Adverse Events with Sedated Pediatric Echocardiography	
Measure Description: Proportion of sedated echocardiograms associated with adverse events.	
Numerator	Number of moderate/deep sedated transthoracic echo procedures associated with minor[2], moderate[3], or severe[4] adverse events. ***Note:*** *Include only the adverse events that occur during the sedation episode[1].*
Denominator	Number of moderate or deep sedated transthoracic echocardiograms performed for children < 3 years of age during the measurement period. **Note**: *Include transthoracic echocardiograms performed by anyone completing a sedated echo (both anesthesiologist and non-anesthesiologists) and at any location, either an echocardiography lab or in partnership with echocardiography labs.*
Denominator Exclusions	Sedated echocardiographic studies where echocardiography is not the sole procedure for which sedation is performed, but which are performed in conjunction with additional procedures (Eg. patient having an echocardiogram performed under the same sedation as a minor urologic surgical procedure). These studies would be excluded from this metric as adverse events occurring may be related to the associated procedure rather than to the sedation requirements of the pediatric echocardiogram.
Denominator Exceptions	None
Definitions / Notes	1. **Sedation Episode**: time of receipt of sedation to discharge by the individual administering the sedation 2. **Minor events** o Desaturation – fall in saturation of 10% or more from baseline and/or unplanned oxygen use o Apnea more than 15 seconds requiring stimulation o Allergic reaction not requiring treatment o Vomiting o Prolonged sedation (greater than 2 hours from initial medication administration to completion of study OR per center's definition, dependent on agent used) o Prolonged recovery (greater than 2 hours from completion of echo to return to baseline OR per center's definition, dependent on agent used) o Inadequate sedation to perform study. 3. **Moderate events** o Oxygenation/ventilation compromise requiring non-invasive ventilation (includes bag and mask and CPAP) o Intubation o Use of reversal agents o Aspiration o Hemodynamic compromise requiring fluid resuscitation o Unplanned overnight observation

	○ Allergic reaction requiring treatment ○ Agitation/delirium requiring treatment (includes use of additional medications) ○ IV related complication ○ Emergent anesthesia/sedation consultation required ○ Hypoglycemia requiring treatment ○ Hypothermia ○ Stridor ○ Wheezing ○ Laryngospasm 4. **Severe events** ○ Cardiopulmonary arrest ○ Permanent injury or disability (especially neurologic) ○ Death
Measurement Period	Quarterly
Sources of Data	Prospective flowsheet, retrospective medical record review, electronic medical records are all appropriate sources of data.
Attribution	This metric should be reported by each echocardiography laboratory performing sedated transthoracic echocardiography. Data will be assessed quarterly, by the laboratory director or his/her designate and reviewed with the laboratory staff involved in the ordering and provision of sedation and in the interpretation of echocardiograms performed under sedation. Some centers may wish to delegate responsibility for collection of data to a member of a sedation team if sedation is not provided directly by the cardiologists.
Care Setting	Outpatient

Rationale

This metric assesses the safety of administration of sedation in the population of vulnerable patients who require sedation for completion of a transthoracic echocardiogram as part of their care for complete delineation of anatomy and physiology. The need for sedated echocardiography in infants and small children whose cooperation cannot always be won is recognized in the pediatric cardiology community. Sedation has recognized potential complications, and there are numerous guideline documents recognizing the need for monitoring and responding to adverse events during sedation. Quality assurance processes should include periodic review of adverse events and consideration of changes in policy to minimize these events; physicians involved in the ordering and performance of these studies should be involved in quality assurance reviews of these procedures within their laboratories.

Clinical Recommendation(s)

ACC/AHA Guidelines
None

Other Guidelines:

References for need for quality assurance review processes:

1. American Academy of Pediatrics American Academy of Dentistry; Cote JC, Wilson S: Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. An update. *Pediatrics* 2006; 118; 2587

The essence of medical error reduction is a careful examination of index events and root-cause analysis of how the event could be avoided in the future. Therefore, each facility should maintain records that track adverse events such as desaturation, apnea, laryngospasm, the need for airway interventions including jaw thrust or positive pressure ventilation, prolonged sedation, unanticipated use of reversal agents, unintended or prolonged hospital admission, and unsatisfactory sedation/analgesia/anxiolysis.

