Clinical Practice Guideline for Utilizing Sugammadex in Reversal of Neuromuscular Blocking Agents

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Abstract

Background: Residual paralysis is ongoing presence of muscle weakness postoperatively following the administration of a neuromuscular blocker and subsequent reversal agent during the intraoperative period. Presence of residual neuromuscular blockade postoperatively has been associated with increased mortality and morbidity, low oxygenation, and respiratory complications. Recent studies have shown incidences of residual neuromuscular blockade ranging from 16 to 60 percent.

Local Problem: A medium sized hospital in Maryland reported postoperative complications associated with residual paralysis. Increased side effects such as muscle weakness, increased length of stay in Post Anesthesia Care Unit, and delay in discharge may be due to the lack of guidelines for reversal of non-depolarizing neuromuscular blockers. A meeting with institutional key stakeholders identified the need for a guideline for the use of sugammadex in prevention of residual paralysis.

Development of CPG: The focus of this project was to develop a Clinical Practice Guideline for the use of sugammadex in the prevention of residual paralysis for high risk patients and in emergent situations such as cannot intubate, cannot ventilate scenarios. A literature review was conducted to support evidence for the Clinical Practice Guideline, gathered data was presented to the key stakeholders. The project proposal was then submitted to the University of Maryland, Institutional Review Board and granted a Non-Human Subjects determination. The quality of the Clinical Practice Guideline was assessed by institutional key stakeholder and analyzed using the AGREE II tool and then presented to the entire anesthesia department for further evaluation. Adjustments to the Clinical Practice Guideline were made following departmental feedback and a final Clinical Practice Guideline along with algorithms were developed for this project and were distributed throughout the perioperative arena. A further assessment was done by the department using Practitioner Feedback Questionnaires. All data collected from the AGREE II tool and the Practitioner Feedback Questionnaires were synthesized, analyzed, and evaluated. The final project manuscript was submitted to the University of Maryland School of Nursing Doctorate of Nursing Practice committee for review.

Results: The results of the final AGREE II Tool were 100% across the 6 domains and for the overall assessment. Each appraiser had a total score of 161/161 points and an overall of 322/322 points. The anesthesia providers, the end users of the guideline, evaluated the Clinical Practice Guideline using the Practitioner Feedback Questionnaires. Majority of anesthesia providers felt the guideline should be approved for practice (95.5%) and felt if the guideline was approved, they would use it in their own practice (100%) and would apply the recommendations to their patients (100%). This analysis demonstrated buy-in and acceptance of the Clinical Practice Guideline by the department.

Conclusion: Study results indicate sugammadex compared to current reversal, neostigmine, is safe and effective in the reversal of neuromuscular blocking agents and reduces adverse events and undesirable side effects. The approval of the Clinical Practice Guideline can change clinical practice and improve patient care. A standardized approach for reversal of neuromuscular blockade with the use of sugammadex will decrease the incidence of residual paralysis in this institution.

Background

The introduction of neuromuscular blocking agents (NMBAs) has had a significant impact on anesthesia practice and the surgical treatment of patients. Clinical anesthesia widely uses NMBAs to facilitate endotracheal intubation and to permit surgical access to body cavities without unwanted muscle contractions. Although NMBAs have contributed to the improvement of surgical conditions their use can lead to many complications, the most common being residual neuromuscular blockade.

Residual neuromuscular blockade is most accurately defined as the continuing occurrence of signs and symptoms of muscle weakness postoperatively after the administration of a NMBA during the intraoperative period, and a Train of Four (TOF) ratio less than 0.9 (Murphy & Brull, 2010). The presence of residual neuromuscular blockade postoperatively has been associated with an increase in mortality and morbidity, and may lead to respiratory complications such as low blood oxygen levels, labored breathing, lung infections, and aspiration (Hristovska, Duch, & Afshari, 2017). The incidence of residual neuromuscular blockade varies, but recent studies have shown incidences ranging from 16 to 60 percent (Hristovska et al., 2017).

The most common reversal agent used by anesthetists is neostigmine, a cholinesterase inhibitor (CI). Neostigmine works by antagonizing aminosteriodal NMBAs by inhibiting the breakdown of acetylcholine in the neuromuscular junction (Hristovska et al., 2017). When using neostigmine, the use of a muscarinic antagonist is required to compensate for the cholinergic side effects such as bradycardia, hypotension, and postoperative nausea and vomiting, however the use of muscarinic antagonists also has side effects such as tachycardia, blurred vision, and dry mouth (Hristovska et al., 2017). After the administration of neostigmine, 20 to 60 percent of patients arriving in the post-anesthesia care unit (PACU) still shown signs of residual paralysis

(Brueckmann et al., 2015). Patient's continuing to have residual paralysis are at a higher risk or reintubation.

Residual paralysis after the administration of NMBAs continues to be problematic and can result in respiratory failure and a delay in discharge. The reversal of neuromuscular blockade is essential for the acceleration of patient recovery, prevention of respiratory failure, and the reduction of mortality and morbidity linked with anesthesia management. It is clear that there is a clinical need for a new reversal agent with minimal side effects, the ability to reverse NMBAs effectively, regardless of depth, and with the absence of residual paralysis.

One potential option to aid in overcoming the limitations and side effects of CI and improve the safety and efficacy of NMBA reversal is sugammadex. Sugammadex in a modified gamma cyclodextrin (CD) selective relaxant binding agent (SRBA) (Martini, Boon, Bevers, Aarts, & Dahan, 2013). Sugammadex works by directly encapsulating aminosteroid NMBAs and rendering them inactive. By reversing aminosteroid induced NMBAs, associated risks caused by residual block can be avoided, operating room time can be shortened, and the patient's quality of recovery and discharge time can be improved (Hristovska et al., 2017).

A medium size community hospital in Maryland is the target institution of this project. Current practice is the use of neostigmine for the reversal of NMBAs, and there is no available data on complications with the use of neostigmine within the facility. However, with the use of neostigmine side effects are seen: increased side effects such as muscle weakness, postoperative nausea and vomiting, the increased length of stay in PACU, and a delay in discharge. As this facility did not have a policy on the use of sugammadex and the use of it was restricted, the purpose of this project was to develop a clinical practice guideline (CPG) that provides clear guidelines for utilizing sugammadex in the reversal of NMBAs. An anesthesiologist and a nurse

anesthetist employed at the facility were identified as key stakeholders and helped navigate the direction of this project to meet the needs of the facility. This CPG provides guidance for the use of sugammadex in emergent situations such as cannot intubate, cannot ventilate scenarios for individuals who remain deeply blocked at the end of a procedure and does not meet the criteria for use of neostigmine. It is anticipated that there will be a decrease in side effects and residual neuromuscular blockade, a decrease in PACU stay, and a decrease in delay in discharge. The project focused on the short-term goal of completion of a sustainable CPG draft by March 17, 2018, with an initial review by the expert panel by March 31, 2018. Long-term goals included adoption of the CPG by the institution as part of practice by December 18, 2018, resulting in overall reduction of adverse events and residual NMBA, and an increase in provider knowledge on sugammadex.

Theoretical Framework

The Ottawa Model of Research Use (OMRU) (Graham & Logan, 2004) was chosen as the framework for guidance of this project. Key elements from the OMRU helped guide and develop interventions through the project. The OMRU is made up of several elements, each impact and are influenced by each other to assess, monitor and evaluate research. The key elements of the OMRU are: practice environment, potential adopters, evidence-based innovation, transfer strategies, adoption and outcomes. The OMRU also consists of three phases: assessment, monitoring and evaluation (AME). AME helps to identify barriers, ways to overcome barriers, monitor progress, and assess evidence-based advances and primary outcomes. These key elements and phases occur over time, and in no certain order. The order is reliant on each component's state within a certain situation (Graham & Logan, 2004).

The OMRU model helped guide the development of the proposed intervention, reversal of NMBAs using sugammadex. To the prevalence of the problem, the organization that will benefit from implementation, and the assessment of practice guidelines; the elements of practice environment, potential adopters and evidence-based innovations were used (Graham & Logan, 2004). To monitor the developed evidence-based innovations transfer strategies were used. Lastly, to evaluate the quality of the clinical practice guideline, adoption and outcomes were used (Graham & Logan, 2004). An effective clinical practice guideline was developed with the successful use of the elements within the OMRU, which provide assessment, monitoring and evaluation of the clinical practice guideline.

Literature Review

A search was conducted using CINAHL, Cochrane Library, and PubMed databases for literature. The publication dates of the articles were limited to January 2008 to March 2018. The search was conducted using the keywords "sugammadex" and "neostigmine" which yielded numerous results. The search criteria was made more specific using "sugammadex and residual paralysis", "residual neuromuscular blockade," and "residual paralysis" which resulted in 128 articles more specific to the topic. All literature that was relevant to the topic was considered during evaluation, a total of six articles were identified to be most relevant for the development of this CPG.

The purpose of this literature review is to describe the effectiveness of sugammadex in comparison to Neostigmine in the reversal of neuromuscular blockade. The literature review aims to highlight the significance of four articles which include two systematic reviews of randomized control trials (RCTs), one meta-analysis of RCTs, and one RCT. The review

discusses the safety and efficacy of sugammadex, and the decrease of residual neuromuscular blockade when sugammadex is used.

Carron, Zarantonello & Tellaroli (2016), completed a meta-analysis of randomized control trials (RCTs) to compare the safety and effectiveness of sugammadex administration versus neostigmine in the reversal of neuromuscular blockade. The analysis consisted of 13 studies with the following inclusion criteria: sugammadex was used for reversal of steroidal induced neuromuscular blockade, neostigmine was used for reversal as the comparator. Other inclusion criteria included: English speaking adult patients over the age of 18, and the presence of a safety assessor unaware of which reversal was given. The meta-analysis found that when compared to neostigmine, sugammadex was notably faster in reversing neuromuscular blockade ($P < 0.0001$), and was associated with a higher train-of-four ratio at extubation ($P < 0.0001$). Sugammadex was also found to have lower adverse respiratory events ($P = 0.0386$), lower cardiac adverse events ($P = 0.0036$), and significantly lower global adverse events ($P = < 0.0001$) (Carron, Zarantonello, & Tellaroli, 2016). Similarly, Hristovska, Duch, Allingstrup & Afshari (2017), similarly compared the efficacy and safety of sugammadex to neostigmine. This systematic RCT consisted of 41 studies with the inclusion criteria: adults, American Society of Anesthesiologist (ASA) class I to IV, who received a non-depolarizing NMBA for elective surgery. Outcomes of the review found sugammadex to be 6.6 times faster than neostigmine in reversal of moderate NMB and 16.8 times faster in reversal of deep NMB (Hristovska, Duch, & Afshari, 2017). With the use of sugammadex adverse events such as bradycardia and postoperative nausea and vomiting are reduced up to 40 percent (Hristovska et al., 2017).

