Policy to Practice Change:

The Development and Implementation of Sedation Policy and Protocols

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Author Note

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Abstract

Sedation exists along a continuum; and, it is impossible to predict a patient's exact response to a medication administered to induce any level sedation. Under the direction of a licensed independent practitioner (LIP), registered nurses (RN) in the Emergency Department (ED) have been permitted to administer propofol for time-sensitive, moderate sedation procedures (e.g. orthopedic reductions). In 2019, this changed when a Board of Nursing (BON) in the Southwestern United States posted an Advisory Opinion (AO) limiting the circumstances under which acute care RNs could administer propofol. The purpose of this doctoral project was to revise the 2019 AO to remove specific medication names and to generate recommendations for aligning hospital-based adult sedation policies and procedures (P&P) with the revised AO. In May 2020, the BON enacted the revised AO. Enactment endorses RNs practicing at the top of their scope and justifies amending existing hospital-based sedation P&Ps. Not restricting nurses' scope of practice according to medication name supports medication selection based on patient condition and clinical situation and safeguards provision of timely, personalized healthcare to communities statewide.

Keywords: Moderate sedation, procedural sedation, non-anesthesiologist-administered sedation, nurse, emergency department, cardiopulmonary, safety

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Sedation exists along a continuum; sedatives and opioids can produce any sedation depth, including general anesthesia, depending on the dose administered and patient response (Green et al., 2019). Thus, specific sedation agents cannot be designated as intended or not intended for general anesthesia (Green et al., 2019). Medications used for moderate sedation include opioids, benzodiazepines, barbiturates, ketamine, propofol, dexmedetomidine, etomidate, and nitrous oxide (Green et al., 2019). The American Society of Anesthesiologists (ASA) acknowledges the impossibility of always predicting patient response to sedation. Thus, the ASA advises health care providers (HCP) be proficient in airway management and advanced cardiovascular life support to manage adverse effects of deeper-than-intended sedation, and return the patient to the initially intended level of sedation (Committee on Quality Management and Departmental Administration, 2019). For this paper, non-anesthesiologist-administered sedation is the administration of moderate sedation by licensed registered nurses, doctors of medicine (MD), or doctors of osteopathic medicine (DO). This manuscript appraises the safety, efficacy, and utility of propofol for moderate sedation and details a doctorate of nursing practice project that revises a state BON's sedation protocols and integrates them into a local hospital system's P&P.

Problem Statement

Regulatory bodies, like the Joint Commission and the Centers for Medicare and Medicaid Services (CMS), typically do not mandate policies and guidelines regarding sedation. Instead, sedation guidelines are specialty driven (Green et al., 2019).

The 2019 AO states acute care RNs may not directly inject propofol into the vascular system unless: The patient is intubated, mechanically ventilated, or when assisting with rapid

sequence intubation. This verbiage is a departure from typical AOs that address RN scope of practice regarding medication classes, not specific medications. Limiting nurses' scope of practice according to specific medications restricts them from practicing to the full extent of their licensure. Furthermore, such restrictions are an inefficient use of existing healthcare resources that threaten patients' receipt of effective, affordable, and personalized healthcare. Ultimately, the AO prevents the safe use of effective medication for diagnostic and therapeutic procedures requiring only moderate sedation.

Purpose

The purpose of this manuscript is to appraise the safety, efficacy, and utility of propofol for moderate sedation, and compare the procedural, patient, and organizational implications of anesthesiologist-administered and non-anesthesiologist-administered sedation.

This project had two aims. First, this project aimed to revise existing AO verbiage to support acute care RNs administration of propofol IV push, under the direction of a LIP, for diagnostic and therapeutic procedures requiring moderate sedation. Second, this project aimed to generate recommendations for developing and revising hospital-based adult sedation P&P.

Background and Significance

Population

Patients present to the ED in physiological states that may necessitate they undergo urgent or emergent diagnostic or therapeutic procedures to optimize their health outcomes (Green et al., 2019). Time-sensitive procedures may include imaging, fracture and dislocation reduction, upper endoscopy, cardioversion, foreign body removal, central venous line placement, arthrocentesis, and tube thoracostomy. These procedures are typically brief and may or may not require analgesia to perform.

Intervention

Providers should aim to achieve the lowest level of sedation necessary to induce amnesia and complete the procedure successfully, without compromising cardiorespiratory function (Schick et al., 2019).

When administering moderate sedation, the current standard of care is the presence of at least two licensed HCPs—a sedation provider and a sedation monitor. The sedation provider, usually the treating MD or DO, decides the appropriate sedative medication and dosage to administer based on physical exam findings, indication for sedation, patient comorbidities, anatomical variations, and patient age (Lameijer et al., 2017). The sedation provider also oversees the sedation encounter and performs the therapeutic or diagnostic procedure. The sedation monitor, typically a RN, continuously monitors the patient and documents the encounter (Green et al., 2019). The most frequent adverse event of sedation is respiratory depression (i.e., hypoxia, apnea, hypoventilation). Cardiovascular events, such as bradycardia and hypotension, may also occur but are less common. The occurrence of adverse events during moderate sedation does not denote clinical significance. To consider an adverse event clinically significant, it must impact the patient or procedural outcome (Bellolio et al., 2016).

Current State

For decades, HCPs have used propofol to achieve moderate sedation for diagnostic and therapeutic procedures. However, ASA semantics have caused hospital administrators and practice committees to question, and even restrict, non-anesthesiologist-administered propofol (NAAP) sedation, without scientific evidence to support this practice change.

The ASA intends its' sedation guidelines to apply to all providers. The ASA states only HCPs trained in general anesthesia, and not performing the diagnostic or therapeutic procedure,

should administer propofol (Committee on Ambulatory Surgical Care, 2019). The Food and Drug Administration's labeling of propofol mirrors this statement by the ASA. However, it is arguable that product labeling should not supersede evidence-based literature and clinical practice (Green et al., 2019).

CMS (2011) acknowledges the ED is a unique and complex environment that necessitates HCPs to perform unscheduled procedures to prevent patient morbidity and mortality. CMS (2011) also recognizes ED providers' skill to manage patient airway and ventilation and asserts they are uniquely qualified to administer all levels of sedation. Like the ASA, CMS (2011) does not define moderate sedation as anesthesia. Hospitals must determine for themselves if sedation administered in the ED is to be considered anesthesia or analgesia, and base their determination on nationally recognized sedation guidelines by a professional organization of their choosing (CMS, 2011). This freedom of choice allows hospitals to select the professional organization whose sedation guidelines best support their unique needs and patient population. However, this freedom also has the potential to create highly-charged interdisciplinary struggles within the organization. CMS (2011) does not define or discuss RN role in sedation but does delineate fundamental criteria for administering anesthesia/analgesia under the direction of a MD or DO. All criteria are within RN scope of practice.

The American College of Emergency Physicians (ACEP) is the authoritative body for establishing sedation guidelines for ED physicians. The ACEP asserts qualified ED nurses with demonstrable competencies can safely administer propofol and other sedatives. The ACEP also recommends that ED physicians and ED nurse leadership collaborate to develop institutional policies regarding nurses' role in sedation (ACEP, 2017). The ACEP urges state boards of nursing to permit trained RNs to administer all medications used for moderate sedation under the

direction of a LIP (Green et al., 2019). Endorsement of nurse-administered, LIP-supervised sedation continues to vary according to each state's nurse practice regulations, and some state boards do not have readily identifiable positions on sedation.

Outcome

No single medication, or combination of medications, has outperformed others in all areas of sedation efficacy and safety. Furthermore, no single drug is ideal for all situations and patients (Bellolio et al., 2016).

Propofol's rapid onset, short half-life, and low cost make it preferable to longer-acting benzodiazepines and opioids for diagnostic and therapeutic procedures requiring moderate sedation (Ghojazadeh et al., 2019). Propofol is also safe to use in patients with liver and kidney dysfunction and exhibits antiemetic properties (Hatamabadi et al., 2015). Unlike propofol, benzodiazepines and opioids have been associated with delayed and reemergent cardiopulmonary depression, because of a longer half-life and cumulative dosing effect (Schick et al., 2019). Some individuals insist the availability of reversal agents make benzodiazepines and opiates definitively safer than drug classes without reversal agents. However, the availability of reversal agents does not significantly affect sedation safety; prolonged and persistent respiratory depression may occur and reoccur despite their administration (Schick et al., 2019). While offering no improvement in sedation safety, the availability of reversal agents does exert a positive psychological effect on the sedation provider (Han et al., 2017).

Anesthetics, such as propofol, are more often associated with deep sedation, while benzodiazepines, such as midazolam, are more commonly associated with moderate sedation. When used to achieve the same target depth of moderate sedation, medications associated with either deep or moderate sedation result in similar adverse events (Miner et al., 2017). Propofol

does tend to produce deeper levels of sedation than benzodiazepines, even when targeting a moderate depth of sedation. The incidence of cardiorespiratory events correlates with the depth of sedation achieved, not the specific medication administered (Green et al., 2019; Lameijer et al., 2017; Miner et al., 2017). Propofol is more often associated with adverse respiratory events; although, these adverse events are less often clinically significant and more often remedied by simple, non-invasive interventions (Lameijer et al., 2017). Variable respiratory effects have occurred at standard propofol doses, and providers must consider dose adjustments for patients over 65 years of age (Homfray et al., 2018). Propofol is at least as safe and effective as medications specifically designated for moderate sedation, including benzodiazepines and opiates (Han et al., 2017; Hatamabadi et al., 2015; Miner et al., 2017).

