**Chapter 18
Risk management**

**Karen Pickard, Raymond L. Fowler, and Melanie J. Lippmann**

**Introduction**

In order to adequately understand the process of risk management, the best approach would be to start with a definition of risk. Although there are varied definitions, there are some common threads: uncertainty, potential for harm, and potential for loss are a few examples. The US Fire Adminis- tration [1] defines risk as the objective or subjective probability that something negative will occur. In the prehospital environment, risk management is tightly integrated into all aspects of patient care, training, and supervision. One must consider both the probability that an event that is undesirable will occur and that there is potential for harmful consequences. Managing those events proactively is the ideal, but the problem that we often have is how to best create an ideal environment. In addition, we need to know how to classify risks in terms of frequency and severity. Two components to be considered are the internal and external aspects of risk management. Internal components are safety, training, health and wellness, personnel management, and equipment readiness. External components are prevention programs, public education programs, and one of the most important, the perception of the public.

In 1989, Valenzuela reported that fewer than 65% of emergency medicine residency training programs provided formal instruction in EMS risk management [2]. Both present and future EMS medical directors must become active, knowledgeable participants in prehospital risk management.

Risk assessment and root cause analysis are critical factors in risk management. They will be addressed in this chapter, along with training, supervision, and incident investigation.

**Components of prehospital risk management**

**Risk assessment**

Assessing risk in health care involves identifying those things that place us at risk and then attempting to predict the frequency and severity of occurrences. It is important to know what to monitor. Activities classified as “high frequency, high risk” obviously should be monitored closely. Low-frequency, low-risk activities or even high-frequency, low-risk activities do not require as much of our attention. In fact, the costs of monitoring these types of activities may outweigh the benefits. The two high-risk activities that require most of our attention are intubations (low-frequency) and no-transports (high-frequency). We look at historical data to determine those activities that require frequent monitoring and typically the two mentioned above are the ones that every service wants to closely monitor [1].

Obviously we want to make as few errors in risk assessment as possible. The development of pre-loss and post-loss strategies is one way to achieve that goal. Pre- loss strategies include the use of effective protocols or guidelines, education (both initial and continuing) that is thorough and provides feedback to the field practitioners, good documentation, and an effective quality improvement program. Post-loss strategies include a good investigation, matching behavior to protocols or guidelines, and remediation/education as indicated [1].

**Initial training**

Training of prehospital personnel has great effect on patient care. A solid foundation of knowledge, skills, and attitudes is necessary for EMS personnel to function effectively and provide consistent quality patient care [3]. An awareness of the quality of primary training institutions used to educate EMS personnel is important. Factors such as curriculum, teaching techniques, methods of evaluation, and clinical training have important roles in the student’s preparation for a role providing prehospital care. This knowledge is the responsibility of the EMS medical director, but EMS administrators should also be aware of this background. If the course medical director and the EMS medical director are different people, then communication between them is essential. EMS systems primary training is often provided as part of the individual’s employment, and this facilitates involvement of the system’s medical director in the training process.

**Preemployment screening and orientation**

If a potential EMS field employee received primary training outside the EMS system, it is important for this individual to be assessed in terms of medical knowledge and patient care skills before being released to function independently in the field. As a prehiring assessment, many systems use a written examination that may include tests of basic knowledge such as reading and math. Other assessments that are used include EMS knowledge-based written and skills testing, physical ability testing, interviews, and psychological screening. Most systems have standard administrative procedures, such as background checks [3].

New employees should receive field orientation and evaluation before functioning as patient care pro- viders. Orientation is provided in administration, operations, and medical areas, including protocols, equipment, and field performance standards.

**Medical supervision**

Assurance of quality prehospital health care is provided through the process of medical accountability [4]. The medical supervision of prehospital care is discussed extensively throughout this book. The vital role of the medical director in defining patient care standards, establishing protocols, approving the level of prehospital medical care that may be rendered by all individuals in the system, and positively affecting all the operational aspects that affect patient care cannot be overemphasized. In addition, the medical director should be directly involved in the risk management program.