Another systematic review of RCTs by Ledowski (2015) was completed to examine the optimal use of sugammadex and determine its place in clinical practice. The review was

conducted over 18 months and included 143 studies from January 2013 to July 2014, using the search term "sugammadex." The review concluded that sugammadex is more rapid and more reliable in the reversal of NMBAs. The use of sugammadex results in a more rapid return of muscle strength which assists with easier management of difficult airway situations. Lastly, Brueckmann et al. (2015), completed a RCT to determine if the use of sugammadex in the reversal of rocuronium induced neuromuscular blockade was effective in preventing residual paralysis. The study consisted of 154 adult patients undergoing abdominal surgery who received rocuronium. Inclusion criteria were: 18 years of age or older, ASA class 1 to 3. The patients were randomly assigned to group 1 or group 2. Patients in group 1 received sugammadex for reversal, and those in group 2 received neostigmine. The study revealed that no residual blockade was found in patients in group 1, those who received sugammadex, but 43.4 percent of those in group 2 who received neostigmine had residual blockade (n = 33). Sugammadex was shown to be 3 to 18 times faster in the reversal of rocuronium-induced NMBA when compared to neostigmine. Operating room discharged time was faster following sugammadex (14.7 minutes, $p = 0.02$) when compared to neostigmine (18.6 minutes).

The results of these recent studies indicate that sugammadex is safe and effective for the reversal of NMBAs, and results in reduced adverse events. This is in comparison to the current reversal agent, neostigmine, which has a numerous amount of undesirable side effects. Sugammadex's ability to reverse NMBAs has major implications for routine anesthesia practice. The ability of sugammadex to rapidly reverse NMBAs could play a critical role in the dangerous "cannot intubate, cannot ventilate" situations. All of the studies discussed conclude that sugammadex is superior in reversal of NMBAs in terms of speed, efficacy and side effects.

Methods and Implementation

Design, Sample, and Setting

A CPG was designed and evaluated for utilizing sugammadex in the reversal of NMBAs, specifically in emergent situations such as cannot intubate, cannot ventilate scenarios for individuals who remain deeply blocked at the end of a case and does not meet the criteria for the use of neostigmine (Appendix C). The setting for the CPG evaluation was at a medium-sized hospital in Maryland and applies to any patient undergoing anesthesia where a NMBA is used. The sample for this project varied throughout three stages. The first sample size consisted of three Student Registered Nurse Anesthetists (SRNAs) who designed the CPG, and two volunteer key stakeholders, a CRNA and one Anesthesiologist. The second sample consisted of twenty-two anesthesia staff members including CRNAs, Anesthesiologists, and SRNAs.

Procedures

Development of the CPG was divided into two steps, with the first step focused on generating change on a small scale and the second step being full implementation within the facility. Step one involved three phases: planning, development, and implementation (Appendix D). A timeline for planning, development, and implementation was agreed upon between the project leaders and the stakeholders. A summary of the project proposal illustrates the implementation plan agreed upon by the project team members (Appendix E).

Phase I (February 2018 to July 2018) began with the recruitment of two key stakeholders who worked with project leaders, together this team played an active role in the development of the CPG. The stakeholders were identified as one Anesthesiologist and one CRNA within the identified facility. Phase I also included a presentation of the proposed CPG to the stakeholders, initial CPG draft, and submission of the proposed project to the University of Maryland

Baltimore (UMB) Institutional Review Board (IRB). Following IRB approval, communication between the project leaders and the stakeholders began to identify project goals, purpose, and a clear timeline. An initial CPG draft was created and sent to the stakeholders for evaluation with the Appraisal of Guidelines for Research and Evaluation II (AGREE II) tool (Appendix F). After a thorough review of the CPG using the AGREE II tool, the stakeholders sent the CPG back to the project leaders with suggested revisions. The project leaders then created accounts on the Cicero website where a project summary was submitted for approval.

Phase II (July 2018 to August 2018) consisted of finalizing the CPG, presentation of the CPG to the anesthesia staff, and approval of the CPG by the Chief Anesthesiologist. The project leaders worked with the stakeholders to make final revisions to the CPG before submission to the Chief Anesthesiologist. After all final revisions were made the CPG was then re-submitted to the stakeholders, and submitted to the Chief Anesthesiologist. After review and approval by the Chief Anesthesiologist, the CPG was to be presented to the anesthesia department.

Phase III occurred December 2018, with presentation of the CPG to the anesthesia department and evaluation of the project by the anesthesia staff using the Practitioner Feedback Questionnaire (PFQ) (Appendix G), and a poster presentation of the DNP project. The project was presented to the anesthesia department during an anesthesia staff meeting, and the PFQ was given to all staff members present at the presentation to evaluate the project. Data collected from the PFQs was evaluated to identify areas of possible weakness in the CPG. The data was presented to the stakeholders and the Chief Anesthesiologist and final changes were made before submission for policy change.

Methods to Protect Human Rights and Permission

This project protected and maintained confidentiality by asking participants to place their completed PFQs in a locked box in a secure area. Data was then electronically entered on a password protected computer. Access to the surveys and data was only granted to the project leaders of this project. Other measures taken to protect human rights was to ensure that no specific identifiers were included in the surveys. The proposed project was submitted to UMB IRB for a Non-Human Subjects Research (NHSR) determination before initiation and was granted an exempt status with approval.

Sustainability and Generalizability

The outcome of this CPG was reliant on the engagement of the stakeholders at the facility. Having key stakeholders involved in the early stages of development and implementation of the project assisted in an effective CPG development and practice change. Sustainability of this CPG requires outcomes and quality improvement measures to continuously be monitored. To achieve this, quarterly audits can or will be completed using the electronic health record to determine when, why, and how often Sugammadex was given by the anesthesia provider. Administration of other NMBA reversals should be tracked along with the incidence of adverse effects such as respiratory complications or residual blockade in the PACU or ICU.

This was a quality improvement project for the development of a CPG for utilizing Sugammadex in the reversal of NMBAs, specifically in emergent situations such as cannot intubate, cannot ventilate scenarios for individuals who remain deeply blocked at the end of a case. This CPG was created at the request of the hospital administration. As this is specific for the facility, it is not for use by another entity, and is not intended to be generalized to other facilities or populations.

Data Collection and Analysis

In Phase I of the project, the AGREE II tool was used to collect data about the CPG from the stakeholders. The AGREE II is both valid and reliable and encompasses 23 items organized into 6 quality domains: scope and purpose; stakeholder involvement; rigor of development; clarity of presentation; applicability; and editorial independence. Each of the 23 items targets various aspects of practice guideline quality. The AGREE II also includes 2 final overall assessment items that requires the appraiser to make overall judgments of the practice guideline and considering how they rated the 23 items (AGREE Next Steps Consortium, 2013). A Likert scale is used to measure items, and consists of a seven-point response scale ranging from 1 = 'strongly disagree' to 7 = 'strongly agree.' A score of 1 is where no information is available, and the scores increase as more criteria is met. A score of 7 is for exceptional quality of reporting and where considerations and full criteria have been met (AGREE Next Steps Consortium, 2013). A CPG is considered high quality for any calculated base domain score of greater than 70 percent (Brouwers et al., 2010). The AGREE II tool helped identify areas of improvement and guide revisions to the CPG.

Phase II is where the PFQ was utilized. The PFQ is a valid and reliable tool created specifically for the adopters of a guideline (Brouwers et al., 2010). The PFQ focuses on four areas: scientific quality, methodological rigor, implement ability and applicability, and acceptability of recommendations. It is a 23 item questionnaire which uses a three point Likert scale (strongly agree, strongly disagree, neither agree nor disagree) to score the items (Brouwers et al., 2010). The questionnaire is presented in pencil/pen and paper format, and includes demographic information such as age, years of practice, and title. Data from the PFQ was reviewed and statistical analysis completed.

Results

Evaluation of the quality of the CPG was completed by the stakeholders utilizing the AGREE II tool. The stakeholders evaluated the CPG using the 6 quality domains of the AGREE II tool: scope and purpose; stakeholder involvement; rigor of development; clarity of presentation; applicability; and editorial independence. Team members of the project ensured key stakeholders involvement in the early stages of development of the CPG. The stakeholders reported that the guideline objectives, population, and health questions were specifically described resulting in a 100 percent in domain one, scope and purpose. Domain two, stakeholder involvement was scored at 100 percent. The stakeholders found that the CPG clearly defined target users, view and preferences of the target population were sought, and that individuals from all relevant professional groups were included. Domain three focused on the use of systematic methods to search for evidence, descriptions of strengths and weaknesses, rigor of development, and that recommendations for updating the guideline were provided. Domain three was scored at 100% by the stakeholders. Domains four and five, clarity of presentation and applicability, were scored at 100 percent. The stakeholders found the guideline clear, easy to follow, and applicable to their practice. Lastly, domain 6, editorial independence, was also scored at 100% (Appendix F).

After completion of the CPG presentation, descriptive statistics were calculated for the anesthesia providers who completed the PFQ (N=22). Providers filling out the questionnaire consisted of Anesthesiologists (n=8), CRNA's (n=10), and SRNA's (n=4). The majority of the providers were CRNA's, accounting for 45.5 percent of the population. Years of clinical experience varied among the providers, ranging from no experience to greater than 25 years.

The majority of the providers experience tied at less than 5 years (31.8%) and five to ten years of experience (31.8%).

