Richard L. Roudebush VA Medical Center
Indianapolis, IN 46202
January 14, 2010

Endoscopy Adverse Events Monitoring.

1. PURPOSE:

This GI Endoscopy Unit internal policy provides guidance for monitoring of adverse events during or following endoscopic procedures.

2. BACKGROUND:

a. The safe performance of endoscopic procedures requires tracking and proper management of potential adverse events and complications.

b. Adverse events include those related to sedation and those secondary to the procedure and endoscopic interventions performed at the time of the procedure.

c. **Definitions:**

1- Sedation-related adverse event: change in cardiac or respiratory status requiring administration of reversal agents, ventilation assistance, or invasive intervention to sustain adequate ventilation and perfusion.

2- Hemorrhage: clinically significant post procedure hemorrhage requiring repeat endoscopy with intervention, hospitalization, transfusion, or surgery.

3- Perforation: free intraperitoneal air detected on post procedure radiographs performed for any indication.

4- Post-ERCP pancreatitis: clinically significant abdominal pain following ERCP; associated with elevation in amylase and/ or lipase, and/ or consistent findings on abdominal imaging.

5- Severity: Mild: requiring admission or prolongation of a planned admission up to 3 days; Moderate: hospitalization of 4 to 10 days; Severe: hospitalization of more than 10 days, irreversible sequelae, or death.

3. POLICY:

a. Intra-procedure and immediate post-procedure complications must be reported in the procedure report, including serious sedation adverse events and procedure complications.

b. Follow up phone calls 24 to 48 hours will be made by the nursing staff to all patients to track delayed complications.

c. Patients admitted or readmitted as a result of procedures complications will be systematically followed by the GI service, in consultation with other medical, radiological, and surgical services as appropriate.

d. Delayed procedure complications must be fully documented in the patient's electronic medical record.

e. A detailed adverse event form must be filled by the provider for each adverse event (immediate or delayed).

f. Sedation-related events are further regulated by the hospital-wide sedation policy, and are also reviewed by a monitoring anesthesia committee.

g. All complications are reviewed by a hospital-wide Invasive Procedures Committee on a quarterly basis.

4. ACTION:

Quarterly monitoring reports will be generated, with combined data for the whole endoscopy unit. The reports will include:

- Total number of procedures performed by type
- Number of complications by type
- Incidence of each complication by type
- Brief summary of each adverse event

This report will be finalized by the GI section chief. All physicians will be provided with the data. Any provider or system issues will be identified and addressed as appropriate by the section chief and/or director of endoscopy.

Gastroenterology Section Chief