Non-anesthesiologist-administered propofol sedation

Non-anesthesiologist-administered propofol (NAAP) sedation is a safe, well-tolerated, and less costly alternative to anesthesiologist-administered propofol (AAP) sedation (Goudra et al., 2015; Han et al., 2017). Compared to NAAP sedation, patients undergoing AAP sedation receive higher doses of propofol, achieve deeper levels of sedation, experience higher incidence of airway interventions (e.g. jaw thrust, chin lift, mask ventilation), and have a greater need for procedure interruption and cancellation (Goudra et al., 2015). State-board regulations prohibiting RNs from administering medications used for moderate sedation have required some hospitals to implement policies mandating the presence of either two ED physicians, or an ED physician and anesthesiologist, to perform moderate sedation procedures (Greene, 2015). Requiring the presence of two physicians to perform moderate sedation procedures may be financially, geographically, or physically prohibitive to hospitals, particularly lower-volume EDs (Reibling et al., 2019). Restricting medications RNs may administer under LIP direction for

moderate sedation is an inefficient use of healthcare resources that impedes vulnerable patient populations receipt of safe, effective, and personalized healthcare.

In a state-wide, California-based survey by Reibling et al. (2019), 43% of 211 EDs reported limitations to ED physician procedural sedation practices. The most frequently cited reason for such limitations was the hospital anesthesia director. The most commonly cited outcomes were: use of less effective medications, sending patients to the operating room, having anesthesia on call, and performing procedures appropriate for sedation without sedation (Reibling et al., 2019).

Internal Evidence

Based on stakeholder correspondence, hospitals impacted by this AO equally expressed this change in RN clinical scope of practice to be hindersome to their provision of safe and effective patient care. Healthcare providers in the ED also communicated impediments in workflow efficiency and ED throughput secondary to the resultant practice change. Verbal communication with nurses and doctors revealed the presence of new workarounds, including reporting the physician administered the ordered propofol even though the nurse administered the medication. Additionally, some nurses ignored the AO, citing their familiarity and knowledgeability with prior clinical practices.

PICOT Questions

This inquiry led to the clinically relevant PICOT questions: For adults undergoing moderate sedation for diagnostic or therapeutic procedures in the acute-care setting, how does non-anesthesiologist-administered sedation, compared to anesthesiologist-administered sedation, impact patient and procedural outcomes? For adults undergoing moderate sedation for diagnostic or therapeutic procedures in the acute care setting, how does propofol, compared to

alternative medications, impact patients' cardiorespiratory function during, and immediately after, the procedure?

Search Strategy

An exhaustive literature search of the online databases PubMed, Academic Search Premier, Cochrane Library, and Medline was performed to answer the PICOT question. Concepts that informed keyword combinations were *emergency department, non-anesthesiologist administered procedural sedation, propofol*, *benzodiazepine*, *patient safety*, and *outcomes.* Filters applied to all searches included the date of publication (2015 to 2020), English language, and peer-reviewed journals. Boolean phrases and Mesh terms expanded search results while maintaining topic relevancy.

Preliminary database searches provided a general overview of the literature, informed search terms, and helped to refine keyword combinations. The initial search of PubMed included the keywords *adult patients*, *propofol OR Diprivan*, *midazolam OR benzodiazepine*, *opioid OR opiate*, *safety OR outcomes OR adverse*. Initial searches yielded upwards of 50,000 results. Specifying sedation as the intervention and acute care as the setting limited results to 1981. Additional refinement yielded results between 70 and 219. The initial search of Academic Search Premier included the keywords *emergency department OR emergency room* and *moderate sedation OR conscious sedation OR procedural sedation.* This search yielded 286 results. The addition of *propofol* and *patient safety OR outcomes* limited results to 73. The initial search of Cochrane included the keywords *emergency department*, *sedation*, *propofol*, and *outcome;* and yielded only one result. Changing *outcome* to *respiratory depression* increased results to 32. The initial search of Medline included the keywords *conscious sedation* and

propofol; and yielded 1395 results. Using analogous keywords and limiting results to adults aged 19 and older, produced between three and 62 results.

Article abstracts from final yield searches were reviewed according to inclusion and exclusion criteria. Inclusion criteria were patients aged 18 or older and sedation administration in an acute care setting. Articles from multiple countries were included if they met inclusion criteria. Exclusion criteria were patients younger than 18 years, only anesthesiologist-administered sedation, outpatient sedation, and performance of the procedure in an outpatient setting. Refinement yielded 61 relevant articles for review. Grey literature from the FDA, CMS, specialist societies, and nursing state boards were also examined.

The most relevant articles were read first; and, their references were reviewed for referral to additional evidence. Rapid critical appraisals were performed on 19 articles, and 10 studies were selected for inclusion in the final evaluation table. Article inclusion in the final evaluation table was prioritized according to evidentiary hierarchy, with systemic reviews (SR) being first. Studies included in the SRs were compared; and, if more than half of the studies included overlapped, one of the SRs was removed.

Critical Appraisal and Evidence Synthesis

Ten articles were selected for this literature review. Articles included two meta-analyses, one combined meta-analysis and systematic review, four randomized controlled trials, one observational study, one retrospective cohort study, and one survey (see Appendix B, Table 2). Melnyk and Fineout-Overholt's (2019) rapid critical appraisal was used to evaluate each article's quality.

All articles concerned procedural sedation in the acute care setting, with most sedations performed in the ED by non-anesthesiologists. Overall reporting of demographic information

was inconsistent, with age, sex, and ASA physical status reported by half of the articles (see Appendix B, Table 2). Only the observational study by Josephy and Vinson (2018) included patients younger than 18 years old. Even so, in the Josephy and Vinson (2018) study, the mean age of the one- and two-MD samples were 35.1 and 32.1 years, respectively (see Appendix A, Table 1).

Primary outcomes of interest related to respiratory depression, cardiovascular depression, level of sedation achieved, procedural outcomes, and patient or endoscopist satisfaction score. Most dependent variables were physiologic. Authors not reporting primary outcomes as event rates, unanimously used vital sign monitoring to measure cardiovascular and respiratory depression. Three studies also included capnography as an additional monitoring technique for hypoxia, apnea, and subclinical respiratory depression. Criteria for the parameters defining physiological outcomes, most notably hypoxia, varied slightly among multiple studies (see Appendix A, Table 1). The authors did not routinely perform subgroup analyses according to divergent parameters for defining physiological outcomes. Most authors reported confidence intervals, event rates, proportions, mean, standard deviation, and level of significance (see Appendix A, Table 1).

Evidence Conclusion

The literature demonstrates propofol is as safe as other agents used to induce moderate sedation for diagnostic or therapeutic procedures in the acute care setting. Furthermore, no statistically significant differences in cardiopulmonary complications exist between propofol and midazolam for moderate sedation. Patients demonstrate faster recovery time, shorter duration of sedation, and increased procedural success with propofol. Ultimately, scientific evidence does not substantiate barring propofol from moderate procedural sedation for safety concerns.

For patients undergoing moderate sedation for diagnostic or therapeutic procedures in the acute care setting, non-anesthesiologist-administered sedation is as safe as anesthesiologist-administered sedation. Non-anesthesiologist-administered sedation demonstrates superior gastroenterological procedural outcomes in terms of procedure interruption and cancellation secondary to respiratory complications. Both patients and endoscopists report lower satisfaction scores with non-anesthesiologist-administered sedation. Consideration of the negative impact non-anesthesiologist-administered sedation has on patient satisfaction scores is important; but, should not supersede preserving physiological status. Thus, focusing on such scores may be most appropriate during non-emergent, scheduled sedations.

Implications for Practice Change

Propofol for moderate sedation procedures outside the operating room is well established; and, evidence supports HCPs being able to use the safest and most effective medication for the patient and clinical situation. However, sedation is a continuum. Thus, LIPs must be competent in managing not only the level of sedation intended but also potential complications, including returning the patient to the intended level of sedation should a deeper level occur. To be qualified to assist in sedation procedures, and administer associated medications under LIP direction, RNs must receive education and training specific to the intended level of sedation. Additionally, RNs must demonstrate clinical competency administering medications used in sedation and managing patients throughout sedation. Organizations permitting RNs to assist in moderate sedation procedures must create an instructional program that includes, at minimum, standardized education points as outlined in the revised 2019 AO. These organizations must also create written P&Ps for RN role in moderate sedation, including guidelines for patient monitoring, drug administration, management of complications, and documentation.