All providers (100%) participating in the questionnaire were responsible for care of patients, and agreed that the CPG recommendations were clear and there is a need for a guideline on the use of sugammadex. Providers found the CPG to be suitable for the intended patients, and that it would result in more benefit than harm (100%). Anesthesia providers disagreed that the recommendations were too rigid to apply to individual patients (81.8%), too technically challenging (81.8%), and too expensive to apply (81.8%). Overall, the majority of anesthesia providers felt comfortable with their patient's receiving the care recommended in the guideline (95.5%). Most providers agreed this guideline should be approved for practice (95.5%), and that they would apply the recommendations to their practice (100%). A summary of the PFQ analysis can be found in Appendix G.

The providers goals of providing the best and safest care for the patients was helpful in the implementation process. Most of the staff was knowledgeable about the current research and strived to incorporate evidence into their practice. The expert panel was very familiar with the use of sugammadex, and proved to be a suitable resource for the development of the CPG.

The biggest barrier to the implementation of the CPG was the pharmacy at the facility. The pharmacy stated their concern about the cost-effectiveness of sugammadex, and was unconvinced that the use of sugammadex is superior to neostigmine, therefore they did not support the additional cost of sugammadex. To counter this barrier, the team members increased the amount of research evidence for the effective, superior, and safe use of sugammadex in the reversal of neuromuscular blockade, and a reduction of total hospitalization costs when sugammadex is used. Many providers do prefer the use of sugammadex and the safe, effective

results they witness when it is used. The support of the staff is imperative to counter the pharmacy's negative opinion on the use of sugammadex.

Discussion

The use of sugammadex has clearly been demonstrated to be superior to neostigmine in reversing moderate and deep NMB. Sugammadex more rapidly reverses rocuronium induced NMB, results in higher TOF ratio values at extubation, and lower adverse respiratory and cardiac events after extubation (Carron, Zarantonello, & Tellaroli, 2016). These outcomes may be attributed to the different mechanisms of action of sugammadex and neostigmine. Neostigmine works by increasing the concentration of acetylcholine at the neuromuscular junction. Sugammdex works differently, by directly encapsulating aminosteroid NMBAs and rendering them inactive, facilitating the return of muscle function (Hristovska et al., 2017).

Sugammadex was recently added as an option for anesthesia to use in the reversal of neuromuscular blockade at a medium-sized community hospital. Members of the project team and champions from the anesthesia department of the facility identified the need for standardization of the use of sugammadex. Together the team members and the champions from the anesthesia department developed a CPG with the goal of reducing the incidence of residual paralysis after the use of NDMRs. Key stakeholders for the project evaluated the final CPG yielding high scores using the AGREE II tool. The high scores reflect that the stakeholders found that the CPG would be effective and useful in the daily practice of the anesthesia providers. Some resistance was received from the pharmacy due to the higher cost of sugammadex compared to neostigmine. To counter the resistance further research and evidence was provided to support the use of sugammadex and its effectiveness. Due to a lack of price-points at the current facility, relevant rates from nearby community hospitals were used as

examples. This illustrated numerous ways to use sugammadex in a cost-effective way, and also demonstrated how similar institutions have been successful in its preferential use.

The high scores of the PFQs determined that end users are supportive of accepting and applying the CPG to their practice. In addition to the PFQs, verbal feedback was very positive from the anesthesia staff. The staff verbalized appreciation regarding the research and evidence, the detailed timing and dosing for administration, and the efficacy and safety profile of sugammadex provided by the project members.

Conclusion

Approval of this CPG is anticipated to improve clinical practice and patient outcomes at this facility. Using sugammadex and a standardized approach for the reversal of neuromuscular blockade will potentially reduce the incidence of residual paralysis in this medium sized community hospital. This CPG will provide guidance for the use of Sugammadex in emergent situations such as cannot intubate, cannot ventilate scenarios for individuals who remain deeply blocked at the end of a procedure and does not meet the criteria for use of neostigmine. The CPG will also provide proper timing and dosing and guidance for proper use. Residual paralysis after the administration of NMBAs can result in respiratory failure and a delay in discharge, by preventing the occurrence of residual paralysis there will be a decrease in patient's length of stay and a decrease in overall healthcare costs.

Potential quality improvement for this facility would consist of collecting and providing data to the pharmacy on the effectiveness and improved outcomes with the use of sugammadex, which can result in an overall reduction of costs. Another area of quality improvement would be the education of PACU staff regarding residual paralysis and its signs and symptoms, and to ensure a timely referral to anesthesia staff when it is suspected. This project does have the

potential to be used at other facilities. However, before use at any other facilities it should be tailored to the policy and procedures of the particular facility, and a cost analysis performed and tailored to the particular facility.

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Appendix A

Table 1. *Evidence Review*

Author/Year	Study objective	Design	Sample (N)	Outcomes studied (how measured)	Results	Level of evidence
Brueckmann, Saski, Grobara, Li, Woo, de Bie, Maktabi, Lee, Pino, Sabouri, McGovern, Saehr-Rye, & Eikermann (2015)	This study was to determine if the use of sugammadex in the reversal of rocuronium-induced neuromuscular blockade was effective in preventing residual paralysis.	Randomized Control Trial (RCT)	N=150 Group 1- Sugammadex recipients (n=74). Group 2- Standard of care (n=76).	The incidence of residual blockade with the use of Sugammadex compared to use of Neostigmine and Glycopyrrolate. A Train-of-four measurement was taken upon arrival to the Post Anesthesia Care Unit (PACU). Pain scores were also recorded in the PACU.	Results revealed no residual blockade with Sugammadex use (n=0), but 43.4% residual blockade when Neostigmine and Glycopyrrolate were used (n=33). Readiness to discharge was shorter with Sugammadex. Readiness for operating room discharge was faster following Sugammadex (14.7 minutes, p=0.02), as compared to the Neostigmine/Glycopyrrolate combination (18.6 minutes).	2A
Carron, Zarantonello & Tellaroli (2016)	This analysis reviewed several RCTs to compare the safety and effectiveness of Sugammadex administration vs. Neostigmine in the reversal of neuromuscular blockade.	Meta-Analysis of RCTs	13 studies N=1384	Safety and effectiveness of Sugammadex in reversal of NMB compared to Neostigmine was analyzed. PRISMA methodology was used to organize data from RCTs. Primary outcome was efficacy of Sugammadex, defined as the time to reversal of moderate and deep NMB. Presence of residual blockade was also assessed. Safety of Sugammadex was evaluated as the secondary outcome. The incidence and seriousness of adverse effects were included.	Researchers concluded Sugammadex was faster than Neostigmine and Glycopyrrolate in reversing NMB (p=0.0001), higher a TOFR at extubation (p=0.0001). Sugammadex was shown to be superior in reducing global (p<0.0001), respiratory (p-0.0386), and cardiovascular (p=0.0036) adverse events. The incidence of postoperative residual curarization (p=0.0068) and weakness (p=0.0409) was also decreased.	1A
Hristovska, Duch, Allingstrup & Afshari (2017)	To compare the efficacy and safety of sugammadex versus neostigmine in reversing NMB induced by a non-depolarizing neuromuscular blocker.	Systematic Review of RCTs.	41 studies N = 4206	Primary outcome measured was time required for full reversal of NMB defined by TOFR > 0.9. Risk ratios were used to quantify the risk of AEs and considered as secondary outcomes. The Cochrane risk of bias tool was used to assess for random error in 10 methodological domains through trial sequential analysis. An overall assessment of evidence quality was prepared using the GRADE approach.	Sugammadex was 6.6 times faster than Neostigmine in reversal of moderate NMB, 16.8 times faster in reversal of deep NMB. 16% of participants were at risk for adverse events with the use of Sugammadex, as opposed to 28% in the Neostigmine group. Sugammadex was associated with significantly less risk of bradycardia (NNTB 14), PONV (NNTB 16), and residual paralysis (NNTB 13)	1A

Ledowski (2015)	To examine the optimal use of Sugammadex discovered in the first 18 months after approval in Australia, and determine its place in clinical practice.	Systematic Review of RCTs.	N=143 Studies from 1/1/2013-7/31/2014 reviewed. Studies include optimum dose, recovery times expected, postoperative outcomes, side effect profile, and comparison to Neostigmine.	The outcomes of this study were to identify definitive evidence for the use of Sugammadex as the optimal choice for reversal, and to determine what further information was needed to promote its use in clinical practice. All articles found in PubMed using the search term, "Sugammadex." Categorized in the form of questions reflecting where they contribute to new knowledge. Articles on the pharmacology of Sugammadex, review articles, letters to the editor, or published comments were excluded. Studies before 2013 cited only if required in context of newer investigations.	Sugammadex was found to be more effective (3-8 times faster) over Neostigmine in the rapid and reliable reversal of residual neuromuscular blockade. Evidence also reveals additional benefits in the management of difficult airway scenarios and patients allergic to Rocuronium. Additional prospective, randomized, and blinded studies examining the cost/benefit ratio of Sugammadex is recommended.	1A
Martini, Boon, Bevers, Aarts, & Dahan (2013)	Comparison of deep NMB (DNMB) vs. moderate NMB (MNMB) in the facilitation of optimal surgical conditions in patients undergoing retroperitoneal laparoscopic prostatectomy or partial kidney resection.	RCT	N=24 Group 1 (n= 12) DNMB Group 2 (n= 12) MNMB	To determine the degree of which NMB depth affected surgical conditions. Outcome was measured with a rating tool on a scale of 1 (poor conditions) to 5 (optimal conditions) by the surgeon at 15-minute intervals. To provide visual representation, video images were captured at time of scoring Randomized samples of these images (n=10) were presented to 12 anesthetists blinded to NMB level and study goals. Anesthesia experts utilized the same rating tool to measure the surgical condition depicted.	Sugammadex significantly enhanced surgical conditions and decreased extubation times. The mean score of surgical conditions reported for MNMB (4) and DNMB (4.7) were deemed statistically different (p=0.001). Differences in time between reversal of NMB and acceptable extubation conditions with Sugammadex (5.1 minutes) vs. Neostigmine (10.9 minutes) was statistically different (*p*=0.01).	2A