**Continuing medical education**

Continuing medical education (CME) serves multiple purposes in an EMS system, including updating personnel on protocol changes, providing reviews, presenting medical information and technology, and evaluating knowledge and skills of field personnel. A number of studies have demonstrated deterioration of knowledge and skills in EMS providers. In 1980, Latman and Wooley demonstrated that personnel certified at the now-defunct Emergency Medical Technician-Ambulance (EMT-A) level lost 50% of their basic skills proficiency, and paramedics lost 61% of their basic skills proficiency within 2 years of training [5]. In 1987, Skelton and McSwain reported a correlation between the amount of technical skill deterioration and increasing length of time from completion of the training program [6]. One role of continuing medical education is to evaluate and enhance knowledge and skills of field personnel.

Other roles of CME include updates on protocol changes, patient care reviews, and new medical information and technology. CME also serves as a forum for EMS personnel to both provide and receive feedback regarding patient care. In 1990, Goldberg published a review of litigation in a large metropolitan EMS system and suggested that medicolegal continuing education could protect EMS systems and paramedics from future litigation [7].

**Documentation**

The Joint Commission (TJC, formerly JCAHO) requires that a medical record is established and maintained on every patient seeking emergency department care [8]. TJC mandates certain elements be included in the record; other elements may be added to conform with state regulations and hospital requirements. In comparing this with the prehospital arena, it is apparent that documentation requirements for EMS patient records vary widely. Patient records are required for all transported patients, yet specific elements of the record are far from universal. A number of states have standardized EMS patient records, but use of such a patient care report (PCR) may not be required.

Many systems maintain limited or no patient documentation if a patient is not transported. In 1992, Zachariah reported serious, even fatal, outcomes in patients not transported by EMS. Situations in which EMS personnel either denied transport or mutually agreed with the patient not to transport by ambulance were twice as likely to result in hospitalization than cases in which the patients declined transportation against the advice of the EMS personnel [7]. In 1990, Selden studied medicolegal documentation of prehospital triage and suggested that, rather than an abbreviated form or small section of the usual PCR, the release form (when a patient is not transported) must be at least as detailed as the usual incident report [9]. In 1985, Solar reported on the 10-year malpractice experience of a large urban EMS system and stated that a properly completed PCR is the best defense against a malpractice allegation [10]. Documentation remains one of our most critical areas for risk exposure.

Other important areas of documentation include the new employee’s application, pre-employment screening, and field orientation. Some systems document the new employee’s knowledge of written protocols, thus holding him or her accountable for the information and providing written evidence of that accountability. All aspects of patient care incident management should also be documented.

**Quality management and risk management**

Quality management (QM) of the patient care rendered in an EMS system may identify actual or potential risks to patients and the system. This identification allows for the proactive management of such risks, and takes the EMS system out of the reactive mode of dealing with problems in patient care. The QM loop forms a continuous action loop, starting and ending with protocols and education. Documentation of variance from or compliance with protocols forms the basis for analysis of the quality of care delivered [11].

Quality management and risk management are closely linked. The goals and objectives of a risk management program must be clearly understood, measurable, and attainable. There must be buy-in from all of the personnel within the organization. There are five principal steps in the development of an effective risk management program: (1) identifying risk exposure, (2) evaluating risk potential, (3) ranking and prioritizing risks, (4) determining and implementing control actions, and (5) evaluating and revising actions and techniques as needed. These steps include identifying and addressing those internal and external factors that create risk within the organization [12].

**Other factors**

Other incidents may occur in an EMS system that have potential effects on patients. If an ambulance is involved in an accident, the patient may receive injuries directly or have increased morbidity from a delay in transport. In 1992, Bowers reported on 182 incidents of alleged negligence involving prehospital care providers; 40% of the cases involved ambulance accidents (although some of these cases involved several identified categories of negligence) [13]. This is compared with 42% of the cases that were related to negligence involving treatment or care. A provider who is injured while extricating a patient may no longer be able to provide patient care at the scene, potentially affecting patient care. Equipment malfunctions such as defibrillator failure may have direct bearing on morbidity and mortality for a patient. Steps should be taken to identify and address potentially preventable occurrences, such as driver training programs and regular equipment checks.

**Patient expectations**

The concept of patient expectations concludes the components of prehospital risk management. Locales, socioeconomic status, cultural influences, and many other factors play a role in a patient’s expectations of the EMS system. It is important that patient expectations are taken into consideration. As a group, patients come to the health care system with fairly realistic expectations. They expect that the healing professionals will treat them with dignity and regard their welfare as a principal concern [14]. When the expectation of the patient is different from that of the EMS crew, conflict may arise. Discussions with EMS personnel regarding potential patient expectations and responses to possible conflicts may have significant positive con- sequences for an EMS system.

