Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

Virginia Board of Nursing Ad Hoc Committee
Guidance Document - RN Role in Procedural Sedation
September 15, 2015
Conference Center – Suite 201
2:00 P.M.

Call To Order and Introductions – Kelly McDonough, DNP, RN

Old Business

- Minutes of May 19, 2015 minutes and review Committee activities

New Business

- Consideration of University of Virginia Health Policy Students Policy Brief on Procedural Sedation

- Review and consideration of draft Guidance Document #90-

Public Comment

Next Steps

From: Mary Kay Apple [mailto:mkapplern@aol.com]
Sent: Wednesday, June 17, 2015 6:12 PM
To: Douglas, Jay P. (DHP)
Cc: James Pickral; Pamela C Kimeto; matthew payne; Matt Burns; Connie Brooks; rhys williams; joseph freeze; shannon darner
Subject: Policy brief on procedural sedation by Virginia Registered Nurses

Mr. Douglas,

Attached is a well researched and succinct policy brief created by University of Virginia Health Policy students, who are practicing emergency department Registered Nurses throughout Virginia. We respectfully request that the policy brief be made available to Board of Nursing members, as part of their consideration in formulating guidelines for procedural sedation. We look forward to hearing from you and/or the Board of Nursing regarding the suggested policy options and remain…

Respectfully yours,
Mary Kay Goldschmidt, DNP, RN, CLCP
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Procedural Sedation: Regional Practice by Registered Nurses

Connie Brooks RN, Matthew Burns RN, Jonathan Kling RN
Shannon Darner RN, Matt Payne RN, Rhys Williams RN,
Joseph Freeze RN

Contact: *Mary Kay Goldschmidt*
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Issue

This policy brief will address the draft guidance document 90-63 created by The Virginia Board of Nursing (VBON) titled "The Role of the Registered Nurse in Procedural Sedation."[1] The 90-63 guidance document defines the continuum of sedation, education and training requirements for the registered nurse (RN), the role of the RN as a sedation provider, and accepted standards of documentation and monitoring.

The 90-63 guidance document identifies the administration of propofol (Diprivan) for procedural sedation as outside of the scope of practice for the RN. Limiting the RN's ability to administer specific anesthetic agents should be carefully considered, as it contradicts established procedures in Emergency Departments (ED) and Intensive Care Units (ICU) of many hospitals across the Commonwealth of Virginia. This policy brief aims to provide recommendations to the 90-63 guidance document that will promote patient safety without creating limitations on currently accepted practices of procedural sedation.

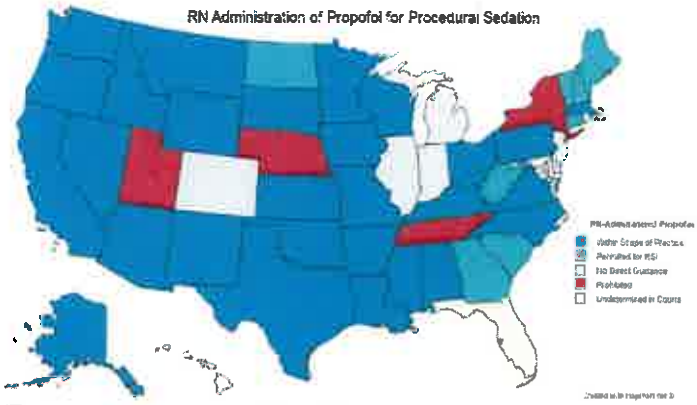
Background Information

Procedural sedation is indicated for patients who require a painful procedure but not an advanced airway. The Food and Drug Administration (FDA) labels propofol for use as a "general anesthetic".[2] In the ED and ICU setting, it is common practice for the RN to administer propofol and other general anesthetic medications (i.e. ketamine and etomidate) for procedural sedation. Propofol is a common choice due to its rapid onset of action and recovery of the patient to baseline mentation. With proper dosage and monitoring, procedural sedation utilizing propofol is safe and effective at reducing the patient's pain and improving procedure outcomes.