Theoretical Model

The theory used to explain evidence and underpin this project is the Diffusion of Innovation Theory (DOI) (see Appendix B, Figure 1). E.M. Rogers initially developed the DOI theory in 1962 and modernized it in 2003. Rogers (2003) defines diffusion as "the process by which an innovation is communicated through certain channels over time among the members of a social system" (p. 26). Innovation, communication channels, time, and systems are the four core elements of the diffusion process. This social science theory illuminates decision-making factors and contexts that limit and facilitate the implementation of novel ideas, processes, and evidence. Ultimately the DOI theory helps one understand how people and systems receive, adopt, and adapt new information (Bowen & Zwi, 2005).

In the case of this project, the DOI theory informed how to examine, frame, and communicate evidence to educate BON members about the issue and persuade them to vote to approve proposed changes to the 2019 AO. The DOI theory also informed how changes to the AO and hospital P&Ps were communicated to HCPs and relevant stakeholders.

Implementation Framework

The implementation framework selected to guide this project was the evidence-informed policy and practice pathway, also called the pathway to evidence-informed policy (see Appendix C, Figure 1). Bowen and Zwi (2005) created this pathway as a progressive, three-stage framework for sourcing, using, and implementing evidence-based policy within the context of individuals, organizations, and social systems.

The first stage of this framework is evidence sourcing. Evidence should provide a multidimensional understanding of both the problem and the context in which the problem exists (Bowen & Zwi, 2005). Evidence includes research, expert views, professional opinions, politics,

and economics that, collectively, demonstrate the importance of the clinical problem, and that the proposed 2020 AO is a well-supported, potential solution. The second stage is using sourced evidence. This stage comprises the phases of introduction, interpretation, and application (Bowen & Zwi, 2005). Research evidence was introduced in various articles that inform the background and situation. These articles were interpreted with critical appraisal and evaluated according to their contextual applicability, acceptability, and utility. The third and final stage in the pathway to evidence-informed policy is assessing implementation capacity (Bowen & Zwi, 2005). The evidence used to inform the 2020 AO had to be relevant and usable statewide. All individuals, organizations, and systems, despite their unique knowledge, resources, and economics, must have been able to implement AO objectives.

Methods

This project occurred in partnership with a hospital system in the Southwestern United States serving local, national, and international adult patients. This was a dual-phasic project with each phase having a unique aim. Phase one of this project sought to revise the 2019 AO to support acute care RN administration of propofol IV push, under the direction of a LIP, for diagnostic and therapeutic procedures requiring moderate sedation. Phase two of this project sought to generate recommendations for developing and revising hospital P&Ps incongruent with the guidelines and standards of practice delineated in the 2020 sedation AO.

Ethical Considerations and Human Subject Protection

There were no participants enrolled in this study and no human subject data, patient, or protected health information was collected. Arizona State University's Intuitional Review Board deemed this project exempt (see Appendix D, Figure 1).

Project Description

Phase one of this project revised the 2019 AO and presented these revisions to the BON Scope of Practice (SOP) committee. In collaboration with project site champions, the verbiage and content of the 2019 AO was revised numerous times. Deadlines for revisions were determined based on SOP committee meeting dates. Near document completion, informal feedback was solicited from ED nursing directors from several local hospitals. In February 2020, the completed document was electronically submitted to the SOP committee and presented to committee members at the BON. It was determined the document required minor amendments prior to the committee vote. The amended document was re-submitted to the SOP committee and presented virtually to committee members during the May 2020 SOP meeting.

Phase two of this project compared existing hospital-based adult sedation P&Ps to the 2020 AO and aggregated known organizational information about departmental processes related to sedation. No recruitment materials were needed because this study had no participants. Due to COVID-19, this project was conducted online utilizing Zoom and Arizona State University email to correspond with the site champions.

Data Collection and Analysis

A crosswalk analysis of the organization's existing P&Ps and May 2020 AO was performed to determine areas of alignment and areas where P&Ps were restrictive relative to the AO. Documents were evaluated for inconsistencies in personnel and equipment required for sedation administration, RN and LIP role in sedation, criteria for RN administration of sedation medications, and RN education requirements. A summary of inconsistencies, potentially relevant stakeholders, and clinical areas where changes to current P&Ps would be most impactful was produced and presented to site champions. A stakeholder analysis was performed to clarify who is impacted and impactful to the success or failure of this project, and how stakeholder

relationships may be leveraged to achieve project success. Known organizational information generated by site champions about departmental processes related to sedation was aggregated, and final recommendations for developing and revising existing hospital P&Ps were generated.

All organizational data was collected by this graduate student and was stored on this student's computer, which is password protected. After recommendations for the development and revision of hospital P&Ps were completed, all stored organizational data was deleted.

Deliverables

The deliverable for project phase one was the 2020 Advisory Opinion. Phase two deliverables pertained to organizational adaptation of the 2020 AO and were a crosswalk analysis of existing hospital-based adult sedation P&Ps, recommendations to make P&Ps congruent with AO verbiage, guidelines, and standards of practice, and a stakeholder analysis illuminating how best to leverage relevant stakeholders.

Outcomes

In May 2020, the BON approved revisions to the 2019 AO and enacted the revised AO supporting RN administration of any sedation medication, under LIP direction, for diagnostic and therapeutic procedures requiring moderate sedation in the acute care setting. This 2020 AO successfully shifted the focus from which medications nurses can and cannot administer to nurses' knowledge and competency to provide safe patient care at the intended level of sedation.

Crosswalk analysis of the 2020 AO and existing hospital-based adult sedation P&Ps revealed several inconsistencies. The most notable were that P&Ps did not allow the same degree of RN-physician collaboration or RN assessment of patient's response to the medication administered. For instance, P&Ps did not designate the pre-sedation assessment and the development of a sedation plan as collaborative processes between the sedation RN and the

proceduralist. Furthermore, P&Ps did not permit RNs to administer sedation medications to clinical response/therapeutic effect when a qualified LIP was present at the bedside. The stakeholder analysis determined interdisciplinary members of the hospital's sedation subcommittee were most impactful to project acceptance and implementation within the organization.

The 2020 AO facilitates the use of existing healthcare resources and personnel to address community health needs at the point of service and to provide timely and equitable healthcare to individuals throughout the state. Effective use of existing healthcare resources and personnel decreases financial expenditures related to procedural care for the healthcare system, organization, and patient. Removing medication names from the AO increases the document's longevity, thereby reducing the direct and indirect costs associated with updating AOs. Stakeholders plan to use project outcomes to improve hospital sedation procedures and to expand nurses' role in sedation within the organization.

Discussion

Facilitators

Project site champions' competence, experience, and past successes pioneering and implementing initiatives supporting RNs practicing at the top of their scope increased local hospital systems' and the BON's confidence in this endeavor. Unified conviction from most hospitals and emergency department healthcare providers to remove pharmacologic restrictions from the 2019 AO was beneficial to obtain support and ensure facility and staff investment in the desired future state. Within the DNP project site, partnerships among ED healthcare providers and a collaborative and innovative organizational culture encouraged the appraisal of current clinical practices and the implementation of progressive, evidence-based P&Ps.

Challenges

The potential for contextual, organizational, and social discord due to the diversity of healthcare systems affected by the AO was an obstacle to this project. However, guidelines and criteria in the revised AO were made sufficiently flexible to be adapted to the unique needs, culture, and environment of each healthcare system; yet, kept rigid enough to protect patient safety regardless of the differences among these systems.

Impact

Local

The 2020 AO allows hospitals to independently determine which, if any, medications RNs can administer for moderate sedation. Hospitals must develop and maintain sedation P&Ps, inclusive of nurses' role in sedation. RNs administering sedation medications must receive formal education and training specific to the intended level of sedation and must demonstrate clinical competency in administering sedation medications and managing patients throughout sedation.

Ensuring hospital P&Ps align with the BON AO is essential to guarantee organization and state expectations and standards for RN administration of medications for moderate sedation are synonymous. Department leaders and clinical staff must collaborate to identify areas of opportunity to improve sedation practices within their specialty. Leaders and staff must then determine how to align P&Ps with the AO to improve sedation administration within their department.

National

Enactment of the 2020 AO sets a national precedent for RNs safely practicing at the highest level within their scope and for hospitals effectively using existing healthcare resources

to provide patients safe, efficient, and personalized healthcare. Enactment of the 2020 AO validates HCP assessment and expertise as foundational to appropriate clinical decision making and supports medication selection based on suitability for patient condition and clinical situation.

Future Directions

Continual assessment and analysis of clinical practices are necessary to recognize emerging patterns and anticipate future directions in nursing and healthcare. This DNP project provides a foundation for future initiatives advocating for RN scope of practice and demonstrates the power of HCPs at the point-of-service to catalyze change.

Recommendations to revise existing, hospital-based adult sedation P&Ps are ongoing. Evidence and project outcomes continue to be shared with pertinent departmental leaders.

