Policy: **Patient Safety – The Prevention, Recognition, and Management of Adverse Outcomes**

Date of Implementation **February 18, 2003**

Product: **Specialty**

To protect the health and safety of members, American Specialty Health – Specialty (ASH) has identified quality of care strategies for making practitioners aware of the need to implement office-based methods to reduce clinical errors and improve patient safety. These strategies include encouraging practitioners to adopt evidence-based health care approaches to patient care, maintain their clinical skills at or above broadly accepted professional standards of care, and follow applicable care management guidelines. ASH monitors practitioners in their delivery of care and then compares them to other network practitioners via ASH clinical and administrative criteria set forth through the Clinical Performance System. Practitioner performance is a helpful indicator during the recredentialing process.

It is important to note that all forms of healthcare service carry some potential risk of harm. Implementing basic risk management procedures that prevent, identify, and manage actual or alleged adverse outcomes can help practitioners minimize the risk of harm or injury to the member.

ASH has identified the following goals in improving member safety:

- Identify types of adverse outcomes;
- Educate practitioners regarding patient safety standards;
- Decrease the incidence of adverse events through the identification and management of preventable events and risk factors;
- Facilitate the appropriate reporting of adverse outcomes;
- Evaluate clinical diagnostic and therapeutic procedures applicable to the specialty services represented by ASH against professionally recognized standards of practice, current scientific evidence, and consensus of appropriate experts for safety, plausibility, efficacy and/or diagnostic utility, and evidence-based practices [see the *Evidence Based Health Information Evaluation / Technology Assessment (QM 32 – ALL)* and *Evidence Selection and Evaluation (QM 33 – ALL)* policies for additional information];
- Identify and act in the event of a medical emergency [see the *Emergency Communication Triage (MBR 2 – ALL)* policy*]*; and
- Support or participate in studies to improve patient safety-related clinical outcomes.

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Patient Safety Defined

ASH accepts the Institute for Healthcare Improvement (IHI) definition of patient safety as: *"Ensuring every person receives safe, reliable, effective, and equitable care, achieved through a total systems approach grounded in evidence and the science of improvement, aiming to eliminate harm and save lives."*

ASH also accepts the Institute of Medicine Aims for the 21st Century published in their text, *Crossing the Quality Chasm* (2001). Page 5 of this report states:

"The committee proposes six aims for improvement to address key dimensions in which today's health care system functions at far lower levels than it can and should. Health Care should be:

Safe – avoiding injuries to patients from the care that is intended to help them.

Effective – providing services based on scientific knowledge to all who could benefit, and refraining from providing treatment/services to those not likely to benefit (avoiding under-utilization and over-utilization, respectively).

Patient Centered – providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all medical/clinical decisions.

Timely – reducing wait times and sometimes harmful delays for both those who receive and those who give care.

Efficient – avoiding waste, including waste of equipment, supplies, ideas, and energy.

Equitable – providing care that does not vary in quality because of patient characteristics such as gender, geographic location, or socioeconomic status."

Patient safety, which is one of many domains of health care quality concerns, is the subject matter of this document. Two other domains of quality concerns are:

- Practices that are consistent with current clinical or scientific knowledge and with best practices; and
- The ability to meet client/customer/member-specific values and expectations.

ASH's clients, customers, and members place great significance on the outcome measure of *patient satisfaction,* including satisfaction with the clinical outcome. Patient safety is a driving force behind patient satisfaction.

ASH recognizes that patient safety has three primary components:

- Risk factor assessment (Prevention)
- Recognizing adverse outcomes (Identification)

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- Management of adverse outcomes (Amelioration)

Risk Factor Assessment (Prevention)

A thoughtful and attentive patient evaluation, which includes special attention to general risk factors and risks associated with the type of intervention considered is used to identify patients at risk. Knowledge of basic risk assessment procedures minimizes the liability risks inherent in the practitioner's practice. The following should be considered as part of the clinical evaluation:

Assessment of Red Flags

The 'red flag' approach is utilized broadly in patient care. At any time the patient is under care, the practitioner is responsible for seeking and recognizing signs and symptoms that require additional diagnostics, treatment/service(s), and/or referral. This ongoing process is necessary to discover potential serious underlying conditions that may either need urgent attention or an alteration in the treatment approach. Red flags can present themselves at several points during the patient encounter and can appear in many different forms.

