Position Statement on Patient Monitoring During Procedural Sedation:
The Physician-Patient Alliance for Health & Safety Recommends the Use of Capnography Monitoring During Procedural Sedation

Introduction - Need for Improved Patient Care During Procedural Sedation

The number of noninvasive and minimally invasive procedures performed outside of the operating room has grown exponentially over the last several decades. Depending on the patient and the medical procedure, many of these are performed under sedation to manage the patient's pain and/or anxiety without inducing general anesthesia. A medical procedure involving procedural sedation may seem "simple and routine." As described by John Hopkins Medicine:

> *Procedural sedation is used only for short, straightforward procedures. It is not used for complex surgeries. Some [examples of] procedures that use this type of sedation include:*
>
> - *Bone or joint realignment to fix a broken bone or dislocated joint*
> - *Breast biopsy to evaluate a lump in the breast*
> - *Bronchoscopy to evaluate lung conditions*
> - *Dental surgery*
> - *Electrical cardioversion to restore a normal heart rhythm*
> - *Endoscopy for gastrointestinal problems*
> - *Lumbar puncture to check for neurological disease*
> - *Minor foot or skin surgery*

According to the American Society of Anesthesiologists (ASA) Continuum of Depth of Sedation Scale, procedural sedation "is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation," as shown in the chart below:

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	Minimal Sedation Anxiolysis	*Moderate Sedation/ Analgesia ("Conscious Sedation")*	*Deep Sedation/ Analgesia*	*General Anesthesia*
Responsiveness	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Notwithstanding the "mid-range" classification of procedural sedation - as less than general anesthesia, but more than light sedation where the patient can "respond purposefully to verbal commands" - the recent release of two major guidelines in the United States in 2018 indicate that there are patient safety concerns and gaps in the standard of care when patients undergo procedural sedation.

One is from the American Society of Anesthesiologists, "Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018," which provide:

> *"Observational studies indicate that some adverse outcomes (e.g., unintended deep sedation, hypoxemia, or hypotension) may occur in patients with preexisting medical conditions when moderate sedation/analgesia is administered."*

These Guidelines are particularly noteworthy because they are a consensus statement of the American Society of Anesthesiologists Task Force on Moderate Procedural Sedation and Analgesia, the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dentist Anesthesiologists, and Society of Interventional Radiology. These organizations all felt the joint need to issue these Guidelines to "assist the practitioner and patient in making decisions about health care."

The other is from the American Society for Gastrointestinal Endoscopy (ASGE) - "Guidelines for sedation and anesthesia in GI endoscopy," which states:

> *"One recent retrospective study of more than 1 million patients undergoing endoscopy and colonoscopy confirmed that the ASA class is associated with a risk of adverse events during GI procedures and may be useful in stratification of risk for GI endoscopy. Analysis of the Clinical Outcomes Research Initiative database has demonstrated that increasing ASA class is associated with increased risk of unplanned cardiopulmonary events during endoscopy."*

Like the ASA Guidelines, the ASGE Guidelines involved other medical organizations; they were were reviewed and endorsed by the American Association for the Study of Liver Diseases, the American College of Gastroenterology, and the American Gastroenterological Association.

Patient Safety Concerns During Procedural Sedation:

The difficulty with managing is sedation is that it is a continuum, and as experts have warned, patients may quickly move from moderate sedation to deep sedation. This is particularly of concern whenever propofol is administered. Although the use of propofol is popular and growing as a medication for sedation, it is critical that providers be aware of the increased risk of unintended deep sedation and general anesthesia when administering propofol.

As Richard Merchant, MD, FRCPC (Clinical Professor, University of British Columbia, Department of Anesthesia, Pharmacology, & Therapeutics) explained in a clinical education podcast with Matt Kurrek, MD, FRCPC (Professor, Department of Anesthesia, University of Toronto), "Capnography Monitoring: Yesterday's Luxury, Today's Necessity During Conscious Sedation":

> *if you give something intravenously, … the patient for whom you intend to give mild sedation may temporarily pass into a state of deep sedation before the anesthetic distributes in the body and before you end up in the targeted sedation depth ...*

This is because it is impossible to predict how an individual patient may react when provided an opioid. As Frank Overdyk, MSEE, MD, who organized the two conferences on opioid-induced respiratory depression for the Anesthesia Patient Safety Foundation, explained in a clinical education podcast, "Preventing Avoidable Deaths: Monitor for Respiratory Compromise:"