Conclusion

Contextual and literary substantiation is foundational to clinical practice. Current evidence supports non-anesthesiologist use of propofol for moderate sedation and demonstrates propofol is at least as safe and effective as medications specifically designated for moderate sedation, including benzodiazepines and opiates. Prohibiting competent RNs from administering medications used for moderate sedation mandates the presence of two ED physicians, or an anesthesiologist, to perform moderate sedation procedures. This mandate may not be financially or geographically feasible for some EDs, thereby impeding patients' access to high-quality, personalized, and timely healthcare. Nurses are competent to make informed decisions about medication administration and to assess patients' actual and potential responses to medications. Each state BON that supports nurses' functioning at the top of their scope of practice helps to set a precedent for nursing practice nationally. However, organizations must actualize this support by implementing P&Ps permitting RNs to function at the top of their scope and to the full extent

of their licensure. Positively impacting the healthcare system, provider, and community ultimately requires political, clinical, and organizational synergism.

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Appendix A

Evaluation and Synthesis Tables

Table A1

Evaluation Table

Citation	Conceptual Framework	Design	Sample/Setting	Variables & Definitions	Measurement	Analysis	Findings	Decision for Use
Bellolio et al. (2016). Incidence of adverse events in adults undergoing procedural sedation in the emergency department: A systematic review and meta-analysis. **Funding:** None **Bias:** None **Country:** USA	Physiologic inferred	**Design:** SR & MA of RCTs and OS **Purpose:** Determine incidence of AE from procedural sedation in the ED.	**N:** 55 25 RCT, 30 OS **Databases searched:** Medline, EMBASE, EBSCO, CINAHL, CENTRAL, Cochrane Database of Systematic Reviews, Web of Science, Scopus. **Demographics:** ED patients ≥ 18 y.o. requiring moderate to	**IV:** Moderate to deep procedural sedation. **DV1:** Agitation **DV2:** Apnea **DV3:** Aspiration **DV4:** Bradycardia **DV5:** Hypotension **DV6:** Hypoxia **DV7:** Intubation	Higgin's & Thompson's I^2; Cohen's unweighted kappa; VS.	DerSimonian-Laird random-effects model; Cochrane Collaboration bias appraisal tool for RCTs; Newcastle-Ottawa Scale to assess bias risk for cohort studies; subgroup and sensitivity analyses.	**DV1** (event/sedation) 137/6631; est. 9.8/1000 (95% CI 6.1-13.5). Highest incidence with ketamine & ketamine/propofol. **DV2** (event/sedation) 68/3264; est. 12.4/1000 (95% CI 7.9-16.9). Highest incidence with midazolam & midazolam/opiate.	**LOE:** II **Strengths:** Assessed risk of publication bias. Subgroup and sensitivity analysis performed. Heterogeneity assessed. Proportion vs. weighted mean when pooling rates from studies with infrequent events. **Limitations:** Lack of

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			deep procedural sedation for any indication. **Inclusion criteria:** Published after 2005, reporting of MS and DS as defined by American College of Emergency Physician Clinical Policy; sedation performed in the ED by ED physicians or advance practice providers (i.e. nurse practitioners or physician assistant). **Exclusion criteria:** Patients < 18 y.o.; sedation not conducted in ED; not original research; mixed adult and pediatric				**DV3** (event/sedation) 1/2370; est. 1.2/1000 (95% CI 0.0-2.6). **DV4** (event/sedation) 11/837; est. 6.5/1000 (95% CI 1.1-11.8). Highest incidence with etomidate and midazolam/opiate. **DV5** (event/sedation) 122/5801; est. 15.2 (95% CI 10.7-19.7). Highest incidence with propofol and midazolam/opiate. **DV6** (event/sedation) 373/7116; est. 40.2/1000 (95% CI 32.5-47.9). Highest incidence with propofol and	standardized definitions and reporting of outcomes variables among studies. **Conclusion:** Intubation, laryngospasm, aspiration rare. Hypoxia, vomiting, hypotension, apnea most frequent. Detectable respiratory events may be precursor to more serious AE. Heterogeneity of included clinical procedures increases generalizability of results to ED settings.

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			populations; not published in past 10 years; AE not reported by medication used; medication not reported; no incidence rates of AE.				midazolam/opiate. **DV7** (event/sedation) 2/3636; est. 1.6/1000 (95% CI 0.3-2.9). Occurred in patient who received propofol.	
Gouda et al. (2017). Safety of non-anesthesia provider administered propofol sedation in non-advanced gastrointestinal endoscopic procedures: A meta-analysis. **Funding:** None **Bias:** None **Country:** USA	Physiologic inferred	**Design:** pooled MA **Purpose:** Evaluate safety of NAAPS in non-advanced gastrointestinal endoscopic procedures (i.e. upper endoscopy, colonoscopy).	**N:** 25 (POS and RCTs) (137,087 patients) **Databases searched:** PubMed, EMBASE, Cochrane Central Register of Controlled Trials, Scopus, and Web of Science **Inclusion criteria:** English and non-English language; published until April 2015; sedation administered by	**IV:** NAAPS **DV1:** Hypoxia **DV2:** Airway related interventions during procedure **DV3:** Airway related complications **Airway related complications:** Laryngospasm, unexpected hospitalization, unplanned conversion to general anesthesia **Airway related interventions**	PRISMA flow diagram, Higgin's & Thompson's I^2, event rate (per patient), $Sp0_2$.	Fixed- and random-effects models; funnel plot; Egger's regression test; sensitivity and subgroup analysis.	**DV1:** 0.014 (95% CI 0.008-0.023) Egger's intercept = -6.48, ($p < 0.01$) **DV2:** 0.002 (95% CI 0.006-0.001) Egger's intercept = -5.096 ($p < 0.01$) **DV3:** 0.001 (95% CI 0.000-0.001) Egger's intercept = -0.762 ($p = 0.23$)	**LOE:** I **Strengths:** Large N. Values with $I^2 > 40\%$ reported from random-effects modeling. Subgroup analysis. **Limitations:** Similar data for anesthesia providers not available for comparison. Possible publication bias with underreporting of hypoxia rates

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			RN under GE direction. **Exclusion criteria:** NAAPS for advanced endoscopic procedures (i.e. ERCP, endoscopic ultrasound, balloon-assisted deep enteroscopy, peroneal endoscopic myotomy, endoscopic mucosal resection, HALO radiofrequency ablation).	**during procedure:** Jaw thrust, BVMV, oral/nasopharyngeal airway, airway-related procedure interruption and intubation **Hypoxia:** $Sp0_2$ ≤ 90%				and airway interventions. **Conclusion:** NAAPS AE rates small. Hypoxemia most common AE.
Goudra et al. (2015). Safety of non-anesthesia provider-administered propofol (NAAP) sedation in advanced	Physiologic inferred	**Design:** MA of pooled AE rates from POS. **Purpose:** Evaluate and compare safety of NAAP & anesthesiologist administered	**N:** 26 **n:** 10 (AAPS) **n:** 16 (NAAPS) **Databases searched:** PubMed, EMBASE, Cochrane Central Register	**IV1:** AAPS **IV2:** NAAPS **DV1:** Hypoxia **DV2:** Airway intervention **DV3:** Endoscopist satisfaction	Higgin's & Thompson's I^2, 10-point satisfaction scale.	Fixed- and random-effect models; funnel plot; influence analysis; subgroup sensitivity analysis.	**IV1 (AAP):** DV1: 0.143 (95% CI 0.128-0.159) DV2: 0.1333 (95% CI 0.118-0.150), $p <$ 0.001 DV3 ($\bar{x}$): 9.06 (95% CI 8.91-	**LOE:** I **Strengths:** Values with $I^2 >$ 40% reported from random-effects modeling. Publication bias assessed.

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gastrointestinal endoscopic procedures: Comparative meta-analysis of pooled results. **Funding:** Not stated **Bias:** None **Country:** USA		propofol sedation for advanced endoscopic procedures.	of Controlled Trials, Scopus, Web of Science. **Demographics:** Age similar in both groups. 34.38% (AAPS) & 37.1% (NAAPS) ASA status 3-4. **Inclusion criteria:** Propofol with or without sedative/analgesic adjuvant; prospective data collection; performance of endoscopic ultrasound, ERCP, or deep small intestinal enteroscopy; sedation administered by anesthesiologist, certified RN anesthetist, GE, or RN under GE direction.	score (10-point scale) **DV4:** Patient satisfaction score (10-point scale) **DV5:** Total propofol administered **Non-anesthesiologist:** GE or RN under GE direction. **Hypoxia**: $Sp0_2 <$ 90%			9.21), $p < 0.001$ DV4 ($\bar{x}$): 9.82 (95% CI 9.76-9.88), $p < 0.001$ DV5 ($\bar{x}$): 340.32 mg (95% CI 327.30-353.33) **IV2 (NAAP):** DV1: 0.133 (9%% CI 0.117-0.152), $p <$ 0.001 DV2: 0.035 (95% CI 0.026-0.047), $p <$ 0.001 DV3 ($\bar{x}$): 6.03 (95% CI 5.94-6.11), $p < 0.001$ DV4 ($\bar{x}$): 7.22 (95% CI 7.17-7.27) DV5 ($\bar{x}$): 251.44 mg (95% CI 244.39-258.49)	Subgroup analysis performed. **Limitations:** High heterogeneity in pooled values. Reporting and physiologic DV definitions inconsistent among included studies. Funding not disclosed. **Conclusion:** NAAPS as safe as AAPS. Patient & endoscopist satisfaction scores lower with NAAPS. Results may not be transferrable to different procedures or settings.

