PRACTICE GUIDELINE FOR THE PERFORMANCE OF PERCUTANEOUS VERTEBROPLASTY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline was revised collaboratively by the American College of Radiology, American Society of Neuroradiology, American Society of Interventional and Therapeutic Neuroradiology, American Society of Spine Radiology, and the Society of Interventional Radiology. A thorough review of the literature was performed. When published data were felt to be inadequate, data from the expert panel members’ own quality assurance programs were used to supplement. Thresholds for quality assurance have been updated in accordance with available data in the literature.

Developed by Deramond and colleagues in France in the late 1980s [1], percutaneous vertebroplasty entails injection of polymethyl methacrylate (PMMA) cement into the collapsed vertebra. The injected bone cement acts as an internal splint to reinforce and stabilize the fracture
for pain alleviation. Re-expansion of collapsed vertebrae or height restoration may be achieved during the process of vertebroplasty.

Radiologic imaging has been a critical part of percutaneous vertebroplasty from its inception. Most procedures are performed utilizing fluoroscopic guidance for needle placement and to monitor cement injection. The use of computed tomography (CT) has also been described for these purposes.

Percutaneous vertebroplasty is an established, safe, and effective procedure for selected patients. Extensive experience documents its safety and efficacy [1-20]. As with any invasive procedure, the patient is most likely to benefit when the procedure is performed in an appropriate environment by qualified physicians.

These guidelines are written to be used in quality improvement programs to assess percutaneous vertebroplasty procedures. The most important processes of care are 1) selecting patients, 2) performing the procedure, and 3) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

This guideline does not address balloon-assisted vertebroplasty (kyphoplasty).

II. DEFINITION

Percutaneous vertebroplasty is the injection of radiopaque bone cement (e.g., polymethyl methacrylate) into a painful osteoporotic or neoplastic compression fracture with the use of imaging guidance.

III. OVERVIEW

Vertebral compression fractures are a common and often debilitating complication of osteoporosis [21-25]. Although most fractures heal within a few weeks or months, a minority of patients continue to suffer pain that does not respond to conservative therapy [26-27]. Vertebral compression fractures are a leading cause of nursing home admission. Open surgical fixation is rarely employed to treat these fractures. The poor quality of bone at the adjacent unfractured levels does not provide a good anchor for surgical hardware, and the advanced age of most affected patients increases the risk of major surgery.

Initial success with percutaneous vertebroplasty for treatment of aggressive hemangiomas [1,2] and osteolytic neoplasms [3,4] led to extension of the indications to include osteoporotic compression fractures refractory to medical therapy [5-19].

IV. INDICATIONS AND CONTRAINDICATIONS

The major indication for percutaneous vertebroplasty is the treatment of symptomatic osteoporotic or neoplastic vertebral body compression fracture(s) refractory to medical therapy. Failure of medical therapy is defined by minimal or no pain relief with the administration of prescribed analgesics or adequate pain relief with narcotic dosages that produce undesirable side effects (excessive and intolerable sedation, confusion, or constipation). There is no indication for the use of vertebroplasty for prophylaxis against future fracture. The indications and contraindications for percutaneous vertebroplasty may change in the future as more research and information become available.

A. Indication

Threshold

Painful osteoporotic or neoplastic vertebral compression fracture(s) refractory to medical therapy.

Note: When fewer than 95% of percutaneous vertebroplasty in an institution are performed for the above indication, it should prompt a review of practices related to selection of patients for this procedure.

B. Absolute Contraindications

1. Asymptomatic vertebral body compression fractures.
2. Patient improving on medical therapy.
3. Nonfractured vertebral levels.
4. Prophylaxis in osteoporotic patients (unless being performed as part of a research protocol).
5. Osteomyelitis of the target vertebra.
6. Myelopathy originating at the fracture level.
7. Uncorrectable coagulopathy.
8. Allergy to bone cement or opacification agent.

C. Relative Contraindications

1. Radiculopathy in excess of local vertebral pain, caused by a compressive syndrome unrelated to vertebral collapse. Occasionally preoperative percutaneous vertebroplasty can be performed before a spinal decompressive procedure.
2. Asymptomatic retroplusion of a fracture fragment causing significant spinal canal compromise.
3. Asymptomatic tumor extension into the epidural space.
4. Ongoing systemic infection.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

In general, the requirements for physicians performing percutaneous vertebroplasty (see Section V.A.3) may be met by adhering to the recommendations listed below:
1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec, and must include performance of successful percutaneous vertebroplasties in at least five patients as the primary operator, under the supervision of a qualified physician, and without complications.

or

Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency fellowship program or an American Osteopathic Association (AOA) approved residency program that included 6 months training in cross-sectional imaging, including CT and MR imaging, and 4 months training in image-guided interventional radiological techniques, including percutaneous vertebroplasty, biopsy and drainage procedures, and vascular embolization. This must include performance of successful percutaneous vertebroplasties in at least five patients as the primary operator, under the supervision of a qualified physician, and without complications.

or

A board eligible physician or one who did not complete an ACGME approved residency or fellowship training program (as listed above) or other postgraduate training that included comparable instruction and experience may meet the requirements by having documented “hands on” training in the performance of percutaneous vertebroplasty. This must include performance of successful percutaneous vertebroplasties in at least five patients as the primary operator, under the supervision of a qualified Physician, and without complications.