Guidelines for monitoring for adverse events/presence of individuals skilled in resuscitation:

2. Guidelines and Standards for Performance of a Pediatric Echocardiogram: A Report from the Task Force of the Pediatric Council of the American Society of Echocardiography *JASE* 2006: 19:1413:

Written policies including, but not limited to, the type of sedatives, appropriate dosing for age and size, and proper monitoring of children during and after the examination should exist for the use of conscious sedation in children. Each laboratory should have a written procedure in place for handling acute medical emergencies in children. This should include a fully equipped cardiac arrest cart (crash cart) and other necessary equipment for responding to medical emergencies in pediatric patients of all sizes.

3. THE JOINT COMMISSION, COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS (CAMH). (2012).
Provision of Care, Treatment, and Services Standards PC.03.01.01, PC.03.01.05, PC.03.01.03, PC.03.01.07
Record of Care Standard: RC.02.01.03
Performance Improvement Standard: PI.01.01.01

Individuals administering moderate or deep sedation and anesthesia are qualified and have credentials to manage and rescue patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally… In addition to the individual performing the procedure, a sufficient number of qualified staff are present to evaluate the patient, to provide the sedation and/or anesthesia, to help with the procedure, and to monitor and recover the patient… For operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia: The hospital has equipment available to monitor the patient's physiological status… For operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia: The hospital has resuscitation equipment available…During operative or other high risk procedures, including those that require the administration of moderate or deep sedation or anesthesia, the patient's oxygenation, ventilation, and circulation are monitored continuously… The hospital assesses the patient's physiological status immediately after the operative or other high-risk procedure and/or as the patient recovers from moderate or deep sedation or anesthesia.

4. Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists: An updated report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. *Anesthesiology* 2002; 96:1004

All patients undergoing sedation/analgesia should be monitored by pulse oximetry with appropriate alarms. In addition, ventilatory function should be continually monitored by observation or auscultation. Monitoring of exhaled carbon dioxide should be considered for all patients receiving deep sedation and

for patients whose ventilation cannot be directly observed during moderate sedation. When possible, blood pressure should be determined before sedation/analgesia is initiated. Once sedation/analgesia is established, blood pressure should be measured at 5-minintervals during the procedure, unless such monitoring interferes with the procedure… Individuals monitoring patients receiving sedation/analgesia should be able to recognize the associated complication. At least one individual capable of establishing a patent airway and positive pressure ventilation, as well as a means for summoning additional assistance, should be present whenever sedation/analgesia is administered. It is recommended that an individual with advanced life support skills be immediately available (within 5 min) for moderate sedation and within the procedure room for deep sedation.

Challenges to Implementation

Not all laboratories have facilities for sedated echocardiography. Laboratories not performing studies under sedation would not use this metric.

There may be difficulty within laboratories in designating specific adverse events as minor, moderate, or severe, though guidelines included in this metric should be helpful.
The definition of prolonged sedation and prolonged recovery will vary between centers using different sedative medications as the time course for sedation and recovery will vary depending on the agent utilized.

Echocardiographic laboratories routinely using sedation services or anesthesia teams to perform sedation may not have direct access to information regarding adverse events and may need to partner with colleagues in other areas such as anesthesia or intensive care to obtain this data. However it is critical that those making decisions to sedate patients for echocardiography, and involved in the performance and interpretation of these echocardiograms be familiar with the adverse events occurring in the course of sedation and modify their practice of referral for and performance of sedation accordingly.

It is anticipated that the number of moderate and major events annually in each lab will be low, which may make it difficult to improve the metric over data review cycles. The process of review of events may be more valuable than the value of the metric itself in guiding the modification of sedation practices to optimize patient care.

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