In a study of 17,271 emergency department (ED) patients, the first and third factors that patients perceived as reflecting quality care were physician courtesy and nurse courtesy. The other factors cited follow in order of importance: comfort of waiting area, satisfactory answers to patient questions, protection of privacy, acceptable waiting time for treatment, cleanliness of treatment area, and satisfaction with pain control [11]. Extrapolation of these findings to the prehospital area is logical, though poorly studied.

In health care, patient satisfaction remains the major product. When expectations are not met, patients feel they are not getting their “money’s worth.” Anger can be expressed in many ways in this culture, and filing a lawsuit is one of them [14].

**Patient care incident management**

As a clearly recognized component of the health care system, EMS personnel are affected by the trend of increasing litigation. Over the 12-year period of Goldberg’s review (1976 to 1987), claims made against Chicago Fire Department EMS increased threefold [7]. Of the 60 lawsuits presented, 47% named a paramedic as a defendant and 3% named the medical director. As the direct medical oversight physician is increasingly recognized as a fundamental component of quality prehospital care, correlative potential liability will necessarily follow [7]. It is likely that oversight physicians will be named more often in lawsuits as time progresses.

In the 1992 study by Bowers, the category of “treatment and care” represented about 43% of the cases [13] ([Table 18.1](https://jigsaw.vitalsource.com/books/9781118990827/epub/OPS/Vol2/c18.xhtml?favre=brett#c18-tbl-0001)). Goldberg reported 77% of the cases in his study involved alleged improper medical treatment [7]. It is important that the physician responsible for medical oversight grasps the full import of this information and responds by using an effective risk management system.

[**Table 18.1**](https://jigsaw.vitalsource.com/books/9781118990827/epub/OPS/Vol2/c18.xhtml?favre=brett#R_c18-tbl-0001) Major categories of alleged negligence involving prehospital care services or providers

Source: Adapted from Bowers MA. Negligence cases involving prehospital care providers and the implications for training, continuing education, and quality assurance. Doctoral thesis. Ann Arbor, MI: University Microfilm International,1992.

| **Category**[**\***](https://jigsaw.vitalsource.com/books/9781118990827/epub/OPS/Vol2/c18.xhtml?favre=brett#c18-note-0002) | **No.** | **%**[**\*\***](https://jigsaw.vitalsource.com/books/9781118990827/epub/OPS/Vol2/c18.xhtml?favre=brett#c18-note-0003) |
| --- | --- | --- |
| Treatment and care | 78 | 42.85 |
| Ambulance accidents | 73 | 40.1 |
| Dispatch and transport | 50 | 27.47 |
| Training, staffing, and administrative | 41 | 2.52 |

[\*](https://jigsaw.vitalsource.com/books/9781118990827/epub/OPS/Vol2/c18.xhtml?favre=brett#R_c18-note-0002)In some cases, more than one category was identified and used in this table.

[\*\*](https://jigsaw.vitalsource.com/books/9781118990827/epub/OPS/Vol2/c18.xhtml?favre=brett#R_c18-note-0003)Percent based on entire 182 cases.

**Patient care incident**

A patient care incident is any situation where there is a concern or complaint regarding patient care. This concern or complaint may be related to the commission or omission of actions on the part of EMS personnel, bystanders, other prehospital personnel, physicians providing direct medical oversight, or others that affect or potentially affect patient care and outcome of the situation.

At times, extenuating circumstances such as pro- longed scene time may affect patient care, but could not have been prevented. Equipment failures, scene injuries to crew members, or accidents involving ambulances may affect patient care. The documentation and consideration of such problems are part of patient care incident management.

**Establishing a comprehensive mechanism**

Establishing a comprehensive mechanism for managing patient care incidents is an important aspect of a risk management program. This mechanism includes incident identification, incident investigation, investigation findings, indicated actions, documentation, and system impact. It is important that all are oriented to this mechanism, including field employees, supervisors, and senior level management.

### Incident identification

Incident identification occurs when a patient or other source expresses a verbal or written concern regarding EMS patient care. It also may result from an identified equipment failure or a crew’s assessment of a difficult patient encounter such as a prolonged extrication.