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Completion of an ACGME approved residency fellowship program or an American Osteopathic Association (AOA) approved residency program that included 6 months training in cross-sectional imaging, including CT and MR imaging, and 4 months training in image-guided interventional radiological techniques, including percutaneous vertebroplasty, biopsy and drainage procedures, and vascular embolization. This must include performance of successful percutaneous vertebroplasties in at least five patients as the primary operator, under the supervision of a qualified physician, and without complications.

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A board eligible physician or one who did not complete an ACGME approved residency or fellowship training program (as listed above) or other postgraduate training that included comparable instruction and experience may meet the requirements by having documented “hands on” training in the performance of percutaneous vertebroplasty. This must include performance of successful percutaneous vertebroplasties in at least five patients as the primary operator, under the supervision of a qualified physician, and without complications.

and

2. Substantiation in writing by the director of interventional radiology or the chief of the department of the institution in which the physician will be providing these services that the physician is familiar with all of the following:
   a. Indications and contraindications for percutaneous vertebroplasty.
   b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient, and particularly the recognition and initial management of procedural complications.
   c. Appropriate use and operation of fluoroscopic and radiographic equipment, digital subtraction systems, and other electronic imaging systems.
   d. Principles of radiation protection, hazards of radiation exposure to the patient and the radiologic personnel, and radiation monitoring requirements.
   e. Anatomy, physiology, and pathophysiology of the spine, spinal cord, and nerve roots.
   f. Pharmacology of contrast agents and of polymethyl methacrylate and recognition and treatment of potential adverse reactions to these substances.
   g. Technical aspects of performing this procedure.
   and

3. Possess certain fundamental knowledge and skills that are required for the appropriate application and safe performance of percutaneous vertebroplasty:
   a. In addition to a basic understanding of spinal anatomy, physiology, and pathophysiology, the physician must have sufficient knowledge of the clinical and imaging evaluation of patients with spinal disorders to determine those for whom percutaneous vertebroplasty is indicated.
   b. The physician must fully appreciate the benefits and risks of percutaneous vertebroplasty and the alternatives to the procedure.
   c. The physician is required to be competent in the use of fluoroscopy, computed tomography (CT), and magnetic resonance imaging (MRI); and modalities employed to evaluate potential patients and to guide the percutaneous vertebroplasty procedure.
   d. The physician should be able to recognize, interpret, and act immediately on image findings.
   e. The physician must have the ability, skills, and knowledge to evaluate the patient’s clinical status and to identify those patients who might be at increased risk, who may require additional pre- or postprocedural care, or who have relative contraindications to the procedure.
   f. The physician must be capable of providing the initial clinical management of complications of percutaneous vertebroplasty, including administration of basic life support, treatment of pneumothorax, and recognition of spinal cord compression.
   g. Training in radiation physics and safety is an important component of these requirements. Such training is important to maximize both patient and physician safety. It is highly recommended that the physician have adequate training in and be familiar with the...
principles of radiation exposure, the hazards of radiation exposure to both patients and radiologic personnel, and the radiation monitoring requirements for the imaging methods listed above.

Maintenance of Competence

Physicians must perform a sufficient number of image-guided percutaneous interventions, including sufficient numbers of percutaneous vertebroplasties, to maintain their skills, with acceptable success and complication rates as laid out in this guideline. Continued competence depends on participation in a quality improvement program that monitors these rates. Regular attendance at postgraduate courses that provide continuing education on diagnostic and technical advances in percutaneous vertebroplasty is necessary.

Continuing Medical Education

The physician’s continuing education should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME).

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology considers that certification and continuing education in the appropriate subfield(s) demonstrate that an individual is competent to practice one or more of the subfields in medical physics, and to be a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR) or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields in medical physics for this guideline are Radiological Physics and Diagnostic Radiological Physics.

The continuing education of a Qualified Medical Physicist should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME). 2006 (Res. 16g)

C. Radiologist Assistant

A radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled “Radiologist Assistant: Roles and Responsibilities” and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. 2006 (Res. 34)

D. Radiologic Technologist

The technologist, together with the physician and the nursing personnel, should be responsible for patient comfort. The technologist should be able to prepare and position the patient for the vertebroplasty procedure and, together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform regular quality control testing of the equipment under the supervision of the medical physicist.