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Han et al. (2017). Efficacy of midazolam-versus propofol-based sedations by non-anesthesiologists during therapeutic endoscopic retrograde cholangiopancreatography in patients aged over 80 years. **Funding:** Soonchunhyang University Research Fund **Bias:** None **Country:** South Korea	Physiologic inferred	**Design:** Prospective, comparative RCT **Purpose:** Investigate efficacy and safety of NAAP- and midazolam-based sedation.	**N:** 100 **n:** 50 (MF) **n:** 50 (PF) **Demographics:** Patients scheduled for MS, therapeutic ERCP. $\bar{x}$ age 84 (MF) & 83 (PF). **Setting:** Tertiary care center in Asia. **Inclusion criteria:** ≥ 80 y.o. **Exclusion Criteria:** Uncontrolled coagulopathy, ASA physical status V, known allergy to drugs used, history of complications with prior sedation, sedative or alcohol abuse, inability to provide	**IV1:** MF **IV2:** PF **DV1:** Cardiopulmonary complications **DV2:** Procedure interruption **DV3:** Recovery time **DV4:** Induction time **DV5:** Patient satisfaction (10-point scale) **DV6:** Endoscopist satisfaction (10-point scale) **DV7:** RN satisfaction (10-point scale) **Cardiopulmonary complications**: Hypotension, bradycardia, tachycardia, or hypoxia **Hypoxia:** SpO_2 < 90% on supplemental oxygen	10-cm VAS; modified OAA/S; modified Aldrete score; VS; ASA Continuum of Depth of Sedation criteria; 10-point satisfaction scale.	Chi-squared, Fisher's exact test, t-test, Mann-Whitney test. SPSS statistical software.	**DV1:** MF: 24%, PF: 22% $p = 0.812$ **DV2:** MF: 4%, PF: 6% $p = 0.648$ **DV3:** minutes (SD) MF: 17.91 (6.29) PF: 14.11 (4.66) $p < 0.001$ **DV4:** minutes (SD) MF: 3.57 (2.33) PF: 3.60 (2.46) $p = 0.953$ **DV5:** $\bar{x}$ (SD) MF: 8.94 (1.51) PF: 8.80 (2.10) $p = 0.680$ **DV6:** $\bar{x}$ (SD) MF: 8.38 (1.53) PF: 8.44 (1.31) $p = 0.906$ **DV7:** $\bar{x}$ (SD) MF: 8.70 (1.54) PF: 8.64 (1.36) $p = 0.678$	**LOE:** II **Strengths:** Standardized protocol for medication administration. **Limitations:** Small N. Power analysis not performed. Variability in patient positioning during procedure. Incomplete blinding on repeated injection of sedation medications. **Conclusion:** Difference in cardiopulmonary complications between sedation groups insignificant. Faster recovery from propofol.

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			informed consent, previous sphincterotomy/ choledochoduod enostomy. **Attrition:** All subjects retained.	**Hypotension:** Systolic BP < 90 mmHg **Bradycardia:** HR < 50 **Tachycardia:** HR >120 **Recovery time:** Minutes from ERCP completion to modified Aldrete score of 10.				Patient, endoscopist, RN satisfaction lower with non-anesthesiologist-administered sedation.
Hatambadi et al. (2015). Propofol versus Midazolam for procedural sedation of anterior shoulder dislocation in emergency department. **Funding:** Shahid Beheshti University of Medical Sciences research grant **Bias:** None. **Country:** Iran.	Physiologic inferred	**Design:** Prospective, double-blind RCT **Purpose:** Compare efficacy and AE of procedural sedation PF and MF	**N:** 48 **n:** 19 (PF) **n:** 29 (MF) **Demographics:** 100% male; 31.9 y.o. ($\bar{x}$); 82.4 kg ($\bar{x}$). **Setting:** Emergency department in Tehran. **Inclusion criteria:** Male & female ED patients ≥ 18 y.o. with	**IV1:** PF **IV2:** MF **DV1:** Apnea **DV2:** Bradycardia **DV3:** Attempted joint reductions **DV4:** Total propofol or midazolam administered **D5:** Time from first injection to sedation induction **D6:** Time from sedation to awakening	VS	Fisher exact test, Mann-Whitney U test.	**IV1 (PF):** DV1 (event/sedation): 1/19, $p = 0.39$ DV2 (event/sedation): 2/19, $p = 0.34$ DV3 ($\bar{x}$): 1.55, $p = 0.21$ DV 4 ($\bar{x}$): 1.7 mg/kg DV5 ($\bar{x}$): 2.1m, $p < 0.001$ DV6 ($\bar{x}$): 4.7m, $p < 0.001$; DV 7 ($\bar{x}$): 8.6m, $p < 0.001$. **IV2 (MF):**	**LOE:** I **Strengths:** Adequately powered. Same reduction technique for all patients. Standardized protocol for medication administration. **Limitations:** Apnea not defined. Subjective definitions of several key

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			anterior shoulder dislocation. **Exclusion criteria:** Hypersensitivity to midazolam, propofol, fentanyl, or eggs; other injury; oral intake in past 4 hours; sensorimotor impairment; alcohol or recreational drug use in past 6 hours; pre-existing airway difficulty; pre-existing vascular problems. **Attrition:** Not stated.	**D7:** Time from sedation to full awareness of time, location, and individuals **Sedation:** Spontaneous eyelid closure. **Awakening:** Participant first opening eyes after tapped between eyebrows. **Bradycardia:** HR < 60			DV1 (event/sedation): 0/29, $p = 0.39$ DV2 (event/sedation): 1/29, $p = 0.34$ DV3 ($\bar{x}$): 1.3, $p = 0.21$ DV4 ($\bar{x}$): 1.0 mg/kg DV5 ($\bar{x}$): 4.6m, $p < 0.001$ DV6 ($\bar{x}$): 11.7m, $p < 0.001$ DV7 ($\bar{x}$): 32m, $p < 0.001$.	concepts. Lack of MD blinding. **Conclusion:** Faster induction and recovery with propofol. Shorter sedation and analgesia with propofol. No significant difference in apnea or bradycardia between groups. Homogeneity of participants may restrict utility of results to patients with similar demographics.
Josephy & Vinson (2017). Feasibility of single- vs two-physician procedural sedation in a	Physiologic inferred	**Design:** Retrospective (before/after) OS of prospectively collected data.	**N:** 381 **n:** 246 (1-MD) **n:** 135 (2-MD) **Demographics:** Consecutive	**IV1:** Single-MD sedation **IV2:** Two-MD sedation **DV2:** Unanticipated	ASA Continuum of Depth of Sedation criteria; number and proportion of events for categorical data;	Descriptive statistics; bivariate comparison; Fisher's exact test (categorical data); t-test	**IV1 (single-MD):** DV1 (event/sedation) 0/246 (0%). DV2	**LOE:** II **Strengths:** Pilot testing of data collection instrument. Blinding of

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small community emergency department. **Funding:** None **Bias:** None **Country:** USA		**Purpose:** Examine feasibility and safety of single- and two-MD procedural sedation in ED.	series of ED patients. Single-MD—35.1 y.o. ($\bar{x}$); 66% male; 26% < 13 y.o.; 93.1%, targeted dissociative/DS and 6.9% targeted MS. Two-MD—32.1 y.o. ($\bar{x}$); 67% male; 32% < 13 y.o., 68.2% targeted dissociative/DS and 31.9% targeted MS. Joint/fracture reduction most common procedure in both groups. **Setting:** Small, semi-rural, geographically isolated community hospital with single-physician ED coverage. **Inclusion criteria:** ED	escalation of care **DV2:** BVMV with or without apnea > 30s **DV3:** Hypoxemia **DV4:** Procedure termination secondary to sedation-related complication **Unanticipated escalation of care:** Unplanned intubation and mechanical ventilation, cardiac arrest, dysrhythmia, unplanned hospitalization attributable to sedation. **Hypoxemia:** $Sp0_2$ < 90% for ≥ 1m	means with standard deviations for continuous variables	(continuous variables); relative frequency	(event/sedation) 8/246 (3.3%) p = 0.51 Difference 0.02 (95% CI -0.03-0.05) DV3 (event/sedation) 1/246 (0.4%) p = 0.28 Difference 0.01 (95% CI -0.03-0.05) DV4 (event/sedation) 1/246 (0.4%) p = 1.0 Difference 0.01 (95% CI -0.03-0.05) **IV2 (two-MD):** DV1 (event/sedation) 0/135 (0%) DV2 (event/sedation) 2/135 (1.5%) p = 0.51 DV3 (event/sedation) 2/135 (1.5%) p = 0.28	personnel to study hypothesis. Standardized protocol for monitoring and documenting sedation in electronic health record. Evaluated inter-rater reliability. **Limitations:** Small N. n assignment non-randomized. Potential for missing data. Confounding variables limit comparison of BVMV endpoint between groups. **Conclusion:** No significant difference in sedation outcomes between groups. Single-MD administration of procedural sedation in the