Quality management studies and reviews may show areas that need improvement, such as success rate for initiation of IVs. The risk management pro- gram itself may identify trends in patient care inci- dents that indicate necessary systemwide intervention. It is important that a mechanism be in place to identify, document, receive information, and initiate the process for handling a patient care incident.

### Serious or critical patient care incidents

Serious or critical patient care incidents are occurrences that involve significant injury to a patient or negatively affect patient care, morbidity, or mortality. These incidents should be reported immediately. Usually the system has a chain of command for reporting incidents, and it is vital that this chain includes contacting the medical director.

### Incident investigation

Incident investigation is a uniformly applied, prearranged mechanism for investigating a patient care incident. It includes a chain of command that identifies roles for all of the players in the system and provides a routing mechanism for information and documentation obtained in the investigation. Certainly, all interactions related to the investigation should be documented; an investigation worksheet is a useful tool for the personnel investigating a patient care incident. This worksheet contributes consistency to investigations and also serves as a reminder for necessary actions to be taken and items to be obtained. A list of critical checklist ingredients is shown in [Box 18.1](https://jigsaw.vitalsource.com/books/9781118990827/epub/OPS/Vol2/c18.xhtml?favre=brett#c18-fea-0001).

## Box 18.1 Incident investigation checklist

* Discussions with involved EMS crew members
	+ Name/date:
	+ Name/date:
* Documentation of discussions with EMS crew members
* Discussions with other personnel (patient, physician, etc.) Name/date:
	+ Name/date:
	+ Name/date:
* Documentation of discussion with other personnel
* Crew member incident reports
* Patient care record (delete name and assign number)
* Other appropriate documentation
	+ Photographs
	+ Tape transcripts
* Equipment or products causal to the incident

The personnel responsible for carrying out the investigation should be educated in this aspect of their work. These investigators should respond in a timely manner to patients or other sources expressing negative comments or concerns about patient care. Many complaints may be resolved quickly with the education of the person who calls or writes about some aspect of prehospital medical care. For example, a physician may be concerned because his patient was not brought to the desired hospital. When the EMS supervisor explains that the patient was critically ill, and that it is the policy of the system to transport criti- cal patients to the closest hospital, the physician gains a better understanding of the process, and the problem may be resolved.

Some EMS systems require receipt of a formal written complaint before initiating an investigation. This is short-sighted, and it profoundly limits the scope of risk management. Some systems have less formal requirements for when an investigation may be initiated; prompt notation, however, of all complaints and discussions is important.

Emergency medical services crew members involved in an incident should have the opportunity to respond verbally and in writing to a concern that is being investigated. These written incident reports serve as information sources and are a routine part of the investigation. Other individuals may be asked to make oral or written statements regarding the events surrounding an incident. For example, the ED physician who finds an endotracheal tube placed in the esophagus and notifies the EMS system should be interviewed by the investigator.

Any other information, tape transcripts, PCRs, and equipment pertinent to the investigation should be collected. These materials are then collated with the incident reports and other relevant information to formulate the summary of the investigation. EMS ad- ministration and the medical director should evaluate this information through a formal process and make a disposition of the incident. Further discussions, interviews, or investigations may be necessary.

Patient privacy must be respected, and the PCR should be treated with the same concern for privacy as a physician record. This is a logical extension of the premise that providers function under the delegated authority of the physician medical director. States such as Texas protect PCRs in the same fashion as hospital medical records. Any unnecessary written or verbal reference to an incident report or its contents lessens the confidentiality of the report, contributes to potential negative repercussions, and minimizes the resultant value of its completion [15].

In most states the limits on discoverability of hospital incident reports are much better defined than for EMS incident reports. In general, only necessary copies of the report should be made and those who receive them should be in the appropriate reporting pathway. It may help to clearly label the recipient of each incident report that it is being prepared for possible use by legal counsel. Because there may be multiple regulations and statutes involved, such as those protecting peer-review material, it helps to design the incident report and the risk management program with consultation from all appropriate medical, administrative, and legal entities.

All aspects of the investigation should be fair and involve due process for the employee, including the employee’s prospective understanding of how the risk management program functions and how investigations are conducted. Some systems have review panels that include field personnel. EMS medical directors are the key individuals in the resolution of a patient care incident; therefore, they should be made aware of the initiation of an investigation for minor incidents and be actively involved for more serious or critical incidents. Medical directors must have final authority on the evaluation of the clinical aspects of the incident.