Torensma, Martini, Boon, Olofsen, Veld, Liem, Knook, Swank & Dahan (2016)	Evaluation of surgical conditions and postoperative pain using DNMB vs. MNMB in laparoscopic bariatric surgery. Rapid reversal of DNMB was facilitated with the use of Sugammadex.	Double blind RCT	N=100 Group 1 (n=50) DNMB Group 2 (n=50) MNMB	Quality of the surgical field based on the depth of the neuromuscular blockade was studied. To rate the quality of the surgical field by surgeons, a Leiden-Surgical Rating Scale (L-SRS) was used. This Likert scale ranged from 1-5, with 1 indicating extremely poor surgical conditions, and 5 indicating optimal conditions. Pain scores were measured q4h in the postoperative period.	Results indicated that L-SRS scores for surgical conditions differed significantly (p<0.001) between MNMB (4.2) and DNMB (4.8). DNMB lead to lower pain scores in the PACU (p=0.03) and reduced the incidence of referred shoulder pain (p=0.03) postoperatively. The study concluded that the use of Sugammadex, and its ability to reverse DNMB safely, made the conception of this study possible.	2A
Welliver, McDonough, Kalynych, Redfern (2015)	This review investigates the finding, development, and clinical application of Sugammadex. Phases I-III human clinical studies are discussed in detail.	Systematic Review of RCTs.	Phase I (N=29) Phase II 6 studies (N=384) Phase III 12 studies (N=624)	The time between administration of Sugammadex and reversal of neuromuscular blockade (as defined by a TOF > 0.9) was measured and averaged to reflect the mean among study participants.	Phase I: The researchers determined that Sugammadex safely and effectively reversed neuromuscular blockade induced by rocuronium. Phase II: Reversal with Sugammadex was compared with cholinesterase inhibitors and was found to be superior in reversal speed and thoroughness; resulting in improved patient safety. Phase III: Use of Sugammadex was found to be safe in patients with impaired renal function, pulmonary disease, and cardiac comorbidities. Reversal time in patients >65 years of age was increased by 0.6 minutes (p=0.022). There was a significant decrease in the incidence of tachycardia and dry mouth.	1A

Note. [b]ASA = American Association of Anesthesiologists Physical Status Classification System. (Melnyk & Fineout-Overholt, 2014; Newhouse, 2006)

Table 2. Rating System for Hierarchy of Evidence

Level of the Evidence	Type of the Evidence
I	Evidence from systematic review, meta-analysis of randomized controlled trails (RCTs), or practice- guidelines based on systematic review of RCTs.
II	Evidence obtained from well-designed RCT
III	Evidence obtained from well-designed controlled trials without randomization
IV	Evidence from well-designed case-control and cohort studies
V	Evidence from systematic reviews of descriptive and qualitative studies
VI	Evidence from a single descriptive or qualitative study
VII	Evidence from the opinion of authorities and/or reports of expert committees

(Melnyk & Fineout-Overholt, 2014)

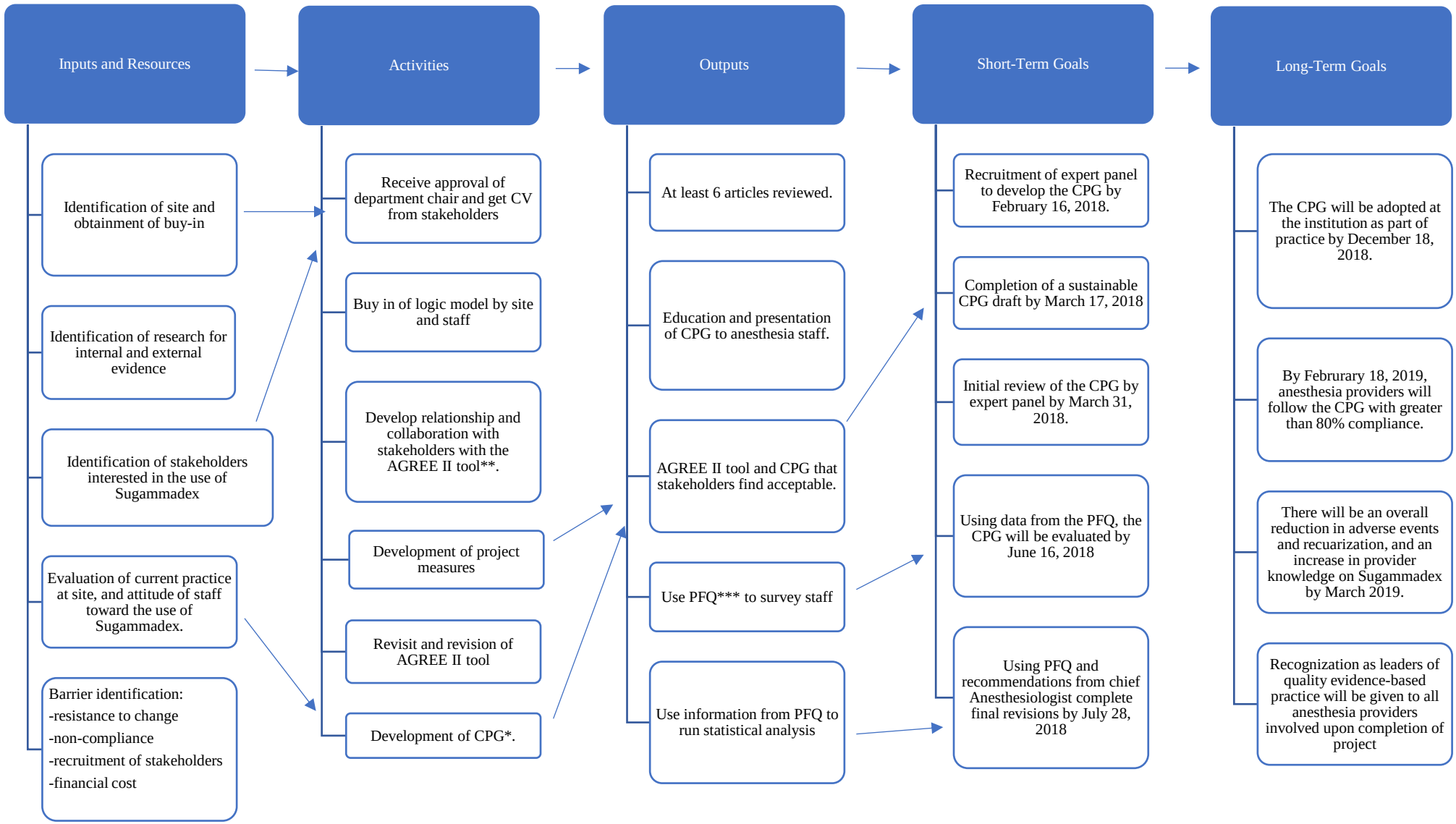
Table 3. Rating Scale for Quality of Evidence

Quality Rating Level Rating Description	Quality
A	High – consistent results with sufficient sample, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific literature.
B	Good – reasonably consistent results; sufficient sample, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence.
C	Low/major flaw – Little evidence with inconsistent results; insufficient sample size; conclusions cannot be drawn

(Newhouse, 2006)

Appendix B

Figure 1. *Logic Model*



Appendix C

CLINICAL PRACTICE GUIDELINE: THE USE OF SUGAMMADEX FOR THE REVERSAL OF NEUROMUSCULAR BLOCKADE

Background and Significance

One of the commonly observed challenges of anesthesia is generalized muscle weakness or residual neuromuscular blockade (RNMB) after administration of neuromuscular blocking agents (NMBAs) (Murphy et al., 2011). Neuromuscular blocking agents are most often used in general anesthesia to produce neuromuscular blockade (NMB) or muscle paralysis intraoperatively. Muscle paralysis facilitates intubation and decreases patient movement which increases operating conditions. The degree of paralysis can be monitored with the use of a nerve stimulator that activates muscle contraction. Nerve stimulators are used to produce a train-of-four (TOF) or post tetanic counts (PTC) that allow the provider to assess the depth of neuromuscular blockade (Srivastava & Hunter, 2009).

Residual neuromuscular blockade is "incomplete neuromuscular recovery in the early postoperative period defined as a TOF ratio of less than 0.9" (Murphy et al., 2011, p.946). Risks of RNMB are multifactorial including patient factors (i.e. age, comorbidities, etc.), pharmacological causes (i.e. drug interactions), duration and type of anesthesia (i.e. opioid use, benzodiazepine use, etc.), and metabolic causes (i.e. acidosis, etc.) (Srivastava & Hunter, 2009). Residual neuromuscular blockade impairs airway patency increasing the risk of post-operative complications such as reduced upper airway volumes, airway obstruction and hypoxemia events. In fact, 38 – 64% of patients who receive intermediate- acting NMBAs experience RNMB. In a study of more than 200,000 cases where paralytics were administered, 64% of cardiac arrests were related to airway complications in the PACU (Ellis et al., 2014). 23% of these cases occurred within the first 24 hours of the perioperative period, with a mortality rate of 29% (Ellis et al., 2014). The absence of residual paralysis not only can decrease poor outcomes, but more importantly the capability to save a patient's life. Awake volunteers, with a TOF ratio of 0.7-0.75, described RNMB as "unpleasant symptoms" such as generalized fatigue, decreased grip strength, visual disturbances, facial weakness, difficulty speaking, keeping their eyes open and swallowing (Murphy et al., 2011, p. 947).

Delayed discharge from the PACU has been shown to be a concerning direct result of residual paralysis. In a study of 248 patients, 22% experienced residual paralysis. This resulted in a 114-minute increase in PACU length of stay (Butterly et al., 2010). Regarding the surgical patient population as a whole, the absence of residual paralysis would allow anesthesia providers and PACU nurses the ability to recover, extubate, and progress patients to the next level of care without fear of consequences associated with its presence. This translates into increased efficiency in overall PACU flow and scheduling of surgical cases. According to Miller et al. (2010), a shorter length of stay can lead to decreased institutional costs by lessening the need for overtime personnel such recovery room nurses and nursing aids. In turn, this has the potential for enhanced staff satisfaction. Decreased wait times, faster discharges, and better outcomes naturally lead to a rise in patient and family satisfaction.