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			patients of any age who received MS-DS for any procedural indication from 1/2013 to 12/2016. **Exclusion criteria:** None stated.				DV4 (event/sedation) 0/135 (0%) p = 1.0	ED as safe and effective as two-MD administration.
Lameijer et al. (2017). Propofol versus Midazolam for procedural sedation in the emergency department: A study on efficacy and safety. **Funding:** None **Bias:** Not stated **Country:** Netherlands	Physiologic inferred	**Design:** Multicenter retrospective cohort from 2011-2015. **Purpose:** Compare incidence of procedure success and AE with propofol versus midazolam sedation.	**N:** 592 **n:** 284 (P) **n:** 308 (M) **Demographics:** ED patients 68 y.o. ($\bar{x}$) with hip/orthopedic dislocation, requiring fracture reduction, abscess I&D, or other procedure for which procedural sedation indicated. **Setting:** One of five ED hospitals in	**IV1:** P **IV2:** M **DV1:** Procedure success **DV2:** Sedation AE **DV3:** ≥1 sedation event **DV4:** Apnea responding to verbal or tactile stimulus **DV5:** Oxygen desaturation **DV6:** Interventions during total sedation events **DV7:** Sedation depth achieved **DV8:** Sedation duration	VS	Kolmogorov-Smirnov test with Lilliefors' correction, Chi-square test, Independent t-test and Mann Whitney, Loglinear analysis. SPSS statistical software.	**DV1:** P: 92%, M: 81% p = < 0.001 Missing 8 **DV2:** P: 0, M: 0 **DV3:** P: 23%, M: 11% p = < 0.001 Missing 3 **DV4:** P: 20%, M: 10% p = 0.004 **DV5:** P: 1%, M: 8% p = 0.001 **DV6:** (% of total sedation events) P: 61%, M: 66% Missing 26 **DV7** Missing 111 *Deep-*	**LOE:** III **Strengths:** Medication and monitoring for all patients per Dutch national guidelines. **Limitations:** Missing data. Bias not stated. Possible over-/under-representation of results from some facilities due to implementation of national documentation template for

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			northern Netherlands. **Inclusion criteria:** ≥ 18 y.o.; single-agent sedation with only propofol **Exclusion criteria:** < 18 y.o.; receipt of muscle relaxant in addition to sedative; sedation with nitrous oxide, etomidate, or ketamine; receipt of >1 sedative or hypnotic. **Attrition:** Not discussed.	**Sedation depth:** According to ASA Continuum of Depth of Sedation criteria. **Sedation adverse events:** Aspiration, laryngospasm, airway obstruction not relieved by SAMs, need for intubation, hospitalization, or mortality. **Sedation events:** Agitation, vomiting, airway obstruction alleviated by SAMs, apnea responding to verbal or tactile stimulus, hypotension, oxygen desaturation. **Apnea:** Absence of spontaneous breath for ≥ 20s			P: 45%, M: 25% p = < 0.001 *Moderate-* P: 35%, M: 52% p = < 0.001 *Light-* P: 12%, M: 20% p = 0.02 **DV8 (minutes):** P: 10 (8-15), M: 17 (12-26) p = < 0.001 Missing 371	procedural sedation, from which data collected, at different times. **Conclusion:** Higher rate of procedure success with propofol. Comparable sedation events between groups. Propofol more effective, and as safe as midazolam for procedural sedation in the ED.

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				Oxygen desaturation: $Sp0_2$ < 90% for > 30s **Hypotension:** Systolic BP < 90 mmHg.				
Miner et al. (2017). Randomized clinical trial of propofol versus Alfentanil for moderate procedural sedation in the emergency department. **Funding:** not stated **Bias:** not stated **Country:** USA	Physiologic inferred	**Design:** RCT **Purpose:** Determine frequency of AREs requiring clinical intervention with alfentanil and propofol MS.	**N:** 108 **n:** 56 (propofol) **n:** 52 (Alfentanil) **Demographics:** Propofol—36 y.o. ($\bar{x}$), 86 kg ($\bar{x}$); 45% male; abscess I&D (73%) and fracture/dislocation reduction (27%); 58% with ASA status = 1. Alfentanil—32 y.o. ($\bar{x}$), 86 kg ($\bar{x}$); 56% male; abscess I&D (54%) and fracture/dislocation reduction (46%); 34% with ASA status = 1.	**IV1:** Propofol sedation **IV2:** Alfentanil sedation **DV1:** Experience ≥ 1 ARE requiring ≥ 1 clinical intervention. **DV2:** Experience ARE **DV3:** Require clinical intervention **DV4:** Sedation efficacy **DV 5:** Sedation depth achieved (OAA/S score) **ARE:** Hypoxia (SpO_2 < 92%), central apnea, sub-clinical respiratory depression,	VS, nasal $ETCO_2$, OAA/S sedation depth	Chi square test, STATA 10.0, descriptive statistics for secondary outcomes, frequency and percentage of occurrence for categorical data, medians and quartile ranges for continuous data.	**IV1:** 11/56 (20%) experienced ≥ 1 ARE requiring ≥ 1 clinical intervention; 25/56 (45%) experienced an ARE and 25/56 (45%) required a clinical intervention; sedation efficacy 75%; sedation depth achieved (OAA/S) = 2 ($\bar{x}$) **IV2:** 12/52 (23%) experienced ≥ 1 ARE requiring ≥ 1 clinical intervention; 29/52 (56%) experienced an ARE and 18/52 (35%) required a	**LOE:** I **Strengths:** Standardized protocol for medication administration. Adequately powered. **Limitations:** 24% more participants in propofol group having ASA status > 1. Fracture/dislocation reductions disproportionate between groups. Lack of MD blinding. Funding and bias not disclosed.

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			Setting: Urban, county medical center. **Inclusion criteria:** ≥ 18 y.o. **Exclusion criteria:** Unable to consent, ASA status > 2, known hypersensitivity to alfentanil or propofol, pregnant, prisoner, signs of intoxication. **Attrition:** 18 did not undergo sedation (7 in propofol and 11 in alfentanil group)	complete airway obstruction, laryngospasm, aspiration **Central apnea:** $ETCO_2$ waveform absence > 6s **Sub-clinical respiratory depression:** $ETCO_2$ decrease > 10 mmHg or MD report of partial upper airway obstruction **Complete upper airway obstruction:** Absent $ETCO_2$ waveform and MD report of ventilatory effort **Clinical interventions:** Supplemental oxygen added or increased during procedure; BVMV; repositioning to improve ventilation;			clinical intervention; sedation efficacy 12%; sedation depth achieved (OAA/S) = 3 ($\bar{x}$)	**Conclusion:** Propofol as safe as alfentanil for MS. Deeper sedation depth achieved with propofol. Frequency of AREs similar between groups.

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				stimulation to induce ventilation; use of airway adjunct.				
Reibling et al. (2018). Emergency department procedural sedation practice limitations: A statewide California American College of Emergency Physicians survey. **Funding:** None **Bias:** None **Country:** USA	Physiologic inferred	**Design:** Survey **Purpose:** Estimate frequency and describe nature of procedural sedation restrictions, based on sedation depth and drug, in California EDs statewide.	**N:** 211 **n:** 91 (restricted) **Demographics:** 176 ED medical directors (i.e. MD in charge of ED) and 35 (17%) staff ED physicians. 42 government owned, 135 nonprofit, 34 profit. 205 general population and 6 pediatric. 25 teaching hospitals. 49 trauma centers. 40,041/year Median patient volume. **Setting:** General and pediatric EDs throughout California.	**IV1:** Procedural sedation in ED **DV1:** Extent of restrictions imposed **DV2:** Reasons to support restrictions as cited by respondents indicating some-total restriction **DV3:** Creator and enforcer of restrictions as cited by respondents indicating some-total restriction **DV4:** Most common alternative care provided due to restrictions as cited by respondents indicating some-total restriction	Questionnaires; hospital demographics	Descriptive; multiple logistic regression for predictors of restrictions	**DV1:** None: MS: 176 (83%) DS: 128 (61%) P: 146 (69%) M: 197 (93%) Some: MS: 32 (15%) DS: 41 (19%) P: 49 (23%) M: 10 (5%) Total: MS: 1 (0.5%) DS: 37 (18%) P: 13 (16%) M: 1 (0.5%) **DV2:** 20/91 (22%) anesthesia chief's personal judgement; 21/91 (23%) Joint Commission standards; 18/91 (20%) ASA guidelines; 26/91 (29%)	**LOE:** IV **Strengths:** Convenience sample of sedation experts and medical directors' reviewed survey for relevance and clarity. Pilot prior to implementation. Process to eliminate duplicate responses and permit contact of non-responders. Adequately powered regression analysis. **Limitations:** Lack of respondent

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			Inclusion criteria: Licensed ED hospital in the state of California. **Exclusion criteria:** Hospital/facility without licensed ED. **Attrition:** 117 EDs did not respond.	**DV5:** Perceived clinical result of alternative care options as cited by respondents indicating some-total restriction **Restrictions on procedural sedation:** Inability to administer moderate-deep sedation and/or propofol, ketamine, midazolam, fentanyl, etomidate for sedation in accordance with ACEP sedation guidelines			unknown or other. **DV3:** 56/91 (62%) Anesthesia medical director; 27/91 (30%) hospital medical staff or medical executive committee; 15/91 (16%) ED medical director; 15/91 (16%) hospital administration. **DV4:** Using less effective or less safe sedatives (27/91); performing procedures without sedation in situations where sedation preferred (15/91). **DV5:** 29/91 (32%) inadequate levels of sedation and pain control; 28/91 (31%)	anonymity. 64% response rate. **Conclusion:** Substantial and widespread barriers to MD administration of ED procedural sedation. Limitations to procedural sedation practices result in adverse clinical consequences for patients. Influence of local political forces suggested as etiology for restrictions.