The technologist should have documented training and experience in the percutaneous vertebroplasty procedure or similar interventional procedures and be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license.

E. Nursing Services

Nursing services are an integral part of the team for pre- and postprocedural patient management and education and may assist the physician in monitoring the patient during the percutaneous vertebroplasty procedure.

VI. SPECIFICATIONS OF THE PROCEDURE

A. Technical Requirements

Several technical requirements are necessary to ensure safe and successful percutaneous vertebroplasties. These include adequate institutional facilities, imaging and monitoring equipment, and support personnel. The following are minimum facility requirements for any institution in which percutaneous vertebroplasty is to be performed:

1. A procedural suite large enough to allow safe and easy transfer of the patient from bed to procedural table with sufficient space for appropriate positioning of patient monitoring equipment, anesthesia equipment, respirators, etc. There should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other
staff within the room without contaminating the sterile conditions.

2. A high-resolution image intensifier and video system with adequate shielding and capable of rapid imaging in orthogonal planes and capabilities for permanent image recording is essential. Imaging findings are acquired and stored either on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines.

3. Immediate access to CT and rapid (within 30 or 45 minutes) access to MR imaging is necessary to allow evaluation of potential complications. This may be particularly desirable if percutaneous vertebroplasty is planned in patients with osteolytic vertebral metastasis and/or with significant preexisting spinal canal compromise. CT is desirable for evaluation of the spinal canal and intervertebral foramina if significant extravasation of cement is suspected, even if the patient remains asymptomatic.

4. The facility must provide adequate resources for observing patients during and after percutaneous vertebroplasty. Physiologic monitoring devices appropriate to the patient’s needs – including blood pressure monitoring, pulse oximetry, and electrocardiography – and equipment for cardiopulmonary resuscitation must be available in the procedural suite.

B. Surgical and Emergency Support

Although serious complications of percutaneous vertebroplasty are infrequent, there should be prompt access to surgical, interventional, and medical management of complications.

C. Patient Care

1. Preprocedural care
   a. The written or electronic request for percutaneous vertebroplasty should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

   Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

   The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the state scope of practice requirements. 2006 (Res. 35)

   b. The clinical history and findings, including the indications for the procedure, must be reviewed and recorded in the patient’s medical record by the physician performing the procedure. Specific inquiry should be made with respect to relevant medications, prior allergic reactions, and bleeding/clotting status.

   c. The vital signs and results of physical and neurological examinations must be obtained and recorded.

   d. The indication(s) for the procedure, including (if applicable) documentation of failed medical therapy, must be recorded.

   e. The indication(s) for treatment of the fracture should have documentation of imaging correlation and confirmation.

2. Procedural care
   a. Adherence to the JCAHO Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings including bedside procedures. “Time out” must be conducted in the location where the procedure will be done, just before starting the procedure and must:
      • Involve the entire operative team.
      • Use active communication.
      • Be briefly documented, such as in a checklist, and
      • At the least, include:
         ➢ Correct patient identity.
         ➢ Correct side and site.
         ➢ Agreement on the procedure to be done.
         ➢ Correct patient position.
         ➢ Availability of correct implants and any special equipment or special requirements.

   The organization should have processes and systems in place for reconciling differences in staff responses during the “time out”.

   b. Vital signs should be obtained at regular intervals during the course of the procedure, and a record of these measurements should be maintained.

   c. Patients undergoing percutaneous vertebroplasty must have intravenous access in place.
for the administration of fluids and medications as needed.

d. If the patient is to receive moderate or “conscious” sedation, pulse oximetry must be used. Administration of sedation for percutaneous vertebroplasty should be in accordance with the ACR Practice Guideline for Adult Sedation/Analgesia. A registered nurse or other appropriately trained personnel should be present and have primary responsibility for monitoring the patient. A record of medication doses and times of administration should be maintained.

3. Postprocedural care
   a. A procedural note should be written in the patient’s medical record summarizing the course of the procedure and what was accomplished, any immediate complications, and the patient’s status at the conclusion of the procedure (see Section VIII.A.2 below). This note may be brief if the formal report will be available within a few hours. This information should be communicated to the referring physician in a timely manner. A more detailed summary of the procedure should be written in the medical record if the formal typed report will not be on the medical record within the same day.

   b. All patients should be at bed rest and observed during the initial postprocedural period. The length of this period will depend on the patient’s medical condition.

   c. During the immediate postprocedural period, skilled nurses or other appropriately trained personnel should monitor the patient’s vital signs, urinary output, sensorium, and motor strength. Neurological status should be assessed frequently at regular intervals. Initial ambulation of the patient must be carefully supervised.

   d. The operating physician or a qualified designee (another physician or a nurse) should evaluate the patient after the initial postprocedural period, and these findings should be summarized in a progress note on the patient’s medical record. The physician or designee must be available for continuing care during hospitalization and after discharge.