In 2006, a publication of a study about the first use of sugammadex in humans was published. Over the past decade, the number of studies regarding sugammadex and clinical practice using sugammadex has greatly increased proving that sugammadex eliminates post-operative complications, such as RNMB, and improves surgical conditions (Carron,

Zarantonello, & Tellaroli, 2016). Sugammadex is a modified y-cyclodextrin, created to bind to free plasma molecules of aminosteroid NMBAs, specifically rocuronium, which it has high affinity for. The use of sugammadex allows for full reversal with deep NMB within 5 minutes; however, full reversal after sugammadex use most often occurs even faster within 2-3 minutes (Martini, Boon, Bevers, Aarts, & Dahan, 2013).

Sugammadex is proven to be superior, reliable and faster compared to its competition neostigmine. Neostigmine can result in incomplete reversal or RNMB and has potent parasympathetic activity that causes adverse effects, such as bradycardia, nausea and vomiting. The difference between these drugs is a result of their mechanism of action (Carron et al., 2016). Unlike the ceiling effect and adverse effects seen with neostigmine, sugammadex encapsulates the rocuronium and rarely causes RNMB or any adverse events. The sugammadex-rocuronium complex has a high association and low dissociation rate. It is estimated that for every 25 million complexes one complex will dissociate (Nag et al., 2013). By encapsulating the rocuronium it is removed from the neuromuscular junction and allows return of muscle function. Neostigmine increases the concentration of acetylcholine at the neuromuscular junction to compete and displace the rocuronium from the site; however, the rocuronium is not completely removed and can paradoxically compete for the receptor site causing RNMB (Carron et al., 2016).

Evidence supports that sugammadex use is effective, safe, allows rapid reversal of NMB and reduces the incidences of RNMB (Brueckmann et al., 2015). The purpose of this Doctorate in Nursing Practice (DNP) project is to modify the current policy, at a community hospital, regarding the use of sugammadex. Currently, at this institution sugammadex has been used 103 times over an eight-month period. The main reason being failed neostigmine reversal resulting in muscle weakness and low tidal volumes. An evidence-based clinical practice guideline (CPG) will be implemented that clearly identifies when sugammadex can and cannot be used at this Maryland hospital. The anticipated outcome is adoption and implementation of the CPG at the institution. Short-term goals are 1) recruitment of expert panel, 2) draft the CPG, 3) initial, secondary and third revisions of CPG, 4) proposal of CPG to anesthesia department, 5) analysis, synthesis and evaluation of CPG based on feedback, 6) final revisions and draft of CPG. Long-term goals are 1) adoption and implementation of the CPG, 2) greater than 75% of clinicians will use sugammadex for reversal of NMB and 3) to reduce incidences of RNMB and its associated complications.

Scope and Purpose

The purpose of this Doctor of Nursing Practice project is to develop a clinical practice guideline (CPG) for the administration of sugammadex as a reversal agent for paralytics used by anesthesia personnel. This CPG will address the question: Does the use of sugammadex as a reversal agent for rocuronium and vecuronium induced neuromuscular blockade reduce the incidence of residual neuromuscular blockade in adult patients undergoing general anesthesia requiring neuromuscular blockade agents. Presentation of this CPG will facilitate education of Anesthesia Department staff of a medium-sized community hospital on the superiority of sugammadex over Neostigmine in its ability to effectively reverse NMB and thus decrease the incidence of residual paralysis, with additional benefits as a rescue drug in the emergent “cannot ventilate, cannot intubate” scenario. The anticipated outcome is that sugammadex will be more effective in the reversal of neuromuscular blockade with fewer side effects, and no residual paralysis. The audience targeted by this CPG presentation are the anesthesia providers and Post

Anesthesia Care Unit (PACU) registered nurses. The targeted patient population for this CPG will be adults (> or equal to 18 years of age) who are undergoing general anesthesia requiring the use of the neuromuscular blocking agents rocuronium or vecuronium that meet the inclusion/exclusion criteria mentioned below.

Inclusion/Exclusion Criteria

For this guideline, the following inclusion criteria will be used: male/females, ≥ 18 years old, patients undergoing general anesthesia requiring the use of the neuromuscular blocking agents rocuronium or vecuronium. Exclusion criteria includes pediatric patients (< or equal to 17 years of age), neuromuscular disease, pregnancy patients, women breast-feeding and patients with severe renal impairment requiring dialysis.

Stakeholders Involvement

Residual neuromuscular blockade has been identified as an area of improvement for this community hospital. Anesthesia providers responsible for patient care in the perioperative period at this location have identified RNMB as a potential contributor to prolonged PACU stays. Interest in the use of sugammadex as a reversal agent for RNMB has been recognized. An extensive literature reviewed (see below) describes how the information for the CPG was gathered and how practice recommendations were decided upon. Collaboration among an expert panel will facilitate the creation, presentation, and implementation of this sugammadex CPG. A Certified Registered Nurse Anesthetist (CRNA) with a terminal DNP degree, an Anesthesiologist, and three Student Registered Nurse Anesthetists (SRNAs) practicing at this community hospital are members of the expert panel. Additionally, a faculty member at the University of Maryland School of Nursing with a PhD or DNP degree will be a part of the expert panel. Each member will be invested in using their expertise to collaborate on the development and implementation of sugammadex use at this institution. The CRNA, Anesthesiologist and school faculty member will use the AGREE II Tool to aid the students in revising and making changes to the CPG. The final CPG will be finalized by the Chief Anesthesiologist and CRNA at the community hospital. The target audience of this CPG will be perioperative providers such as CRNAs, Anesthesiologists, and Registered Nurses in this area. The guideline will be used to inform standard of care with the use of sugammadex.

Literature Review, Analysis and Synthesis

PubMed, CINAHL, and Cochrane Library electronic databases were searched for literature. The search was limited to articles published between January 2008 to March 2018. Medical Subject Heading (MeSH) terms were used to search for articles and included words such as “sugammadex,” “neostigmine,” “neuromuscular blockade,” “residual neuromuscular blockade,” “residual paralysis,” “anesthesia,” and “neuromuscular blocking agents.” This resulted in 128 articles, which were further narrowed to only include RCTs, meta analyses, and systematic reviews. A total of 6 articles were identified as being most relevant to the development of this CPG and included in the literature review.

The literature review highlights the significance of four articles, two systematic reviews of randomized control trials (RCTs), one meta-analysis of RCTs, and one RCT. The review will discuss the safety and efficacy of sugammadex, and the decrease of residual neuromuscular blockade when sugammadex is used. Carron, Zarantonello & Tellaroli (2016), completed a meta-analysis of randomized control trials (RCTs) to compare the safety and effectiveness of

sugammadex administration versus Neostigmine in the reversal of neuromuscular blockade. The study concluded that when compared to neostigmine, sugammadex was notably faster in reversing neuromuscular blockade ($P < 0.0001$), and was associated with a higher train-of-four ratio at extubation ($P < 0.0001$). Sugammadex was also concluded to have lower adverse respiratory events ($P = 0.0386$), lower cardiac adverse events ($P = 0.0036$), and significantly lower global adverse events ($P = < 0.0001$) (Carron, Zarantonello, & Tellaroli, 2016). Hristovska, Duch, Allingstrup & Afshari (2017), similarly compared the efficacy and safety of sugammadex to neostigmine. the review found sugammadex to be 6.6 times faster than neostigmine in reversal of moderate NMB and 16.8 times faster in reversal of deep NMB (Hristovska, Duch, & Afshari, 2017). With the use of sugammadex adverse events such as bradycardia and postoperative nausea and vomiting are reduced up to 40 percent (Hristovska et al., 2017).

Ledowski (2015) completed a systematic review of RCTs to examine the optimal use of sugammadex and determine its place in clinical practice. The review concluded that sugammadex is more rapid and more reliable in the reversal of NMBAs. The use of sugammadex results in a more rapid return of muscle strength which assists with easier management of difficult airway situations. Lastly, Brueckmann et al. (2015), completed a RCT to determine if the use of sugammadex in the reversal of rocuronium induced neuromuscular blockade was effective in preventing residual paralysis. The study revealed that no residual blockade was found in patients in group 1, those who received sugammadex, but 43.4 percent of those in group 2 who received neostigmine had residual blockade (n = 33). Sugammadex was shown to be 3 to 18 times faster in the reversal of rocuronium-induced NMBA when compared to neostigmine. Operating room discharged time was faster following sugammadex (14.7 minutes, $p = 0.02$) when compared to neostigmine (18.6 minutes).

The results of these recent studies indicate that sugammadex is safe and effective for the reversal of NMBAs, and results in reduced adverse events. This is in comparison to the current reversal agent, neostigmine, which has a numerous amount of undesirable side effects. Sugammadex's ability to reverse NMBAs has major implications for routine anesthesia practice. The ability of sugammadex to rapidly reverse NMBAs could play a critical role in the dangerous 'cannot intubate, cannot ventilate" situations. All the studies discussed conclude that sugammadex is superior in reversal of NMBAs in terms of speed, efficacy and side effects

Methods

The CPG was created by the collaboration of five people who were vested in the success of the CPG to establish a clear standard of care for the use of sugammadex at this community hospital. The expert panel that developed the CPG included three doctoral candidate SRNAs, a CRNA with a terminal degree and an Anesthesiologist at the medical institution of interest. The process used to create, assess and evaluate the CPG is listed below:

1. Identification of the problem, expert panel and current evidence to be used to address the identified problem at the medical institution of interest.
2. Review of literature addressing the use of preoperative carbohydrate loading to decrease postoperative nausea and vomiting.
3. Expert panel completed a review of the preliminary guideline using the AGREE II tool.
4. Several meetings were conducted with the expert panel to address recommendations and comments from the AGREE II tool results. Revisions of the preliminary guidelines were made based on feedback provided.

5. Target users were given a questionnaire to evaluate the attitudes and feasibility of implementing the guideline.
6. The expert panel developed a final guideline incorporating all the feedback of both the AGREE II tool and questionnaire.

Benefits and Risk

Benefits:

- Decreased incidence of residual paralysis
- Increased safety profile with less adverse events such as cardiovascular and respiratory side effects
- Increased muscle strength after NMB
- Decreased PACU length of stay/shorter recovery time
- Useful in "cannot ventilate, cannot intubate" scenarios after NMB

Risks:

- Cost compared to neostigmine
- Rare reports of bradycardia, nausea, vomiting and allergic reaction
- Interacts with contraceptives, decreasing their effectiveness.