> *"… what is not appreciated by patients and by some doctors and nurses is that a patient's response to a 'standard dose of morphine,' for instance, can vary up to 30 fold. And, what that means is if I give a hundred patients the same dose of morphine - ten milligrams of morphine - about ninety patients will get some level of pain relief - some better, some worse - and breath adequately, but there may be one or two patients who slow their breathing or even stop breathing. And, it is very difficult because of that variation in effect to predict which patients will be the one who stops breathing, when you turn your back on them for ten minutes. So, I always say there's no safe first dose of opioids, there's just a starting dose, and it is critically important that the patient be checked regularly to see how the patient responds and then adjust your doses accordingly."*

This difficulty in predicting the effect of opioids is compounded with the great number of procedures and the complexity of patients undergoing such procedures. As stated in the Association for Radiologic & Imaging Nursing (ARIN) Clinical Practice Guideline on Moderate Sedation and Analgesia:

"Minimally invasive procedures performed in imaging departments have increased in complexity. The increase in complexity is due to the evolution of operating room hybridization compounded by an aging population with multiple comorbidities. Accordingly, radiologic and imaging nurses are challenged to leverage the available technology to improve intra‐procedural safety and patient outcomes within this higher risk population."

In reviewing the key recommendations on procedural sedation, to improve patient safety Physician-Patient Alliance for Health & Safety would like to highlight these five key recommendations:

Procedural Sedation Recommendation #1 - Administration of Procedural Sedation Must Be With Trained Personnel, Who SHOULD NOT Also Be Performing the Procedure

The administration of procedural sedation must be with trained personnel. Leaving the provision and administration of procedural sedation to a trained professional may seem to be a requirement that would not need to be stated. As Collège des Médecins du Québec (CMQ) states in "La Sedation Analgesie" (the CMQ statement was issued with the support of l'Ordre des infirmières et infirmiers du Québec and l'Ordre Professionnel des inhalothérapeutes du Québec):

"... all must have the qualifications required in the field of the sedation-analgesia." [PPAHS translation]

Moreover, the analgesia provider should not be the same person performing the medical procedure. As the Canadian Anesthesiologists' Society states in its "Position Paper on Procedural Sedation (RSS refers to the Ramsay sedation scale):"

"In general, the individual performing the procedure will not be the individual administering or supervising intravenous sedation. For deeper levels of sedation (RSS 4-6), this requirement is absolute; for lighter levels, it may be appropriate to delegate monitoring of a sedated patient to an appropriately trained and certified assistant whose sole responsibility is monitoring the sedated patient. However, the responsible physician must be immediately available to intervene should such be necessary. In specific circumstances where light (RSS 1-3) sedation is administered, it may be appropriate for one anesthesiologist to supervise more than one case, provided that an appropriately trained, qualified, and accredited individual, who is approved by the health care institution, is in constant attendance with each patient receiving care. The attending anesthesiologist must assume medical responsibility for the care of all patients and must be immediately available to attend. The institution must establish the number of concurrent cases in light of the intensity and complexity of the cases and the physical status of the patients."

While there may be some discussion as to whether the anesthesia provider could be a clinician other than a doctor, properly trained nurses could perform this critical function, as stated in "Position Statement for Role of the Registered Nurse:"

> *"The Canadian Society of Gastroenterology Nurses and Associates supports the position that competent Registered Nurses trained in the field of gastroenterology, procedural sedation, medication management, and airway management may be given responsibility of administering procedural sedation under direct order and supervision of the physician."*

What is most important during procedural sedation is the qualifications and training of the anesthesia provider, as stated by CMQ in "La Sedation Analgesie:"

- *be able to adequately assess the health condition of the patient and to ensure the clinical surveillance;*
- *know and use wisely the medication as well as its antagonists;*
- *possess the knowledge and skills necessary to intervene in situation of emergency such as cardiopulmonary resuscitation (preferably in advanced care); that is to say, be knowledgeable about the techniques in support of the ventilation, heart massage and of the associated medication;*
- *have the expertise required, according to the targeted clientele and the intervention diagnostic or therapeutic to achieve. [PPAHS translation]*

However, if the administration of sedation and the ongoing monitoring of patients are delegated to a sedation assistant, these tasks must be under the direct supervision of an anesthesiologist. Moreover, it cannot be emphasized enough that the ultimate responsibility, if an error is made, is always the attending physician's.

Procedural Sedation Recommendation #2 - Equipment and Supplies Must Be On-Hand in Case of Oversedation and Respiratory Compromise - and Clinicians Need to Practice How to Use Them!