VII. EQUIPMENT QUALITY CONTROL

Each facility should have documented policies and procedures for monitoring and evaluating the effective management, safety, and proper performance of imaging and interventional equipment. The quality control program should be designed to maximize the quality of the diagnostic information. This may be accomplished as part of a routine preventive maintenance program.

VIII. QUALITY IMPROVEMENT AND DOCUMENTATION

A. Documentation

Results of percutaneous vertebroplasty procedures should be monitored on a continuous basis. Records should be kept of both immediate and long-term results and complications. The number of complications should be documented. Any biopsies performed in conjunction with percutaneous vertebroplasty should be followed-up to detect and record any false negative and false positive results.

A permanent record of percutaneous vertebroplasty procedures should be maintained in a retrievable image storage format.

1. Imaging labeling should include permanent identification containing:
   a. Facility name and location.
   b. Examination date.
   c. Patient’s first and last names.
   d. Patient’s identification number and/or date of birth.

2. The physician’s report of a percutaneous vertebroplasty procedure should include:
   a. Procedure undertaken and its purpose.
   b. Local anesthesia, if used, listing agent and amount.
   c. Moderate sedation, if used, listing medications and amounts.
   d. Listing of level(s) treated and amount of cement injected at each level.
   e. Immediate complications, if any, including treatment and outcome.

3. Followup documentation:
   a. Postprocedure evaluation at 48 hours to assess patient response (pain relief, mobility improvement). Standardized assessment tools such as the SF 36 and the Roland scale may be useful for both pre- and postoperative patient evaluation.
   b. Delayed complications, if any, including treatment and outcome.
   c. Pathology (biopsy) results, if any.
   d. Record of communications with patient and referring physician.
   e. Patient disposition.
Reporting should be in accordance with the Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures.

B. Informed Consent and Procedural Risk

Informed consent or emergency administrative consent must be obtained and must be in compliance with all state laws and should comply with the ACR Practice Guideline on Informed Consent for Image-Guided Procedures. Risks cited should include infection; bleeding; allergic reaction; fracture; pneumothorax (for appropriate levels); and extravasation of cement into the adjacent epidural or paravertebral veins resulting in worsening pain or paralysis, spinal cord or nerve injury, or pulmonary compromise. The potential need for immediate surgical intervention should be discussed. The possibility that the patient may not experience significant pain relief should also be discussed.

C. Success and Complication Rates and Thresholds [1-20]

Although practicing physicians should strive to achieve perfect outcomes (e.g., 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality-improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Procedure thresholds or overall thresholds refer to a group of indicators for a procedure, e.g., major complications. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a minimum threshold, or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes if necessary. For example, if the incidence of fracture of rib or other bone is one measure of the quality of percutaneous vertebroplasty, values in excess of the defined threshold (in this case <1%) should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the complication. Thresholds may vary from those listed herein; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae, but may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix A). The complication rates and thresholds described herein refer to major complications.

Routine periodic review of all cases having less than perfect outcomes is strongly encouraged. Serious complications of percutaneous vertebroplasty are infrequent. A review is therefore recommended for all instances of death, infection, and symptomatic pulmonary embolus.

Success Rates

When percutaneous vertebroplasty is performed for osteoporosis, procedure outcomes can be defined using the criteria by Hodler et al. with patients categorized as worse, same, better, or pain/disability gone. For the purpose of this document pain/disability gone is defined as improved. Therefore patients should be categorized as either improved, the same, or worse. This categorization should be determined by the use of a validated measurement tool.

When percutaneous vertebroplasty is performed for neoplastic involvement, success is defined as achievement of significant pain relief and/or improved mobility as measured by validated measurement tools with a threshold of 50%-60%.

Complications

Major complications occur in fewer than 1% of patients treated for compression fractures secondary to osteoporosis and in less than 5% of treated patients with neoplastic involvement. Published complications rates and suggested thresholds are included below.

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients, e.g., early in a quality-improvement program. In this situation, the suggested threshold is more appropriate for use in a quality-improvement program than is the published rate.
The overall procedure threshold for all complications resulting from percutaneous vertebroplasty performed for osteoporosis is 2%, and when performed for neoplastic indications it is 10%.

IX. RADIATION SAFETY IN IMAGING

Radiologists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This is the concept “As Low As Reasonably Achievable (ALARA)”. Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Patient radiation doses should be periodically measured by a medical physicist in accordance with the appropriate ACR Technical Standard. 2006 (Res. 17)
REFERENCES


Appendix A

Society of Interventional Radiology
Standards of Practice Committee
Classification of Complications by Outcome

Minor Complications

A. No therapy, no consequence.
B. Nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (<48 hours).
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).
E. Have permanent adverse sequelae.
F. Result in death