Practice Recommendations

Surgical patients older than 18 years of age undergoing surgical procedures necessitating the use of paralytics should receive sugammadex as the agent of choice in the reversal of NMB. Consequently, the negative effects associated with the use of Neostigmine such as residual paralysis would be negated. Incorporating sugammadex will reduce postoperative residual neuromuscular blockade and increased patient's outcomes. This CPG is recommended to be used by perioperative providers such as CRNAs, MDAs, Surgeons and Registered Nurses in perioperative areas. The outcomes of the CPG should be continually monitored by the anesthesia staff and evaluated after implementation. Every two to three years a literature review of the current evidence should be conducted to update the CPG. The targeted patient population for this CPG will be adult (> or equal to 18 years old) surgical patients. This guideline should not to be used for patients with any of the following:

- pediatric patients (< or equal to 17 years of age)
- neuromuscular disease
- pregnancy
- women breast-feeding
- patients with severe renal impairment requiring dialysis

Facilitators and Barriers

The implementation of this CPG may create potential barriers. These potential barriers include the cost of the sugammadex, education and training of the perioperative and anesthesia staff and resistance to change by the providers. Facilitators of the sustainability of the CPG include education of staff, staff involvement and feedback, accessibility of the affordable sugammadex and user-friendly guideline that is clear and concise.

Appendix D

DNP Project Name: Implementation of the use of Sugammadex Clinical Practice Guideline.
DNP Project Purpose Statement: The purpose of this Doctor of Nursing Practice project is to develop a clinical practice guideline (CPG) for utilizing Sugammadex in the reversal of NMBAs by January 2019.

Short-Term SMART Objectives: Five anticipated short-term goals were identified:
1). Recruitment of an expert panel to develop the CPG by February 2018.
2). Completion of a sustainable CPG draft by March 2018.
3). Initial review of CPG by the expert panel by June 2018.
4). Data collected from the PFQ will be used to evaluate the CPG by December 2018.
5). Final revisions of the CPG will be completed by January 2019. Revisions will be based on feedback received from the PFQ and the expert panel.

Long-Term SMART Objectives: Four anticipated long-term goals were identified:
1). By February 2019 the CPG will be adopted at the institution as part of practice.
2). By August 2019, anesthesia providers will follow the CPG will greater than 75% compliance.
3). There will be an overall reduction in adverse events and residual muscle blockade, and an increase in provider knowledge of Sugammadex by August 2019.
4). Recognition as leaders of quality evidence-based practice will be given to all anesthesia providers involved upon completion of the project.

Population/Context: The Anesthesia Department at a medium-sized hospital in Baltimore, MD is the target for this CPG. It will apply to any patient undergoing anesthesia where a NMBA is used.

Mobilize: *WHO will help facilitate the changes in structures and processes (practices)?*
The expert panel will consist of:

- Dr. Htut – Anesthesiologist (MD)
- D. Curtis – Certified Registered Nurse Anesthetist (CRNA)
- UMSON SRNAs:
  -Karissa Hansen (self)
  -Danielle Goeren
  -Jennifer Lewin

Others I will mobilize after the draft plans have been developed:

- Dr. Pellegrini – Director of Nurse Anesthesia Program (CRNA, PhD, DNP) at University of Maryland School of Nursing
- Dr. Markas – Chief Anesthesiologist (MD)
- K. Crowley – Chief Nurse Anesthetist

Assess:
WHAT structures and processes (practices) need to change and WHY?
A medium size community hospital in Maryland is the target institution of this scholarly project. Current practice is the use of Neostigmine for the reversal of NMBAs. Currently, there is no available data on complications with the use of Neostigmine within the facility. However, its presence is inferred, with increased side effects such as muscle weakness, postoperative nausea and vomiting, the increased length of stay in PACU, and a delay in discharge. As this facility does not have a policy on the use of Sugammadex and the use of it is restricted, the purpose of this Doctor of Nursing Practice project is to develop a clinical practice guideline (CPG) for utilizing the use of Sugammadex in the reversal of NMBAs. An anesthesiologist and a nurse anesthetist employed at the facility have been identified as key stakeholders and will help navigate the direction of this project to meet the needs of the facility. It is anticipated that there will be a decrease in side effects and residual neuromuscular blockade, a decrease in PACU stay, and a decrease in delay in discharge.

What structure, process, and outcome measures will be used to measure progress?

- The AGREE II tool will be used to rate and grade the draft of the CPG. The AGREE II tool will allow for measurement of progress and development of the CPG before submission to the Chief Anesthesiologist at the medium-sized facility in Baltimore, MD.
- The Practitioner Feedback Questionnaire (PFQ) will be used after presenting the CPG to collect feedback from the Anesthesia Department regarding the quality of the CPG.

Plan: *HOW will these changes be made (strategies and tactics)? WHEN will these changes be made?*
The original CPG will be developed by a group of 5 members focused on the implementation of the use of Sugammadex. The 5 members include an Anesthesiologist, nurse anesthetists, and DNP nurse anesthesia students. The development of the CPG follows a six-step process: 1) development of criteria for research, 2) review of literature addressing the use of Sugammadex in the reversal of neuromuscular blockade, 3) AGREE II tool used by the expert panel to review the CPG, 4) several meetings with the expert panel to be held, recommendations based on the results from the AGREE II tool will be addressed, and revisions of the CPG will be made, 5) target users will be given a Provider Feedback Questionnaire to assess their opinion of implementation of the CPG, 6) all information and data will be used to finalize the CPG.

Phase One:

- A review of current literature and the recruitment of stakeholders will be completed by February 2018
- Initial meeting with the stakeholders, purpose, goals, and timeline determined by March 2018
- First draft of CPG completed by March 2018
- Stakeholders will complete initial review of CPG, feedback from stakeholders about CPG and recommended changes, and submission of project proposal to IRB by June 2018
- Resubmission of CPG to stakeholders for review, changes made based upon recommendations, and resubmission of CPG by the end of June 2018
- Third revision of CPG, and meeting with stakeholders to make any further changes that are needed by July 2018

Phase Two:

- Proposed CPG submitted to Department of Anesthesia by July 2018 for approval
- Meeting with Department of Anesthesia Chief Anesthesiologist to review further recommended changes, and then final CPG sent back to Chief Anesthesiologist by August 2018

Phase Three

- Presentation of CPG to anesthesia department at Thursday morning meeting by December 2018

- PFQ given to staff after presentation with an expected return rate of at least 75% by December 2018
- Data collected from PFQ used to determine staff evaluation of CPG by January 2019
- Final revisions to CPG made by January 2019
- Final CPG implemented at facility by February 2019
- By August 2019 greater than 75% of the anesthesia staff will use Sugammadex based on the CPG guidelines
- By August 2019 there will be a decrease in residual muscular blockade, and adverse events

Implement: *WHAT strategies and tactics were used? WHEN were the desired changes made?*

Step 1: Perform small tests of change

- Work with stakeholders to rate and grade the draft of the CPG.
- Use feedback from the AGREE II tool to revise the project as needed.
- Complete a sustainable CPG draft by March 17, 2018.
- Make revisions to CPG by April 30, 2018.

Step 2: Full-scale implementation

- Education of staff on the use of Sugammadex during presentation of CPG.
- Provide anesthesia staff with PFQ
- Data collected from the PFQ will be used to evaluate the CPG by June 16, 2018.
- Final revisions of the CPG will be completed by July 28, 2018. Revisions will be based on feedback received from the PFQ and the expert panel.
- By December 18, 2018 the CPG will be adopted at the institution as part of practice.
- By February 18, 2019, anesthesia providers will follow the CPG will greater than 80% compliance.
- There will be an overall reduction in adverse events and residual muscle blockade, and an increase in provider knowledge of Sugammadex by March 2019.
- Recognition as leaders of quality evidence-based practice will be given to all anesthesia providers involved upon completion of the project.

Track: *WHAT structures and processes (practices) were changed based on the metrics we used to measure progress (including frequency of assessment)? HOW did these changes affect outcomes? WHAT do we need to do differently to make greater progress toward improving outcomes?*

- The implementation of the use of Sugammadex for the reversal of NMBAs will result in an overall reduction in adverse events and residual muscle blockade, improving patient outcomes.
- Based on the PFQ recommendations will be made to the CPG to improve the quality of the CPG.
- Six months after implementation of the use of Sugammadex an internal evidence review will be completed determine if there has been a reduction in adverse events and residual muscle blockade for patients who received NBMAs.
- Six months after implementation of the use of Sugammadex, PFQ forms will be redistributed to collect feedback from the Anesthesia Department regarding the quality of the CPG.
- Feedback will again be collected from the PFQ and additional changes will be made to the CPG if necessary.

Date: _____ Re-Assessment Date 1: _____ Re-Assessment Date 2:_____, etc.

Plan Developed by (List all contributors: Karissa Hansen, Danielle Goeren, Jennifer Lewin, Deborah Curtis, and Dr. Htut.

Appendix E

Project Proposal Summary

Background: Introduction of neuromuscular blocking agents (NMBAs) has had a vast impact on anesthesia practice and the potentials of surgical treatment of patients, facilitating endotracheal intubation and permitting surgical access to body cavities without unwanted muscle contractions. Although NMBAs have contributed to the improvement of surgical conditions their use can lead to many complications, the most common being residual neuromuscular blockade after surgery. The presence of residual neuromuscular blockade postoperatively has been associated with an increase in mortality and morbidity and may lead to respiratory complications such as low blood oxygen levels, labored breathing, lung infections, and aspiration.

Purpose: The purpose of this Doctor of Nursing Practice project is to develop a clinical practice guideline (CPG) that provides clear guidelines for utilizing Sugammadex in the reversal of NMBAs, specifically in emergent situations such as cannot intubate, cannot ventilate scenarios for individuals who remain deeply blocked after surgery.

Evidence to Support Practice Change: Incidence of residual neuromuscular blockade ranges from 16 to 60%. The most common reversal agent used is neostigmine. When using neostigmine, the use of a muscarinic antagonist is required to compensate side effects such as bradycardia, hypotension, and postoperative nausea and vomiting, however the use of muscarinic antagonists also has side effects such as tachycardia, blurred vision, and dry mouth. After administration of Neostigmine, 20 to 60 percent of patients arriving in the post-anesthesia care unit (PACU) still shown signs of residual paralysis. One option to aid in overcoming the limitations and side effects of neostigmine and improve the safety and efficacy of NMBA reversal is Sugammadex. Sugammadex in a modified gamma cyclodextrin (CD) selective relaxant binding agent (SRBA). Sugammadex directly encapsulates NMBAs rendering them inactive, resulting in no residual blockade. By using Sugammadex, numerous side effects can be avoided, operating room time shortened, and quality of recovery and discharge time can be improved.

