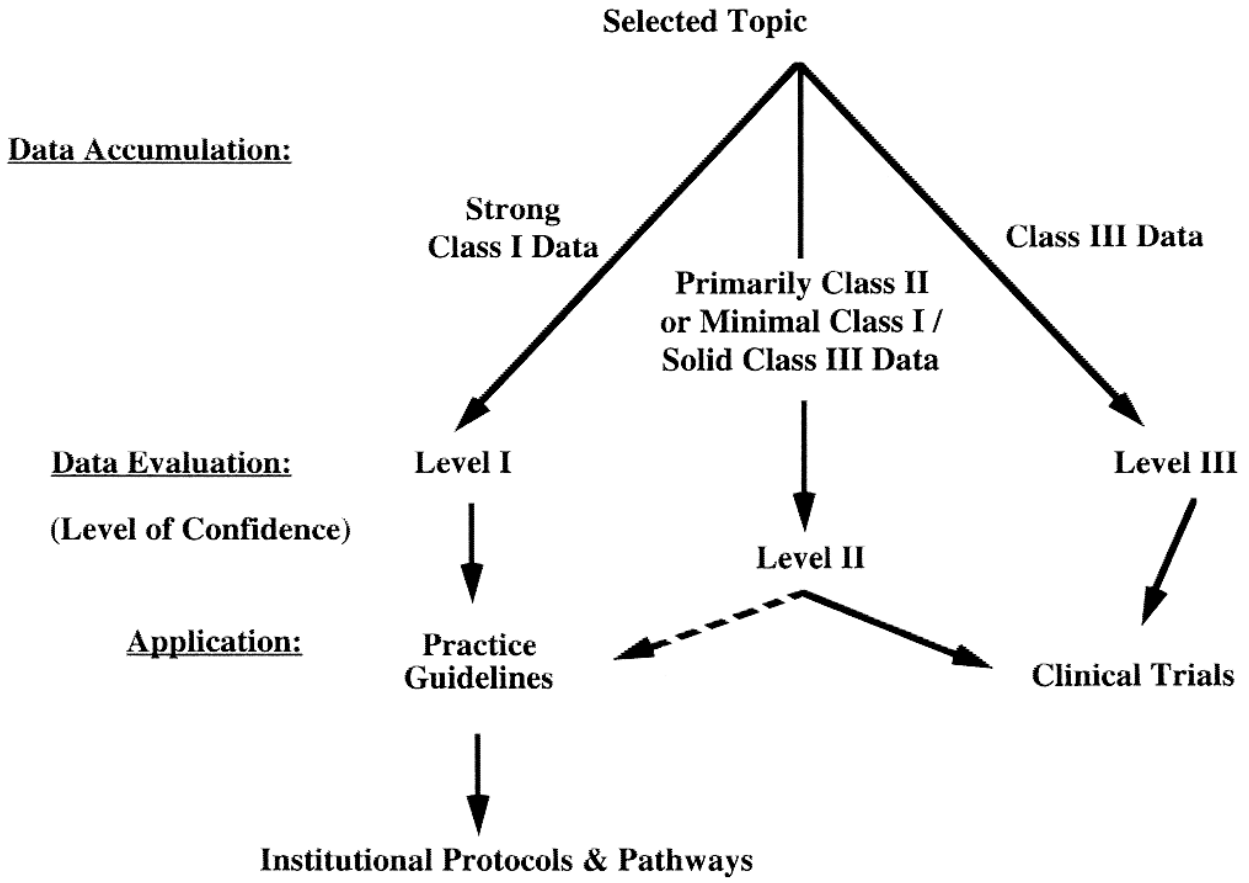

Figure 5. Application of EBOE.

A proposal was sent to the Board of Regents of the ACS to have a consensus conference. They agreed to sponsor an Evidence-Based Trauma Guidelines Conference. That will take place this coming March in Chicago. There will be approximately 30 attendees, including representatives from the ACS, EAST, AAST, WTA, AHCPR, and epidemiologists and methodologists. It should be an excellent meeting. The consensus approach is the key to getting people on the bandwagon, to get a more sophisticated process, and to maximize success and clinical impact.

There are substantial problems to resolve: 1) guideline consistency; 2) continuity of the process-timelines established, literature searched, literature reviewed, documents developed; 3) monitoring utilization and validity; and 4) coordination of clinical trials. To overcome those obstacles, I would propose a Project Office be established. We need to have a methodologist/coordinator and clerical support. The Project Office can perform literature searches, communicate with and coordinate the study groups, and assist in drafting documents. I am concerned we will ultimately be crushed by the weight of the task without such an office. How can we accomplish the important tasks of monitor utilization and validity? The National Trauma Data Bank[trade mark sign] and the Verification Review Committee of the Committee on Trauma would be excellent mechanisms that are already in place. I believe the ACS is fundamental to successful collaboration. Relative to research, the multi-institutional trials committees of EAST, AAST, and WTA can use the EBOEs as the backbone for grant proposals. Federal funding can be approached through the NIH, AHCPR, and the CDC, and the coordinated academic groups can also pursue private foundation grants. As outlined here, this collaborative approach would incorporate nearly all of the surgeons providing trauma care in this country. How better can we assure success?

I want to conclude by thanking the membership for giving me this year. EAST is a working organization that should continue putting ships in flight. I hope that we continue to push the process in the future, following in the footsteps of Ernest Amory Codman.

REFERENCES

1. Louis PCA. Researches on the effects of blood-letting in some inflammatory diseases, and on the influence of tartarised antimony and vesication in pneumonitis. Am J Med Sci. 1836;18:102-111.
2. Rangachari PK. Evidence-based medicine: old French wine with a new Canadian label? J R Soc Med. 1997;90:280-284.
3. Kaska SC, Weinstein JN. Historical perspective: Ernest Amory Codman, 1869 - 1940, a pioneer of evidence-based medicine: the end result idea. Spine. 1998;23:629-633.
4. Reverby S. Stealing the golden eggs: Ernest Amory Codman and the science and management of medicine. Bull Hist Med. 1981;55:156-171.
5. Davidoff F, Haynes B, Sackett D, Smith R. Evidence based medicine. BMJ. 1995;310:1085-1086.
6. Wennberg DE, Lucas FL, Birkmeyer JD, Bredenberg CE, Fisher ES. Variation in carotid endarteretomy mortality in the Medicare population: trial hospitals, volume, and patient characteristics. JAMA. 1998;279:1278-1281.
7. Chassin MR, Kosecoff J, Park RE, et al. Does appropriate use explain geographic variations in the use of health care services? A study of three procedures. JAMA. 1987;258:2533-2537.
8. Heffner JE: Does evidence-based medicine help the development of clinical practice guidelines? Chest. 1998;113:172S-178S.
9. Dickersin K, Scherer R, Lefebvre C. Identifying relevant studies for systematic reviews. BMJ. 1994; 309:1286-1291.
10. Rhodes M. Practice management guidelines for trauma care: presidential address, Seventh Scientific Assembly of the Eastern Association for the Surgery of Trauma. J Trauma. 1994;37:635-644.