The RN's role within the sedation team is integral to safe, timely, and effective procedural sedation. The licensed medical provider manages the sedation plan, determines the proper medication choice, and intended level of sedation prior to the procedure. The administration of these medications by the RN occurs with the provider physically present at the bedside. Throughout the procedure, the RN administers medications as ordered to achieve and maintain the desired level of sedation. The RN provides continuous monitoring of the patient's hemodynamic status and respiratory drive until their recovery to baseline.[3]

Using the previously described process, the administration of propofol by the RN for the purpose of procedural sedation is a safe and established practice that occurs daily in EDs and ICUs across the Commonwealth of Virginia.

National Practice



(Emergency Nurses Association, 2015)

Policy Implications

The restriction of propofol, or other medications defined as general anesthetics, will severely limit timely and effective procedural sedation in the ED and ICU setting. Alternative medications utilized to achieve similar levels of sedation may result in an increased risk of over sedation, extended recovery times, increased ED length of stay, increased risk of respiratory depression, or inadequate sedation. Requiring a designated anesthesia provider to be present to administer propofol for procedural sedation could severely hinder

and delay care at many facilities without readily available anesthesia staff.

Existing Organizational Opinions

- **The Joint Commission:** The Joint Commission states those facilitating sedation must be experienced and have completed "competency-based education and training." Providers must also have the qualifications and skills required to "rescue" patients from over sedation. The Joint Commission dictates only minimum general standards and then permits hospitals to fill in the specific details according to local views, expertise, and resources.[4]

- **Federal Drug Administration:** The 2014 FDA approved propofol (Diprivan) labeling and insert notes, "for general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure," while not specifically referring to any specific licensure requirements. Facilities have successfully created educational programs to train nurses in the administration of propofol for procedural sedation. Many sedatives, including propofol, have off label uses widely accepted in the medical community.[2]

- **Emergency Nurses Association:** The current ENA Procedural Sedation Consensus Statement focuses on Six Quality Aims listed as safe, effective, timely, efficient, equitable and patient centered delivery of procedural sedation. The ENA clearly states the role of the RN in administering procedural sedation medications, including propofol, "procedural sedation medications may be administered by RNs in the presence of a physician, advanced practice registered nurse, or other health care professional credentialed and privileged for procedural sedation."[5] The ENA goes further to specify the education and qualifications required to administer procedural sedation medications including propofol. This consensus statement was endorsed by the following groups: Air & Surface Transport Nurses Association, American Academy of Emergency Medicine, American Association of Critical Care Nurses, American College of Emergency Physicians, American Nurses Association, American Radiological Nurses Association, American Society for Pain Management Nursing, Emergency Nurses Association, National Association of Children's Hospitals and Related Institutions.[5]

- **Physician Input:** Dr. Alice Gouvernayre is a board certified emergency physician and Medical Director of Sentara Northern Virginia Medical Center, Emergency Department. After reviewing the policy 90-63, Dr. Gouvernayre had the following thoughts.
  - Nursing staff has the most training in administering medications safely.
  - Nurses already administer a multitude of drugs that have similar side effect profiles as propofol under MD supervision with great success.
  - By allowing the nurses to administer propofol, it would allow physicians to focus more on the patients' respiratory status and hemodynamics.
  - By having nurses administer propofol, we can standardize the administration and in fact make the administration of this drug safer for our patients.