Due to the rarity of actual red flag diagnoses in clinical practice, it is emphasized that the practitioner does not need to perform expensive or invasive diagnostic procedures (e.g., x-ray, imaging, laboratory studies) in the absence of suspicious clinical characteristics. As an example, there is no need to screen the patient for red flag conditions by taking x-rays or other imaging studies if the initial presentation is consistent with mechanical musculoskeletal pain without red flags.

Important red flags and events as well as the points during the clinical encounter at which they are likely to appear include:

Health History:

- Personal or family history of cancer;
- Current or recent urinary tract, respiratory tract, or other infection;
- Anticoagulant therapy or blood clotting disorder;
- Metabolic bone disorder (Osteopenia and osteoporosis);
- Unintended weight loss;
- Significant trauma sufficient to cause facture or internal injury;
- Trauma with skin penetration
- Immunosuppression (e.g. AIDS/HIV/ARC);
- Intravenous drug abuse, alcoholism;
- Prolonged corticosteroid use;
- Previous adverse reaction to substances or other treatment modalities;

- Use of substances or treatment which may contraindicate proposed services; and/or
- Uncontrolled health condition (diabetes, hypertension, asthma, etc.).

Present Complaint:

- Writhing or cramping pain;
- Precipitation by significant trauma;
- Pain worse at night or not relieved by any position;
- Suspicion of vascular/cerebrovascular compromise;
- Symptoms indicative of progressive neurological disorder;
- Unexplained dizziness or hearing loss;
- Complaint inconsistent with reported mechanism of injury and/or evaluation findings; and/or
- Signs of Psychological distress.

Physical Examination/Assessment:

- Fever, chills, or sweats of unknown origin;
- Neurologic deficit (special senses, peripheral sensory, motor, language, cognitive);
- Positive vascular screening tests (carotid stenosis, vertebrobasilar insufficiency, abdominal aortic aneurysm, etc.);
- Surface lesions or infections in area to be treated;
- Widespread or multiple contusions;
- Abnormal vital signs;
- Signs of allergic reaction;
- Signs of Abuse/Neglect;
- Signs of psychological distress;
- Unexplained severe tenderness or pain;
- Inability to reproduce symptoms of musculoskeletal diagnosis or complaints;
- Uncontrolled hypertension;
- Signs of nutritional deficiency.

Pattern of Signs/Symptoms Not Consistent with Benign Disorder:

- Chest tightness, difficulty breathing, chest pain;
- Headache of morbid proportion;
- Rapidly progressive neurological deficit;
- Significant, unexplained extremity weakness or clumsiness;
- Change in bladder or bowel function;
- New or worsening numbness or paresthesia;
- Saddle anesthesia;

- New or recent bilateral radiculopathy.

Lack of Response to Appropriate Care:

- History of consultation/care from a series of practitioners or a variety of health care approaches without resolving the patient's complaint;
- Unsatisfactory clinical progress, especially when compared to apparently similar cases or natural progression of the condition; and/or
- Signs and symptoms that do not fit the normal pattern and are not resolving.

Assessment of Yellow Flag(s)

Yellow flags are adverse prognostic indicators with a psychosocial predominance associated with chronic pain and disability. Yellow flags signal the potential need for more intensive and complex treatment and/or earlier specialist referral.

When yellow flags are present, clinicians need to be vigilant for deviations from the normal course of illness and recovery. Examples of yellow flags include depressive symptoms, injuries still in litigation, signs, and symptoms not consistent with pain severity, and behaviors incongruent with underlying anatomic and physiologic principles.

Error Prevention

Another important aspect of safety and prevention of adverse events is error prevention. To prevent errors, a clear understanding and acceptance of the causes of clinical errors and unsafe practices is necessary along with an active management approach to ensure the potential for errors is eliminated from the clinical interaction. Some causes of clinical errors include:

- Prescription of an incorrect/inappropriate treatment/service or modality for the patient's health status or condition.
- Recommendation of an ingested or topical product (e.g., supplement or balm) having an ingredient to which the patient has had a prior adverse reaction.
- Diagnostic errors leading to the application of an incorrect/inappropriate therapy such as failure to implement a needed diagnostic test that would more clearly define the patient's condition, misinterpretation of diagnostic results and tests, and failure to act appropriately on abnormal examination or test results.
- Therapeutic/diagnostic equipment failure.
- Misunderstanding or misinterpretation of clinical information provided to the treating practitioner by a third party clinician.
- Inadequate medical records that do not clearly identify information necessary to avoid injury or adverse outcome by the clinician at a future date or a third party using the medical record to render treatment/services in the absence of the author. (Paraphrased from the Agency for Healthcare Research and Quality; Publication Number 00-PO37 Feb 25, 2000)