Implementation Plan: The CPG will be apportioned into three phases. Phase I will begin with the recruitment of two key stakeholders, presentation of the proposed CPG to the stakeholders, initial CPG draft, and submission of the proposed DNP project to the University of Maryland Baltimore (UMB) Institutional Review Board (IRB). Phase II consists of finalizing the CPG, presentation of the CPG to the anesthesia staff, and approval of the CPG by the Chief Anesthesiologist. Phase III involves presenting the CPG to the anesthesia department, data analysis by the anesthesia staff using the Practitioner Feedback Questionnaire (PFQ), and a poster presentation of the DNP project.

Data Collection and Analysis: The Appraisal of Guidelines for Research and Evaluation II (AGREE II) tool is valid and reliable and encompasses 23 items organized into 6 quality domains: scope and purpose; stakeholder involvement; rigor of development; clarity of presentation; applicability; and editorial independence. Each of the 23 items targets various aspects of practice guideline quality. The AGREE II includes 2 final overall assessment items that requires the appraiser to make overall judgments of the CPG considering how they rated the 23 items. A 7 point Likert scale is used to measure items, ranging from 1 = 'strongly disagree' to 7 = 'strongly agree.' The AGREE II tool will identify areas of improvement and help guide revisions to the CPG. The Provider Feedback Questionnaire (PFQ) is a valid and reliable tool created specifically for the adopters of a guideline. The PFQ focuses on four areas: scientific quality, methodological rigor, implement ability and applicability, and acceptability of recommendations. It is a 23 item questionnaire which uses a three point Likert scale (strongly agree, strongly disagree, neither agree nor disagree) to score the items. The questionnaire is presented in pencil/pen and paper format, and includes demographic information such as age, years of practice, and title. Data from the PFQ will be reviewed and statistical analysis.

Measures to Protect Human Rights: To protect and maintain confidentiality, participants will place completed PFQs in a locked box in a secure area. Data will be electronically entered on a password protected computer. Access to the surveys and data will only be granted to the DNP students assigned to

this project. To protect human rights, no specific identifiers are included in the surveys. The proposed project will be submitted to UMB IRB for a Non-Human Subjects Research (NHSR) determination.

Appendix F

AGREE II Tool

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA
DOMAIN 1: SCOPE AND PURPOSE	
1. OBJECTIVES *Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.*	Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) Expected benefit(s) or outcome(s) Target(s) (e.g., patient population, society)
2. QUESTIONS *Report the health question(s) covered by the guideline, particularly for the key recommendations.*	Target population Intervention(s) or exposure(s) Comparisons (if appropriate) Outcome(s) Health care setting or context
3. POPULATION *Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.*	Target population, sex and age Clinical condition (if relevant) Severity/stage of disease (if relevant) Comorbidities (if relevant) Excluded populations (if relevant)
DOMAIN 2: STAKEHOLDER INVOLVEMENT	
4. GROUP MEMBERSHIP *Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations.*	Name of participant Discipline/content expertise (e.g., neurosurgeon, methodologist) Institution (e.g., St. Peter's hospital) Geographical location (e.g., Seattle, WA) A description of the member's role in the guideline development group
5. TARGET POPULATION PREFERENCES AND VIEWS *Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.*	Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) Outcomes/information gathered on patient/public information How the information gathered was used to inform the guideline development process and/or formation of the recommendations

6. TARGET USERS *Report the target (or intended) users of the guideline.*	The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators) How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)
DOMAIN 3: RIGOUR OF DEVELOPMENT	
7. SEARCH METHODS *Report details of the strategy used to search for evidence.*	Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL) Time periods searched (e.g., January 1, 2004 to March 31, 2008) Search terms used (e.g., text words, indexing terms, subheadings) Full search strategy included (e.g., possibly located in appendix)
8. EVIDENCE SELECTION CRITERIA *Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.*	Target population (patient, public, etc.) characteristics Study design Comparisons (if relevant) Outcomes Language (if relevant) Context (if relevant)
9. STRENGTHS & LIMITATIONS OF THE EVIDENCE *Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.*	Study design(s) included in body of evidence Study methodology limitations (sampling, blinding, allocation concealment, analytical methods) Appropriateness/relevance of primary and secondary outcomes considered Consistency of results across studies Direction of results across studies Magnitude of benefit versus magnitude of harm Applicability to practice context
10. FORMULATION OF RECOMMENDATIONS *Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.*	Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered) Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures) How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)

11. CONSIDERATION OF BENEFITS AND HARMS *Report the health benefits, side effects, and risks that were considered when formulating the recommendations.*	Supporting data and report of benefits Supporting data and report of harms/side effects/risks Reporting of the balance/trade-off between benefits and harms/side effects/risks Recommendations reflect considerations of both benefits and harms/side effects/risks
12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE *Describe the explicit link between the recommendations and the evidence on which they are based.*	How the guideline development group linked and used the evidence to inform recommendations Link between each recommendation and key evidence (text description and/or reference list) Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline
13. EXTERNAL REVIEW *Report the methodology used to conduct the external review.*	Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) Methods taken to undertake the external review (e.g., rating scale, open-ended questions) Description of the external reviewers (e.g., number, type of reviewers, affiliations) Outcomes/information gathered from the external review (e.g., summary of key findings) How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)
14. UPDATING PROCEDURE *Describe the procedure for updating the guideline.*	A statement that the guideline will be updated Explicit time interval or explicit criteria to guide decisions about when an update will occur Methodology for the updating procedure
DOMAIN 4: CLARITY OF PRESENTATION	
15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS *Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.*	A statement of the recommended action Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects) Relevant population (e.g., patients, public) Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply) If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline
16. MANAGEMENT OPTIONS *Describe the different options for managing the condition or health issue.*	Description of management options Population or clinical situation most appropriate to each option

17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms Specific recommendations grouped together in one section
DOMAIN 5: APPLICABILITY	
18. FACILITATORS AND BARRIERS TO APPLICATION *Describe the facilitators and barriers to the guideline's application.*	Types of facilitators and barriers that were considered Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography) How the information influenced the guideline development process and/or formation of the recommendations
19. IMPLEMENTATION ADVICE/TOOLS *Provide advice and/or tools on how the recommendations can be applied in practice.*	Additional materials to support the implementation of the guideline in practice. For example: Guideline summary documents Links to check lists, algorithms Links to how-to manuals Solutions linked to barrier analysis (see Item 18) Tools to capitalize on guideline facilitators (see Item 18) Outcome of pilot test and lessons learned
20. RESOURCE IMPLICATIONS *Describe any potential resource implications of applying the recommendations.*	Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) How the information gathered was used to inform the guideline development process and/or formation of the recommendations
21. MONITORING/ AUDITING CRITERIA *Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.*	Criteria to assess guideline implementation or adherence to recommendations Criteria for assessing impact of implementing the recommendations Advice on the frequency and interval of measurement Operational definitions of how the criteria should be measured
DOMAIN 6: EDITORIAL INDEPENDENCE	

22. FUNDING BODY *Report the funding body's influence on the content of the guideline.*	The name of the funding body or source of funding (or explicit statement of no funding) A statement that the funding body did not influence the content of the guideline
23. COMPETING INTERESTS *Provide an explicit statement that all group members have declared whether they have any competing interests.*	Types of competing interests considered Methods by which potential competing interests were sought A description of the competing interests How the competing interests influenced the guideline process and development of recommendations

AGREE Next Steps Consortium (2013). The AGREE II Instrument [Electronic version]. Retrieved from http://www.agreetrust.org/wp-content/uploads/2013/10/AGREE-II-users-manual-and-23-item-instrument_2009_UPDATE_2013.pdf.

AGREE II Tool

Domain 1. Scope and Purpose

1. The overall objectives of the guideline are specifically described.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

2. The health question covered by the guideline is specifically described.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

3. The population to whom the guideline is meant to apply is specifically described.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

Domain 2. Stakeholder Involvement

4. The guideline development group includes individuals from all relevant professional groups.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

5. The views and preferences of the target population have been sought.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

6. The target users of the guideline are clearly defined.

1 2 3 4 5 6 7
☐ ☐ ☐ ☐ ☐ ☐ ☐
Strongly Disagree Strongly Agree
Comments:

Domain 3. Rigour of Development

7. Systematic methods were used to search for evidence.

1 2 3 4 5 6 7
☐ ☐ ☐ ☐ ☐ ☐ ☐
Strongly Disagree Strongly Agree
Comments:

8. The criteria for selecting the evidence are clearly described.

1 2 3 4 5 6 7
☐ ☐ ☐ ☐ ☐ ☐ ☐
Strongly Disagree Strongly Agree
Comments:

9. The strength and limitations of the body of evidence are clearly described.

1 2 3 4 5 6 7
☐ ☐ ☐ ☐ ☐ ☐ ☐
Strongly Disagree Strongly Agree
Comments:

10. The methods for formulating the recommendations are clearly described.

1 2 3 4 5 6 7
☐ ☐ ☐ ☐ ☐ ☐ ☐
Strongly Disagree Strongly Agree
Comments:

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

1 2 3 4 5 6 7
☐ ☐ ☐ ☐ ☐ ☐ ☐
Strongly Disagree Strongly Agree
Comments:

12. There is an explicit link between the recommendations and the supporting evidence.

1 2 3 4 5 6 7
☐ ☐ ☐ ☐ ☐ ☐ ☐
Strongly Disagree Strongly Agree

13. The guideline has been externally reviewed by experts prior to its publication.

1 2 3 4 5 6 7
☐ ☐ ☐ ☐ ☐ ☐ ☐
Strongly Disagree Strongly Agree

Comments:

14. A procedure for updating the guideline is provided.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

Domain 4. Clarity of Presentation

15. The recommendations are specific and unambiguous.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

16. The different options for management of the condition or health issue are clearly presented.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