### Investigation findings

Investigation findings are the conclusions from the investigation of a patient care incident. The medical director must play an active role in evaluating investigation findings to determine appropriateness and accuracy. Results of the investigation may show that the incident was related to:

* environmental influences
* safety factors
* training
* employee clinical performance
* employee behavior
* judgment error
* equipment deficiency or failure
* incomplete documentation
* patient expectations
* protocol or policy problems
* actions of other personnel
* direct medical oversight.

### Incident investigation using root cause analysis

The goal of a root cause analysis is to determine what happened, what the scope of the problem is, and what the best actions are to keep the problem from happening again. In prehospital care, when we see an EMS practitioner make a mistake, it often looks on the surface as though he or she made a mistake and the problem is a simple one of human error. Although that may very well be the case, we would be remiss if we did not look at the root cause of each incident as it occurs. In essence, we need to develop strategies for preventing problems in the future. To be effective, the analysis must include a determination of all of the factors involved, a review of the systems and processes involved, the factors that potentially contributed to the error, and the best method for remedy [12].

The initial evaluation looks at what happened, and the root cause analysis determines the scope of the problem and the appropriate action to take.

### Indicated actions

Indicated actions depend on a number of factors, including seriousness of the incident from an admin- istrative, medical, or media standpoint; system response to previous similar incidents or similar types of incidents; and the employee’s long-term performance and disciplinary history. Indicated actions are administrative or medical. There is overlap at times, and communication between the administration and the medical director is essential.

Administrative actions usually fall into the generic classification of employee personnel actions. Medical actions generally fall into the categories of no action, policy or protocol revisions, product changes, remedial education, and corrective measures such as decertification. Remedial education actions include classroom education, clinical hospital education, testing, and supervised field preceptorship. Actions of an educational nature may also include systemwide training or retraining through continuing medical education. Potential corrective measures include counseling, probation, and decertification. The physician charged with medical oversight by contract has final authority on medical actions in response to patient care incidents.

Generally, for an initial performance problem, the employee receives some type of counseling and retraining that is specific to his or her needs. This process should be viewed as education based rather than discipline based, unless there are circumstances for which disciplinary measures are truly indicated.Even in the latter case the educational aspects must still play a vital role and represent a positive system response to a problem.

### Documentation

Documentation of the investigation and resolution of patient care incidents cannot be overemphasized, as it facilitates a more complete and consistent understanding of the investigation and ensures fairness and due process. Decisions regarding documents to be used and to whom information may be disseminated should be defined by the risk management program

## Future directions – prehospital medical error

Medical error is a topic of an increasing body of literature and of increasing public awareness. In 1999, the National Institute of Medicine reported that medical errors kill from 44,000 to 98,000 Americans each year. For example, medication prescribing/dispensing errors kill an estimated 7,000 patients per year. Yet little literature exists on medical error in the prehospital setting [16].

Medical error is what risk management programs seek to manage, and more importantly, to prevent. Risk management is more than responding to errors or potential errors, and includes a response to studies that objectively evaluate or refine techniques used to treat patients, and to studies that seek to reduce error in patient care [17].

In a study of CPR techniques using mannequins, a high rate of error was noted for emergency health- care providers (EMTs, firefighters, first responders, and CPR instructors) [18]. Though the application of this to the patient care setting has limitations, CPR is a standardized technique that was monitored for adherence and found to have significant error rates. Recommendations were made to modify training programs. In a landmark study of pediatric intubation, Gausche et al. found that the addition of out-of-hospital endotracheal intubation to a paramedic scope of practice that already includes bag-valve-mask use did not improve survival or neurological outcome of pediatric patients treated in an urban EMS system [19]. This study was done because of the difficulty associated with intubation of small children and because of intubation error, including unrecognized esophageal intubation. An EMS system risk management program should in- clude a review of these types of studies. Changes to a particular EMS system may or may not be needed as a result, but the system should be aware of the studies.

One effective tool used by multiple industries to reduce error is already in place in EMS systems: standardization. Examples of standardization in EMS systems include protocols that guide patient care, consistency in the type and location of equipment used by EMS personnel, operational protocols that guide scene management, and dispatch protocols. And because of the “system” nature of EMS, prehospital care providers are in a unique position of being able to implement systemwide changes.