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							extended ED stays; 26/91 (29%) unknown or other.	
Schick et al. (2019). Randomized clinical trial comparing procedural amnesia and respiratory depression between moderate and deep sedation with Propofol in the emergency department. **Funding:** UMF Medical Student Research Grant **Bias:** None **Country:** USA	Physiologic inferred	**Design:** Prospective RCT **Purpose:** Determine if assigning a target depth of sedation affects procedural amnesia and incidence of AREs	**N:** 116 **n:** 54 (MS) **n:** 53 (DS) **Demographics:** No significant differences between groups. ASA status 1-2. Sedation for abscess I&D, orthopedic reduction, cardioversion, other. Age ($\bar{x}$) 41.5 y.o. (MS) & 39 y.o. (DS). **Setting:** Urban county ED. **Exclusion Criteria:** Non-English speaking, pregnant, clinically intoxicated, incarcerated.	**IV1:** MS **IV2:** DS **DV1:** Respiratory depression by sedation level achieved **DV2:** Occurrence of one ARE by sedation level achieved **DV3:** Occurrence of >1 ARE by sedation level achieved **DV4:** Total AREs by sedation level achieved **DV5:** Achieved pre-procedure targeted level of sedation **DV6:** Sedation depth achieved (OAA/S)	10-cm VAS, OAA/S sedation depth, nasal $ETCO_2$, VS, visual memory test.	Descriptive statistics, Wilcoxon Rank-sum test.	**DV1:** MS: 54%, DS: 78% $p = 0.04$ RD with 95% CI: 0.24 (0.06-0.41) **DV2:** MS: 13%, DS: 57% $p = 0.001$ RD with 95% CI: 0.45 (0.26-0.57) **DV3:** MS: 3%, DS: 29% $p = 0.02$ RD with 95% CI: 0.27 (0.13-0.39) **DV4:** MS: 6, DS: 64 $p = 0.001$ RD = 0.79 with CI of 95% (0.62-0.88) **DV5:** MS: 50%, DS: 77% $p = 0.02$ RD with 95% CI: 0.25 (0.06-0.41)	**LOE:** I **Strengths:** Adequately powered. **Limitations:** No standardized protocol for medication administration. **Conclusion:** Procedural recall comparable between groups. Sedation depth achieved often different than targeted. Greater number AREs with DS. Targeting MS decreases occurrence of >1 ARE, but not overall incidence.

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			Attrition: 7.76%. One participant left ED before procedure performed, two withdrew, four did not undergo sedation, one could not see visual prompts; one protocol violation.	**DV7:** Procedural recall (VAS score in cm) by sedation level achieved **ARE:** ≥1 feature of respiratory depression plus ≥1 associated SAM. **SAM:** Use of airway adjuncts, such as bag-valve mask, airway repositioning, oral airway or nasal trumpet, and/or stimulation to induce respirations. **Respiratory depression:** Hypoxia or $ETCO_2$ waveform absence. **Hypoxia:** SpO_2 ≤ 91% or change in $ETCO_2$ ≥ 10 mm Hg			**DV6:** MS: 3.0 (2.7-3.3) DS: 2.3 (2.1-2.5) $p = 0.001$ **DV7:** MS: 0.13 (0.0-0.2) DS: 0.08 (0.0-0.1) $p = 0.08$	

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				MS & DS: According to ASA Continuum of Depth of Sedation criteria.				

Key: **AAPS** – anesthesiologist-administered propofol sedation; **ACEP** – American College of Emergency Physicians; **AE** – adverse event; **ARE** – adverse respiratory event; **ASA** – American Society of Anesthesiologists; **BP** – blood pressure; **BVMV** – bag-valve-mask ventilation; **DS** – deep sedation; **DV** – dependent variable; **ED** – emergency department; **ERCP** – endoscopic retrograde cholangiopancreatography; **est.** – estimated; **$ETC0_2$** – end-tidal carbon dioxide monitoring (capnography); **GE** – gastroenterologist; **HR** – heart rate; **I&D** – incision and drainage; **IV** – independent variable; **LOE** – level of evidence; **m** – minutes; **M** – midazolam sedation; **MA** – meta analysis; **MD** – medical doctor; **MF** – midazolam and fentanyl; **MS** – moderate sedation; **N** – total number of studies (if SR or MA) or total participants in study; **n** – number of studies (if SR or MA) or number of participants in subset; **OSHPD** – Office of Statewide Health Planning and Development; **NAAPS** –non-anesthesiologist administered propofol sedation; **OAA/S** – observer's assessment of alertness/sedation score; **OS** – observational study(ies); **P** – Propofol sedation; **PF** – Propofol and fentanyl; **POS** – prospective observational studies; **RCT** – randomized control trial(s); **RD** – risk difference (difference in proportion); **RN** – registered nurse; **SAM** – supportive airway maneuvers; **SR** – systematic review; **VAS** – visual analog scale; **VS** – vital signs (HR, BP, $Sp0_2$); **y.o.** – years old

Table A2

Synthesis Table

Citation	Bellolio et al.	Gouda et al.	Goudra et al.	Han et al.	Hatambadi et al.	Josephy & Vinson	Lameijer et al.	Miner et al.	Reibling et al.	Schick et al.
Year	2016	2017	2015	2017	2015	2017	2017	2017	2018	2019
SR	SR									
MA	MA		MA							
RCT				RCT	RCT			RCT		RCT
OS						OS				
Cohort							Cohort			
Survey									Survey	
Sample Size	55 articles	25 articles	26 articles	100	48	381	592	108	211	116
Country										
United States	X	X	X			X		X	X	X
Iran					X					
South Korea				X						
Netherlands							X			
Procedure Setting										
Gastroenterology		GE	GE	GE						
ED	ED				ED	ED	ED	ED	ED	ED
Demographics										
Age (y.o.)	≥ 18	NR	NR	83 ($\bar{x}$) - MF 84 ($\bar{x}$) - PF	31.9 ($\bar{x}$)	35.1($\bar{x}$) – one MD 32.1($\bar{x}$) – two MD	68 ($\bar{x}$)	36 ($\bar{x}$) - P 32 ($\bar{x}$) - A	NR	39 ($\bar{x}$) - DS 41.5 ($\bar{x}$) - MS
	Bellolio et al.	**Gouda et al.**	**Goudra et al.**	**Han et al.**	**Hatambadi et al.**	**Josephy & Vinson**	**Lameijer et al.**	**Miner et al.**	**Reibling et al.**	**Schick et al.**

Key: A – alfentanil; **AAS** – anesthesiologist-administered sedation; **AE** – adverse event(s); **ASA** – American Society of Anesthesiologists; **DS** – deep sedation; **DV** – dependent variable; **ED** – emergency department; **GE** – gastroenterology; **IV** – independent variable; **LOS** – level of sedation; **M** – midazolam; **MA** – meta analysis; **MD** – medical doctor; **MF** – midazolam and fentanyl; **MS** – moderate sedation; **NAAS** – non-anesthesiologist-administered sedation; **NR** – not reported; **OS** – observational study; **P** – Propofol; **PF** – Propofol and fentanyl; **POS** – prospective observational study; **RCT** – randomized control trial; **SR** – systematic review; **y.o.** – years old; $\bar{x}$ – mean

Table A2

Synthesis Table

Sex	NR	NR	NR	NR	100% male	66% - 67% male	NR	45% - 56% male	NR	NR
ASA physical status	NR	NR	3-4	1-4	NR	NR	NR	1-2	NR	1-2
Provider										
AAS			X		NR			NR		NR
NAAS	X	X	X	X	NR	X	X	NR	X	NR
IV - Intervention										
AAS			AAS							
NAAS		NAAS	NAAS						NAAS	
Single-MD sedation						Single-MD				
Two-MD sedation						Two-MD				
LOS	LOS									LOS
Propofol		P	P				P	P	P	
Propofol + Fentanyl				PF	PF					
Midazolam							M	M	M	
Midazolam + Fentanyl				MF	MF					
Other Medication								Other	Other	
DV - Outcomes										
Hypoxia	X	X	X	X		X	X	X		X
Apnea	X				X		X	X		
Hypotension	X			X						
Bradycardia	X			X	X					
Airway intervention	X	X	X			X	X	X		X
	Bellolio et al.	**Gouda et al.**	**Goudra et al.**	**Han et al.**	**Hatambadi et al.**	**Josephy & Vinson**	**Lameijer et al.**	**Miner et al.**	**Reibling et al.**	**Schick et al.**