17. Key recommendations are easily identifiable.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

Domain 5. Applicability

18. The guideline describes facilitators and barriers to its application.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

20. The potential resource implications of applying the recommendations have been considered.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

21. The guideline presents monitoring and/or auditing criteria.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

Domain 6. Editorial Independence

22. The views of the funding body have no influenced the content of the guideline.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

23. Competing interests of guideline development group members have been recorded and addressed.

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Strongly Disagree						Strongly Agree

Comments:

Overall Guideline Assessment

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline

1	2	3	4	5	6	7
☐	☐	☐	☐	☐	☐	☐
Lowest possible quality						Highest Possible quality

2. I would recommend this guideline for use.

☐	☐	☐
Yes	Yes, with modifications	No

Notes:

AGREE II Tool Domain Scores

Summary of Domain Scores

Domain 1	100%
Domain 2	100%
Domain 3	100%

	Domain 4	100%
	Domain 5	100%
	Domain 6	100%
	Overall assessment	100%

		Appraiser 1	Appraiser 2	Total
Domain 1	Item 1	7	7	14
	Item 2	7	7	14
	Item 3	7	7	14
Obtained Scores				42
Calculated Domain Scores				100%
Domain 2	Item 4	7	7	14
	Item 5	7	7	14
	Item 6	7	7	14
Obtained Scores				42
Calculated Domain Scores				100%
Domain 3	Item 7	7	7	14
	Item 8	7	7	14
	Item 9	7	7	14
	Item 10	7	7	14
	Item 11	7	7	14
	Item 12	7	7	14
	Item 13	7	7	14
	Item 14	7	7	14
Obtained Scores				112
Calculated Domain Scores				100%
Domain 4	Item 15	7	7	14
	Item 16	7	7	14
	Item 17	7	7	14
Obtained Scores				42
Calculated Domain Scores				100%
Domain 5	Item 18	7	7	14
	Item 19	7	7	14
	Item 20	7	7	14
	Item 21	7	7	14
Obtained Score				56

Calculated Domain Scores				100%
Domain 6	Item 22	7	7	14
	Item 23	7	7	14
Obtained Scores				28
Calculated Domain Scores				100%
Overall Guideline Assessment		7	7	14
Calculated Domain Scores				100%
Total Obtained Scores		161	161	322

Appendix G

Modified Practitioner's Feedback Questionnaire (PFQ)

Please select the appropriate demographic category that most accurately describes you.
Title: **Anesthesiologist:** 8 (36.4%) **CRNA:** 10 (45.5%) **SRNA:** 4 (18.2%)
Years of Experience: **0-5 years:** 7 (31.8%) **5-10 years:** 7 (31.8%) **10-15 years:** 2 (9.1%)
15-20 years: 3 (13.6%) **20-25 years:** 2 (9.1%) **>25 years:** 1 (4.5%)

1. Are you responsible for the care of patients for whom this guideline report is relevant? This may include the referral, diagnosis, treatment, or follow-up of patients.	Yes 22 (100%)	No 0 (0%)	Unsure 0 (0%)
If you answered "*No*" or "*Unsure*", there is no need to answer or return this questionnaire. If you answered "*Yes*", please answer the questions below and return to the anesthesia department secretary/or designated personnel.			
	Strongly agree	Neither agree or disagree	Strongly disagree
2. The rationale for developing a guideline is clear.	22 (100%)	0 (0%)	0 (0%)
3. There is a need for a guideline on this topic.	22 (100%)	0 (0%)	0 (0%)
4. The literature search is relevant and complete (e.g., no key evidence was missed nor any included that should not have been) in this guideline.	22 (100%)	0 (0%)	0 (0%)
5. I agree with the methodology used to summarize the evidence included in this guideline.	22 (100%)	0 (0%)	0 (0%)
6. The results of the evidence described in this guideline are interpreted according to my understanding of the evidence.	22 (100%)	0 (0%)	0 (0%)
7. The CPG's recommendations in this report are clear.	22 (100%)	0 (0%)	0 (0%)
8. I agree with the recommendations as stated.	22 (100%)	0 (0%)	0 (0%)
9. The recommendations are suitable for the patients for whom they are intended.	21 (95.5%)	1 (4.5%)	0 (0%)
10. The recommendations are too rigid to apply to individual patients.	0 (0%)	4 (18.2%)	18 (81.8%)
11. When applied, the recommendations will produce more benefits for patients than harm.	22 (100%)	0 (0%)	0 (0%)
12. The guideline presents options that will be acceptable to patients.	22 (100%)	0 (0%)	0 (0%)
13. Application of recommendations will require reorganization of services/care in my practice setting.	0 (0%)	7 (31.8%)	15 (68.2%)
14. To apply the guideline, recommendations will be technically challenging.	0 (0%)	4 (18.2%)	18 (81.8%)
15. The guideline recommendations are too expensive to apply.	0 (0%)	4 (18.2%)	18 (81.8%)
16. The guideline recommendations are likely to be supported by a majority of my colleagues.	22 (100%)	0 (0%)	0 (0%)
17. If I follow the guideline recommendations, the expected effects on patient outcomes will be obvious.	20 (90.9%)	2 (9.1%)	0 (0%)
18. The guideline recommendations reflect a more effective approach for improving patient outcomes than is current usual practice. (If they are the same as current practice, please tick ☐ NA).	21 (95.5%)	1 (4.5%)	0 (0%)

19. When applied, the draft guideline recommendations will result in better use of resources than current usual practice. (If they are the same as current practice, please tick *NA* ☐)	20 (90.9%)	1 (4.5%)	1 (4.5%)
20. I would feel comfortable if my patients received the care recommended in the guideline.	22 (100%)	0 (0%)	0 (0%)
21. This proposed guideline should be approved as a practice guideline.	21 (95.5%)	0 (0%)	1 (4.5%)
22. If this proposed guideline were to be approved as a practice guideline, I would use it in my own practice/apply the recommendations to my patients.	22 (100%)	0 (0%)	0 (0%)

Adapted from: Brouwers, M.C., Graham, I.D., Hanna, S.E., Cameron, D.A., & Browman, G.P. (2004). Clinicians' assessments of Adapted from: Brouwers, M., Graham, I., Hanna, S., Cameron, D., & Browman, G. (2004). Clinicians' assessments of practice guidelines in oncology: The CAPGO survey**.** *International Journal of Technology Assessment in Health Care*, *20*(4), 421-6.

Figure 2. Provider Type

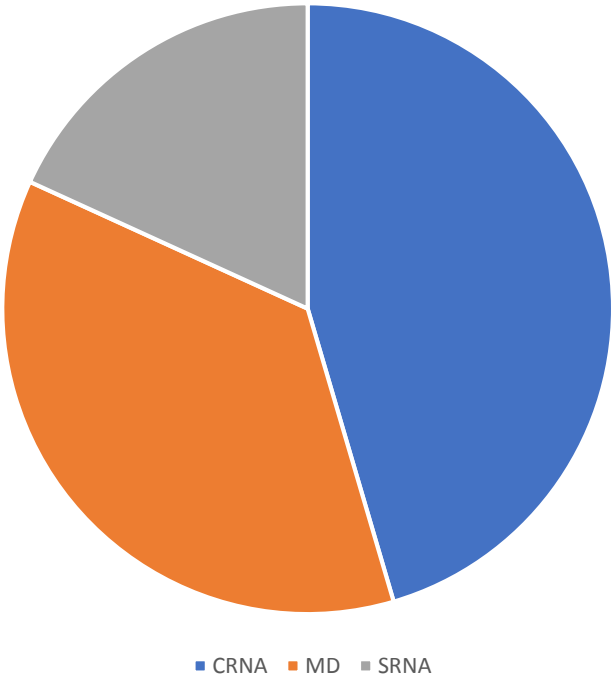


Figure 3. Provider Years of Experience

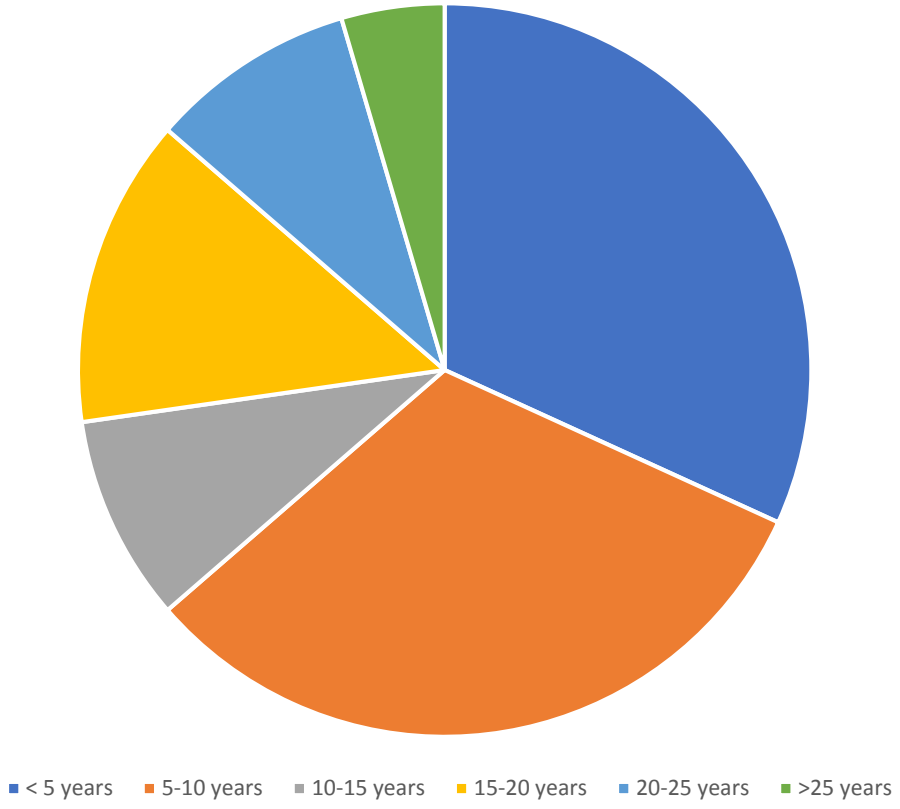


Figure 4. Provider Feedback Questionaire Results