  (A. Gouvernayre, personal communication, June 16, 2015)

- **Current Hospital Policies**: Many hospitals across the Commonwealth have existing policies outlining the use of propofol for procedural sedation, all of which do not restrict the RN from actual drug administration. Historically, nurses have administered medications in these situations under the direct order and supervision of the prescribing provider. A full assessment of the impact on patient care should be reviewed prior to restricting RN procedural sedation practice. [3, 6, 7]

Policy Options and Recommendations

- Limit the scope of this policy to propofol administration during "procedural sedation" only. Clearly state that this policy is not intended to regulate the use of propofol for sedation of intubated patients.
- Maintain the current practice allowing properly trained and educated RNs to administer propofol for the purposes of procedural sedation *in the presence of the prescriber* credentialed and privileged for procedural sedation.
- Define appropriate RN procedural sedation training and education:
    - ACLS Certification
    - PALS Certification (For pediatric patients)
    - Documented competency in patient monitoring, recognition of levels of sedation and documentation of procedure per current anesthesia standards
    - Ability to recognize complications and initiate appropriate interventions
- Clarify propofol drug label warning:
    - Only physicians and CRNAs can prescribe or order a specific dose of propofol for use in procedural sedation
- Definition of appropriate procedural sedation settings with available monitoring equipment to include:
    - ACLS resuscitation equipment in procedure room
    - Sustained oxygen delivery and suction equipment within reach for immediate use during procedure
    - Continuous patient monitoring (ECG, Pulse Ox, End Tidal CO2, Blood Pressure, Respiratory Rate)
    - Must be performed in a critical care capable setting (i.e. ED, ICU, OR etc.) with available personnel to initiate an advanced airway if required

Resources

1. Virginia Board of Nursing (2015). *Role of the registered nurse in procedural sedation* (VBON Guidance Document 90-63). Richmond, VA: Author.

2. Food and Drug Administration. (2008). *Diprivan (propofol) injectable emulsion*. Retrieved from http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/019627s046lbl.pdf

3. Sentara Healthcare. (2015). *Sentara moderate sedation administration by non-anesthesia care providers* [PDF document]. System Policy and Procedure Committee.

4. Joint Commission. (2008). *Moderate sedation medication and patient monitoring*. Retrieved from http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=138&ProgramId=47

5. Emergency Nurses Association. (2008). *Procedural sedation consensus statement*. Retrieved from https://www.ena.org/SiteCollectionDocuments/Position%20Statements/Archived/Procedural_Sedation_Consensus_Statement.pdf

6. Henrico Doctors' Hospital. (2010). *Nursing department critical care policy and procedures: Propofol administration and management for adults* [PDF document]. Richmond, VA: Author.

7. University of Virginia Health System. (2015). *Moderate or deep sedation/analgesia by non-anesthesiology providers for diagnostic or therapeutic purposes* [PDF document]. Charlottesville, VA: Author.

8. Emergency Nurses Association. (2015). *RN procedural sedation rules*. Retrieved June 10, 2015, from https://www.ena.org/government/State/Documents/RNProceduralSedationRules.pdf

VIRGINIA BOARD OF NURSING
Ad Hoc Committee
Guidance Document – RN Role in Procedural Sedation
Minutes
May 19, 2015

TIME AND PLACE: The meeting of the of the Committee convened at 2:30 p.m. in Board Room 3, Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Henrico, Virginia.

MEMBERS PRESENT: Kelly McDonough, DNP, RN; Chairperson
Guia Caliwagan, RN, MAN
Trula Minton, MS, RN

STAFF PRESENT: Jay P. Douglas, R.N., M.S.M., C.S.A.C., Executive Director
Elaine Yeatts, Policy Analyst, Department of Health Professions

OTHERS PRESENT: Ruth Williams, RN, MSN

CALL TO ORDER: Dr. McDonough called the meeting to order.

OLD BUSINESS: **Review of guidance document development process:**
Dr. McDonough reviewed the guidance document development process to date and the charge of the Committee.

Minutes of October 28, 2014:
The minutes of the meeting held October 28, 2014 were reviewed for historical purposes.