Diagnostic and therapeutic adverse outcomes can be minimized by avoiding experimental, untested, or quasi-scientific diagnostic and therapeutic procedures. Some keys to reducing adverse events include:

- Always take into account any contraindications to the intended use of the treatment/service.
- Inform patients of the risks, consequences, or side effects that may arise from diagnostic or therapeutic procedures.
- Patient selection for appropriate use of treatments/services and therapeutic modalities is important. Take into consideration patient tolerances, contraindications, and risk of side effects before applying any treatment/service.

Recognizing Adverse Outcomes (Identification)

Clinical errors are defined as failure of a planned action to be completed as intended (errors of execution) or the use of an incorrect/inappropriate plan to achieve an aim (errors of planning).

- Errors of execution (e.g., commission of direct injury to the patient; can also include omission of a step or procedure that leads to unexpected injury to the patient).

  Slips or Lapses occur when the action conducted was not what was intended. It is an error of execution. A slip is observable and a lapse is not (i.e., a slip of the hand and a lapse of memory).

- Errors of planning (e.g., missed diagnosis, inappropriate application of treatment/service, or incorrect/inappropriate treatment/service selection).
  Mistakes In a mistake the action proceeds as planned but fails to achieve its intended outcome because the planned action was incorrect/inappropriate.

  Slip versus Mistake A slip might be involved when the practitioner chooses an appropriate modality but sets the dial to 10 when the intention was to set the dial to 1.0. A mistake, on the other hand, might be involved when selecting the incorrect/inappropriate modality (e.g., hot pack) because the diagnosis is incorrect/inappropriate (e.g., missed the diagnosis of septic arthritis).

- Slips, lapses, and mistakes in patient care are serious errors and can potentially result in harming patients. Adverse outcomes do not always imply actual injury and may not be a direct result of the treatment. Even when there is no injury to the patient resulting from the error, it may cause the patient to experience concern, which may result in the reporting of a complaint.

A self-limiting treatment/service-induced discomfort that is non-injurious but does cause the patient to experience concern may result in the reporting of a complaint. This discomfort can be considered to be within the range of normal reactions to manipulation, physiotherapy, acupuncture, massage, or other appropriately prescribed care by the practitioner. Beyond reassurance, no intervention is likely to be medically necessary.

Risk Management (Amelioration)

A willingness to acknowledge the reality of an adverse outcome along with quick action to assist the patient is essential to patient safety. Knowledge and use of basic risk management procedures for managing actual or alleged adverse outcomes can help health care practitioners minimize harm or injury to patients. Open and honest dialogue with patients is encouraged.

In the unfortunate occurrence of an adverse event, it is important to properly evaluate the situation, communicate with the patient in a factual manner without assessing blame, select a means to remedy the situation, monitor the outcome of the event, and document these and other relevant event(s) in the medical record.

If the practitioner concludes that the injury is negligible, reassurance and self-care instructions are all that are likely to be medically necessary. However, when an injury is significant, the practitioner should render a diagnosis, ensure delivery of necessary urgent/emergency care, and/or make necessary referrals.

If an adverse outcome is reported, ASH investigates and evaluates the issues and may seek recommendations from the Practice Review Committee (PRC) in order to determine what action may be appropriate.

When professional misconduct or injury is suspected, ASH performs an investigation to assess for:

- Adequate documentation;
- Appropriate monitoring, timely recognition, and treatment/service;
- Appropriate plans for follow-up, implement work-up; and
- Referral in a timely manner, if needed.

Proper risk management strategies maximize patient safety. These strategies include implementing an evidence-based health care approach; accurate, timely practitioner/patient communication, and maintaining best practice clinical skills and knowledge.

Adverse Event Clinical Indicators

Adverse Event Clinical Indicators are utilized to:

- Identify adverse events and protect the health and safety of ASH members.

- Decrease the incidence of adverse events through the identification of preventable events.
- Facilitate the appropriate reporting of adverse outcomes that may result in Corrective Action Plans (CAP).
- Evaluate practitioner performance during the recredentialing process (in addition to the evaluation process that occurs at the time of the event).
- Assist with the development of studies to improve clinical outcomes.