Key: **A** – alfentanil; **AAS** – anesthesiologist-administered sedation; **AE** – adverse event(s); **ASA** – American Society of Anesthesiologists; **DS** – deep sedation; **DV** – dependent variable; **ED** – emergency department; **GE** – gastroenterology; **IV** – independent variable; **LOS** – level of sedation; **M** – midazolam; **MA** – meta analysis; **MD** – medical doctor; **MF** – midazolam and fentanyl; **MS** – moderate sedation; **NAAS** – non-anesthesiologist-administered sedation; **NR** – not reported; **OS** – observational study; **P** – Propofol; **PF** – Propofol and fentanyl; **POS** – prospective observational study; **RCT** – randomized control trial; **SR** – systematic review; **y.o.** – years old; $\bar{x}$ – mean

Table A2

Synthesis Table

Endoscopist Satisfaction score			X	X						
Patient satisfaction score			X	X						
Induction time				X	X					
Recovery time				X	X					
Sedation Duration							X			
LOS achieved							X	X		X
Total dose administered			X		X					
Procedural outcomes					X	X	X	X		
Sedation restrictions									X	

Key: **A** – alfentanil; **AAS** – anesthesiologist-administered sedation; **AE** – adverse event(s); **ASA** – American Society of Anesthesiologists; **DS** – deep sedation; **DV** – dependent variable; **ED** – emergency department; **GE** – gastroenterology; **IV** – independent variable; **LOS** – level of sedation; **M** – midazolam; **MA** – meta analysis; **MD** – medical doctor; **MF** – midazolam and fentanyl; **MS** – moderate sedation; **NAAS** – non-anesthesiologist-administered sedation; **NR** – not reported; **OS** – observational study; **P** – Propofol; **PF** – Propofol and fentanyl; **POS** – prospective observational study; **RCT** – randomized control trial; **SR** – systematic review; **y.o.** – years old; $\bar{x}$ – mean

Appendix B

Theoretical Model

Figure 1

A Model of Five Stages in the Innovation-Decision Process

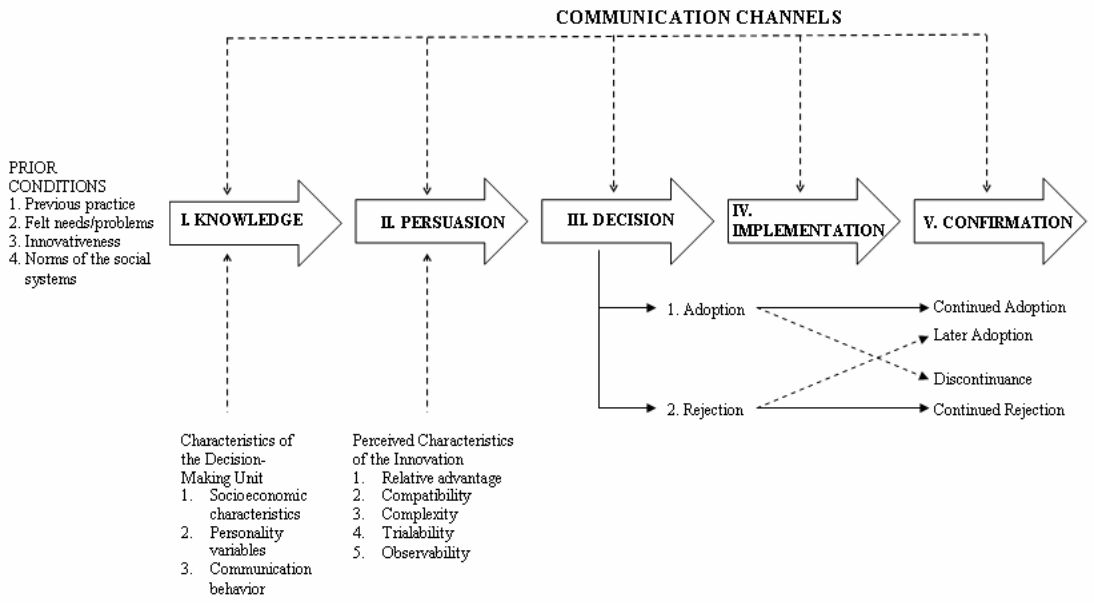

Figure 1. A Model of Five Stages in the Innovation-Decision Process. This figure illustrates the process through which a decision-making entity passes (Rogers, 2003).

Appendix C

Implementation Framework

Figure 1

The Evidence-Informed Policy and Practice Pathway

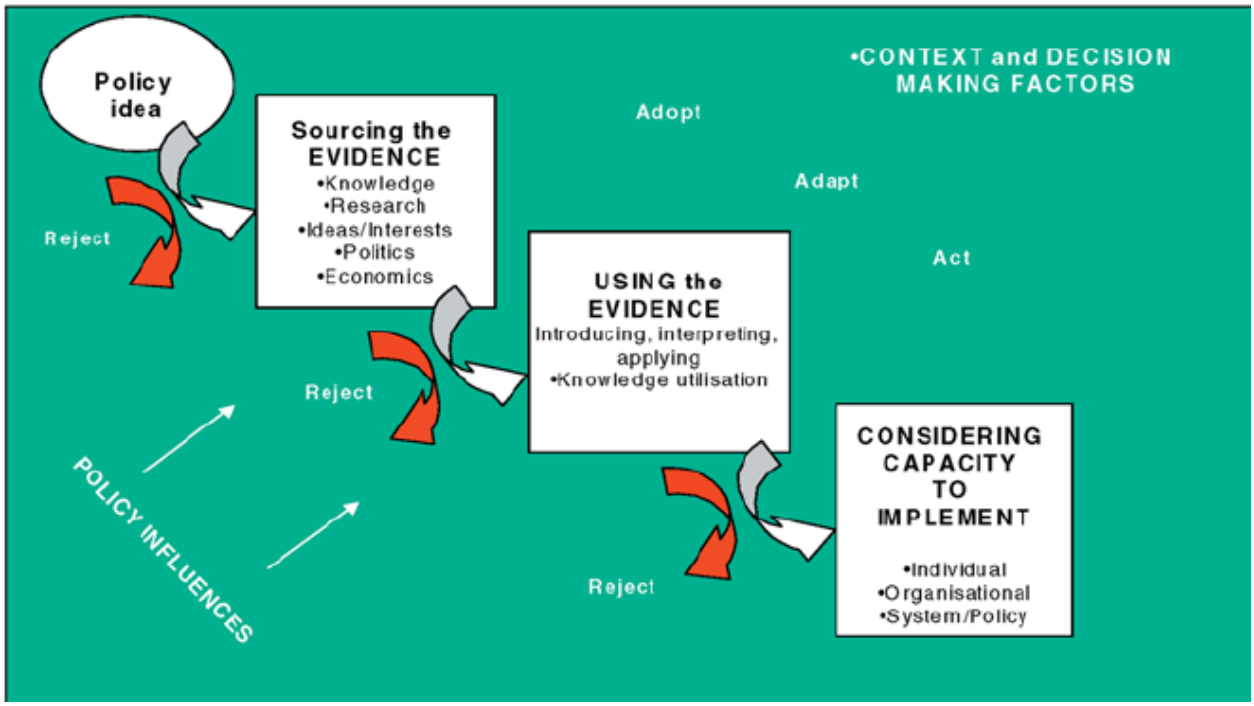

Figure 1. The Evidence-Informed Policy and Practice Pathway. This figure illustrates the evidence-based process of generating and implementing new policies (Bowen, & Zwi, 2005).

Appendix D

Letter of Exemption

Figure 1

IRB Determination of Not Human Subjects Research

NOT HUMAN SUBJECTS RESEARCH DETERMINATION

Erin Tharalson
EDSON: DNP
-
Erin.Tharalson@asu.edu

Dear Erin Tharalson:

On 9/11/2020 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Policy to Practice Change: The Development and Implementation of Sedation Policy and Protocols.
Investigator:	Erin Tharalson
IRB ID:	STUDY00012493
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• Bonfield_B_CITI Training Certificate.pdf, Category: Other; • Sedation Policy and Procedures_Agency Letter of Support_10_09_20.pdf, Category: Other; • Sedation Policy and Procedures_IRB Protocol_10_09_20.docx, Category: IRB Protocol; • Tharalson_E_CITI Training Certificate.pdf, Category: Other;

The IRB determined that the proposed activity is not research involving human subjects as defined by DHHS and FDA regulations.

IRB review and approval by Arizona State University is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether the activities would change the determination, contact the IRB at research.integrity@asu.edu to determine the next steps.