PUBLIC COMMENT: In person public comments were provided by the following:

- Keith Denning, CRNA; Sedasys, a division of Ethicon, a Johnson and Johnson company
- Bruce Lo, MD; Emergency Medicine, Sentara Norfolk
- Katie Payne, Lobbyist for Williams Mullins law firm, school of anesthesiologists
- Michele Satterlund and Jane Belcher, CRNA; Virginia Association of Nurse Anesthetists
- Michael Fallacaro, CRNA; Virginia Commonwealth University School of Anesthesia
- Scott Johnson, Medical Society of Virginia IT Infrastructure Partnership

NEW BUSINESS: Ms. Douglas then summarized verbally the written comments received by the Following:

- Mark Sochor, MD, President, Virginia College of Emergency Physicians – Request changes to the draft to include necessary competencies as outlined

by the Emergency Nurses Association (ENA) and American College of Emergency Physicians (ACEP); and to delete "Limitation on administration of propofol" and substitute with language from the consensus statements from ENA and ACEP.

- Virginia Society of Anesthesiologists (VSA) – Proposes amendments to the role of the RN as sedation provider that address competency and scope of practice requirements; and limitation of propofol section, requests insertion of a statement that limits administration of propofol for procedural sedation to CRNA's or physicians.
- Medical Society of Virginia (MSV) – Requests several changes for emphasis and clarify as well as requiring a pre-sedation assessment and sedation to be completed by a physician. Requests an additional statement that it is not within the scope of practice of an RN to administer propofol.
- Nurse Clinicians Virginia Commonwealth University Health System (VCUHS) – Requests definition/clarification of certain terms "acute care setting", "administration of propofol". Suggestion was made to review CMS and Joint Commission definitions of procedural sedation. Comments requested inclusion of reference to other drugs used for rapid sequence intubation.
- Virginia Nurses Association (VNA) – Fully supports team based approach to provide healthcare and supports guidance outlined in draft. Request inclusion of reference to other drugs used for rapid sequence intubation, specifically ketamine and etomidate and requesting RN's be able to administer via IV push under direct supervision.
- David Volk, DNP, CRNA – Requests inclusion of authorization for RN's to administer propofol under direct supervision of physician or CRNA who is intubating the patient in question.
- Ruth Williams, RN, MSN on behalf of VCUHS nurses – Raised question related to nurses pushing sedative or paralyzing medication under direct supervision by a practitioner who is involved in the procedure.
- Daniel Pambianco, MD, FACG, FASGE – Offered support for use of computer assisted devices like SEDASYS and asked the Board to remove any barriers for practicing gastroenterologists. Requests inclusion of language that states RN administration of propofol is outside scope except when utilizing a US FDA-approved computer assisted device.
- Association of Operating Room Registered Nurses (AORN) – The association defers to state scope of practice for RN administration of propofol moderate sedation and refers to AORN moderate sedation guidelines for propofol which states "only persons trained in general anesthesia should administer propofol for moderate sedation/anesthesia".

NEXT STEPS:

Dr. McDonough identified next steps as:

- Staff review and summary of all comments received.
- Schedule another meeting for the Committee to review all comments and determine what should be included in final draft.

Ms. Yeatts and Ms. Douglas cautioned that the level of specificity requested by some commenters may not be appropriate for inclusion in guidance. Additionally,

Board counsel/Office of the Attorney General would be involved in the final review.

ADJOURNMENT: The meeting was adjourned at 3:45 p.m.

Jay P. Douglas, MSM, RN, CSAC, FRE
Executive Director

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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Memo

To: Procedural Sedation Committee

From: Jay Douglas, Executive Director

Subject: Draft Guidance Document #90-63

Date: September 11, 2015

The second draft of Guidance Document 90-63 related to Procedural Sedation is recommended to you by staff and Board Counsel. This draft takes into consideration:

- Comments received
- Staff recommendations
- Board Counsel review

Virginia Board of Nursing

~~Role of the~~ Registered ~~Nurse in~~ Nurses and Procedural Sedation

Background

Procedural sedation is a continuum. As it is difficult to predict each patient's reaction, care must be individualized with patient safety being the primary concern. Sedation has four identified levels: minimal (anxiolysis); moderate (conscious sedation); deep sedation; and general anesthesia. Definitions of the levels of sedation/anesthesia[1] are