The onset of respiratory compromise may occur in a very short period of time. As CMQ emphasizes in "La Sedation Analgesie," the anesthesia provider:

> *"… must be prepared to manage the passage momentary at a level of sedation higher than that which was planned (i.e. deeper than expected), which can occur at any time during the intervention diagnostic or therapeutic." [PPAHS translation]*

Consequently, it is essential that during the procedure that the appropriate and necessary equipment and supplies be on-hand. As stated by the Canadian Anesthesiologists' Society in its "Position Paper on Procedural Sedation:"

> *"Appropriate equipment, including supplies and equipment to manage unintended oversedation and complications of medications or procedures, must be immediately*

available whenever intravenous medications are administered. Each facility must assess their particular circumstances to ensure that appropriate equipment is available and routinely checked and serviced …

"Reversal agents for benzodiazepines (flumazanil) and narcotics (naloxone) should be used with caution, inasmuch as the duration of action of these agents is much shorter than the duration of action of most of the drugs whose effects they are used to reverse."

Moreover, it is not enough to just have on-hand the necessary equipment and supplies. Clinicians performing the procedural sedation should practice using them. As Kenneth P. Rothfield, MD, MBA, CPE, CPPS (then System Vice President, Chief Medical Officer, Saint Vincent's Healthcare, Ascension Health, now Chief Medical Officer, Medical City in Dallas), who is a member of PPAHS's board of advisors, emphasized in the Washington Post article, "Joan Rivers's death spurs new look at outpatient centers:"

"Unless you have drilled for it, and trained for it, it can be hard to pull off."

Procedural Sedation Recommendation #3 - Early Detection of Respiratory Compromise Will Decrease Adverse Events and Patient Deaths

The Respiratory Compromise Institute, which is a coalition of medical and patient safety organizations, stresses that early intervention is a key to preventing adverse and patient deaths due to respiratory compromise:

"While not all cases of respiratory compromise are preventable, many are preventable through early identification and intervention."

As ARIN states in Clinical Practice Guideline on Moderate Sedation and Analgesia:

"Sedation is a continuum with complexities requiring hyper-vigilant monitoring of multiple physiologic parameters. Early detection of patient progression towards a deeper level of sedation is paramount in preventing a sentinel event."

Or, as the ASA consensus statement describes it:

"Many of the complications associated with moderate sedation and analgesia may be avoided if adverse drug responses are detected and treated in a timely manner (i.e., before the development of cardiovascular decompensation or cerebral hypoxia)."

Procedural Sedation Recommendation #4 - All Patients Undergoing Procedural Sedation Should be Monitored with Capnography

To ensure that continual safety of patients undergoing procedural sedation, the Physician-Patient Alliance for Health & Safety strongly recommends that these patients be continuously

monitored with capnography for the adequacy of ventilation. As CMQ emphasizes in "La Sedation Analgesie:"

> *"CO2 monitoring allows you to identify early complications such as the excessive sedation, hypoventilation and apnea, in addition to better control the level of sedation in function of the intervention diagnostic or therapeutic carried out." [PPAHS translation]*

Consequently, ARIN in its Clinical Practice Guideline on Moderate Sedation and Analgesia stated:

> *ARIN endorses the routine use of capnography for all patients who receive moderate sedation/analgesia during procedures in the imaging environment. This technology provides the critical information necessary to detect respiratory depression, hypoventilation, and apnea, thus allowing the timely initiation of appropriate interventions to rescue the individual patient. Capnography use is associated with improved patient outcomes. Capnography should be used at all times, regardless of whether sedation is administered by an anesthesia provider or a registered nurse credentialed to administer moderate sedation/analgesia medications."*

The recent ASA consensus statement summarizes the literature regarding the use of capnography monitoring and concludes:

> *"Meta-analysis of RCTs indicate that the use of continuous end-tidal carbon dioxide monitoring (i.e., capnography) is associated with a reduced frequency of hypoxemic events (i.e., oxygen saturation less than 90%) when compared to monitoring without capnography (e.g., practitioners were blinded to capnography results) during procedures with moderate sedation (category A1-B evidence)."*

Similarly, ARIN, after an extensive review of the literature, summarized the research and evidence in favor of using capnography:

> *"… the evidence has shown a clear superiority of capnography in evaluation of patient's ventilatory status when compared with current routine monitoring practices resulting in safer patient care. Key concepts found in the literature:*
>
> - *Access to capnography ensured timely provider interventions in response to hypoventilation and resulted in fewer hypoventilatory episodes with a decrease in hypoxic events.(Beitz et al., 2012; Langhan, Shabanova, Li, Bernstein, & Shapiro, 2015; Slagelse, Vilmann, Hornslet, Jorgensen, & Horsted, 2013; van Loon, van Rheineck Leyssius, van Zaane, Denteneer, & Kalkman, 2014)*
> - *Respiratory depression is identified sooner when compared to pulse oximetry monitoring (Adams, Butas, & Spurlock, 2015; Cacho et al., 2010). One study noted an average detection time of respiratory depression 3.7 minutes sooner; another demonstrated that capnography use was 17.6 times more likely to detect*

respiratory depression compared with standard monitoring.(Langhan, Chen, Marshall, & Santucci, 2011; Waugh, Epps, & Khodneva, 2011)

- *There is also a cost benefit advantage to capnography as evidenced by a decrease in adverse events and a potential cost-avoidance.(Friedrich-Rust et al., 2014)*

In the report, "Systematic Review to Develop Clinical Practice Guideline for the Use of Capnography During Procedural Sedation in Radiology and Imaging Settings," ARIN's Capnography Task Force concluded:

> *"Advances in radiology and imaging technologies and the emergent scope of practice have led to the capacity to provide services to a growing population of high-acuity patients with comorbid conditions. These procedures are often performed with the radiology nurse administering procedural sedation. Monitoring patients is challenging due to certain patient conditions and the unique environment, that is, the radiology procedure suite. The addition of capnography monitoring, along with standard monitoring, is a valuable modality that provides a continuous objective assessment of the patient's ventilatory status even when direct visualization of the patient is compromised."*

A great example of a hospital that is monitoring patients undergoing procedural sedation with capnography is Sunnybrook Health Sciences Centre in Toronto, Canada. After reviewing the current literature, Sunnybrook decided that monitoring with capnography resulted in safer patient care. Capnography monitoring provides an early indicator of patient deterioration, which can be crucial in averting adverse events and patient deaths.

In the interview, "Capnography Monitoring During Conscious Sedation," Barbara McArthur, RN, BScN, CPN(C), who is an advanced practice nurse at Sunnybrook Health Sciences, said capnography monitoring is monitoring in "real time. With pulse oximetry, there is a delay, which could be up to a minute in healthy patients. So, that's a significant sort of time that is delayed that reaction could happen."

"Having the monitor can let you know the patient's status sooner," explained Ms. McArthur, "for example, if they're getting into respiratory problems, the nurses can intervene much quicker." As a result, since implementing capnography monitoring, Ms. McArthur says that she is "not aware of any patients receiving reversal or any escalation of care with a rapid response team."

Procedural Sedation Recommendation #5 - Recovery and Discharge of the Patient Must be Supervised by Trained Anesthesia Providers

Before discharging the patient after procedural sedation, it is essential to make sure that the patient has recovered sufficiently from the anesthesia. As the Canadian Anesthesiologists' Society states in its "Position Paper on Procedural Sedation:"

> *"Post-procedural care of the sedated patient may be delegated to appropriately trained and qualified individuals once the patient has recovered to the level of RSS 2 (awake, patient co-operative, orientated, and tranquil). If the patient is to be discharged from the institution, the attending physician must be available to attend to the patient until standards for discharge have been achieved.* ***Patients must remain in the recovery area for a minimum of 30 minutes after the last dose of intravenous sedation or analgesia is given, or for a minimum of 120 minutes after the last dose of intravenous reversal agent is given." [emphasis added]***

We would like to point out that the patient should be monitored for an extended period in an unstimulated environment prior to discharge. Doing so may avoid situations like what happened to Logan Parker, who died shortly after being sent home after a routine medical procedure. The attending clinicians did not ensure that the anesthetics given to Logan were no longer affecting him adversely.

Conclusion - Take These Five Precautions During Procedural Sedation

Although procedural sedation is generally safe, the Physician-Patient Alliance for Health & Safety recommends that all procedural sedation follow at least these five precautions:

1. Administration of Procedural Sedation Must Be With Trained Personnel, Who SHOULD NOT Also Be Performing the Procedure
2. Equipment and Supplies Must Be On-Hand in Case of Oversedation and Respiratory Compromise - and Clinicians Need to Practice How to Use Them!
3. Early Detection of Respiratory Compromise Will Decrease Adverse Events and Patient Deaths
4. All Patients Undergoing Procedural Sedation Should be Monitored with Capnography
5. Recovery and Discharge of the Patient Must be Supervised by Trained Anesthesia Providers

The Physician-Patient Alliance for Health & Safety would like to thank the following organizations and individuals for reviewing and providing comments in preparing this position statement:

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However, the review and comments by the above-noted organizations and individuals should not be construed as an endorsement of or support for this position statement.