Leape stated that total quality management re- quires a culture in which errors and deviations are regarded not as human failures, but as opportunities to improve the system [16]. The psychology and culture of hospital and prehospital providers will need to change if progress is to be made in reducing errors.

## Conclusion

One major goal for the risk management program is to provide effective patient care incident management so the incident becomes part of the overall quality management program, and does not simply become an isolated circumstance with no system impact. Trends and patterns must be observed and interventions taken as necessary.

The goals for an EMS risk management program extend far beyond reactive management of patient care incidents. A good program allows for the prospective management and evaluation of all the medical care provided in an EMS system; it considers factors and influences that may negatively affect patient care even before an incident occurs. The program affects protocols, continuing education, training, pre-employment screening, medical oversight, and administration.

Change is facilitated through the identification of problems reactively and proactively; all personnel involved in the EMS system become part of the solution. The ultimate benefactors are the patients in the EMS system; their medical care improves through the changes and growth that result from the program.

## Acknowledgment

We would like to acknowledge the previous author of this chapter in the last edition, James Atkins.

## References

1. 1 FEMA, United States Fire Administration. Risk Manag ment Practices in the Fire Service. FA-166. Washington, DC: FEMA, 1996.
2. 2 Valenzuela TD, et al. Evaluation of EMS management training offered during emergency medicine residency training. *Ann Emerg Med* 1989;18:812–14.
3. 3 Cason D, Wainscott MP. Training and evaluation. In: Polsky SS (ed) Continuous Quality Improvement in EMS. Dallas, TX: American College of Emergency Physicians, 1992.
4. 4 Polsky SS, Weigand JV. Quality assurance in emergency medical service systems. *Emerg Med Clin North Am* 1990;8:75–84.
5. 5 Latman NS, Wooley K. Knowledge and skill retention of emergency care attendants, EMT-As, and EMT-Ps. *Ann Emerg Med* 1980;9:183–89.
6. 6 Skelton MB, McSwain NE. A study of cognitive and technical skill deterioration among trained paramedics. *JACEP* 1977; 6:436–8.
7. 7 Goldberg RJ, Zautcke JL, Koenigsberg MD. A review of prehospital care litigation in a large metropolitan EMS system. *Ann Emerg Med* 1990;19:557–61.
8. 8 National Emergency Room Survey: quality of care monitor. Park Ridge, IL: Parkside Associates, 1991.
9. 9 Selden BS. Medicolegal documentation of prehospital triage. *Ann Emerg Med* 1990;19:547–51.
10. 10 Solar JM, et al. The 10-year malpractice experience of a large suburban EMS system. *Ann Emerg Med* 1985;14:982–5.
11. 11 Bukata WR. Emergency department medical record. In: Henry GL (ed) Emergency Medicine Risk Management: A Comprehensive Review. Dallas, TX: American College of Emergency Physicians, 1991.
12. 12 United States Department of Veterans Affairs. Root Cause Analysis. Ann Arbor, MI: VA National Center for Public Safety, 2007.
13. 13 Bowers MA. Negligence cases involving prehospital care providers and the implications for training, continuing education, and quality assurance. Doctoral thesis. Ann Arbor, MI: University Microfilm International, 1992.
14. 14 Patient expectations. In: Henry GL (ed) Emergency Medicine Risk Management: A Comprehensive Review. Dallas, TX: American College of Emergency Physicians, 1991.
15. 15 Shanaberger CJ. Legal issues in medical control. In: Kuehl A (ed) EMS Medical Director’s Handbook. St Louis, MO: CV Mosby, 1989.
16. 16 Leape LL. Error in medicine. *JAMA* 1994;272(23):1851–7.
17. 17 Corrigan J, Kohn LT, Donaldson MS (eds). To Err is Human. Building a Safer Health System. Washington, DC: National Academy Press, 1992.
18. 18 Lieberman M, Lavoie A, Mulder D, et al. Cardiopulmonary resuscitation: errors made by prehospital emergency personnel. *Resuscitation* 1999;42:47–55.
19. 19 Gausche M, Lewis RJ, Stratton S, et al. Effect of out-of-hospital pediatric endotracheal intubation on survival and neurological outcome: a controlled clinical trial. *JAMA* 2000;283(6):783–90.