> **Minimal sedation** means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are unaffected.
>
> **Moderate sedation** means a drug-induced depression of consciousness, during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
>
> **Deep sedation** means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
>
> **General anesthesia** means a drug induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilator function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

It is important to first identify the purpose and level intended, with the acknowledgement that individuals react differently to sedation, so the practitioner must be prepared to handle a deeper level of sedation than intended. If the purpose is to achieve a level of deep sedation or anesthesia, there must be a qualified physician or certified registered nurse anesthetist involved.

Registered nurses may administer mild to moderate sedation under certain conditions. Administration must be in the presence of a health care professional appropriately credentialed

[1] American Society of Anesthesiologists, Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia, October 15, 2014

and privileged for sedation. The health care professional selects and orders the sedation and is available during the entire procedure.

Education and Training

Sedation administration is considered an advanced skill for a registered nurse that requires demonstrated competencies:

- Knowledge of the purpose, actions and side effects of sedating medications;
- Knowledge of the respiratory system and oxygen delivery;
- Demonstrated airway management competency;
- Understanding of cardiovascular system, medication pharmacology and antidotes, dysrhythmia recognition and sedation complications;
- Ability to initiate emergency rescue procedures and resuscitation;
- Identification and differentiation of levels of sedation and common patient assessment risk scales; and
- Competency in pre, intra and post procedural nursing care from initial assessment to discharge.

Advanced training for the registered nurse administering medications for procedural sedation should include advanced training in airway management, treatment of cardio-respiratory complications, and advanced pharmacology training in the medications utilized.

~~**Role of registered nurse as sedation provider**~~

~~The decision to designate sedation responsibilities and assurance of competency requirements rests with the institution or employing health care provider and should include:~~

- ~~Written policies, procedures, clinical guidance and protocols;~~
- ~~Tracking and reporting of patient outcomes and complications;~~
- ~~Mandatory emergency equipment within the procedural area with knowledge to activate emergency procedures and;~~
- ~~Clear documentation requirements.~~

~~Advanced training for the registered nurse administering medications for procedural sedation should include advanced training in airway management, treatment of cardio-respiratory complications, and advanced pharmacology training in the medications utilized. A second person should be involved to assist the physician with the procedure. It is recommended that patients at a higher risk for complications (ASA Class 3 or above, difficult airways, risk of gastric reflux or aspiration or lengthy procedures) should be managed by anesthesia providers.~~

Monitoring and documentation

The registered nurse must understand standards of monitoring and documentation to include:

- Pre-sedation assessment – airway, NPO status, pregnancy, medical history, medication history, allergies, previous complications with sedation and history and physical;
- Collaboration with physician to develop sedation plan;
- Continuous monitoring to include heart rate, respiration, blood pressure, EKG, oxygenation via pulse oximetry and level of sedation; and
- Continuous monitoring into the recovery phase as the patient returns to baseline until discharge.

~~**Limitation on administration of propofol**~~

~~While propofol has the advantages of quickly induced sedation and quicker recovery with little or no nausea, the disadvantages include no reversal agents and ease in which a patient may move into a deeper level of sedation than intended. Drug labeling on propofol includes a warning that the medication should only be provided for procedural sedation by qualified anesthesia providers, such as physicians or CRNA's.~~

~~The administration of propofol in an acute care setting with a ventilated patient is not considered procedural sedation and is considered appropriate for registered nurses.~~

Document source:

Research and presentation on "RN Administered Sedation" by Ruth Williams, BSN,RN, RN-BC, VCU Schools of Nursing, taken from a literature review, information from other states, and key reference articles.

*Replaces Guidance document 90-5: Board opinion of the administration of neuromuscular blocking agents by nurses, adopted November 1990, revised by Board motion, November 18, 2003