

APRIL 2021

VALUE ANALYSIS

MCMURRAY ENHANCED AIRWAY™





NURSE APPROVED

MCMURRAY ENHANCED AIRWAY VALUE ANALYSIS

EXECUTIVE SUMMARY

The McMurray Enhanced Airway (MEA) is a new airway management device designed by an anesthesia expert to quickly and effectively open obstructed airways during anesthesia or cardiopulmonary resuscitation, preventing adverse events or death due to lack of oxygen and ventilation. Existing airway equipment has not evolved significantly over the last 100 years despite changes in the anatomical structures of patients' palates (redundant tissue) leaving a void in effective airway management. Unlike the limitations associated with legacy airway management products, the MEA's unique design stents open the unconscious patient's airway beyond the tongue supporting spontaneous breathing, oxygenation and ventilation.

Outcomes from inadequate ventilation and oxygenation are the most reported closed claims for sedation between 2003 and 2012 yet were found to be preventable. The challenges of keeping the upper airway open, particularly during deep sedation cases, has led to workarounds, either by adapting airway tools meant for other uses (e.g., using nasal airways orally) or requiring additional physical positioning maneuvers like chin lift and jaw thrust. Due to these workarounds or adaptations of tools, patients often emerge from anesthesia with sore and bruised jaws and chins, or dental and palate injuries that can linger for days or cause permanent damage. Healthcare professionals often need to hold patients' heads in position for the duration of the procedure and into recovery, sustaining hand fatigue trying to keep the airway open. The MEA effectively addresses the gap in oral airway management by replacing the need for sustained chin lifts, jaw thrusts or use of the nasal airway orally. The purpose of the MEA Value Analysis was to obtain CRNA expert reviews of the use, safety, and preference of the MEA device.

VALUE ANALYSIS BY CERTIFIED REGISTERED NURSE ANESTHETISTS (CRNA)

Procedure: Certified Registered Nurse Anesthetist (CRNA) Experts (from different geographic areas and surgical facilities) with at least 5 years experience working in an Operating Room as a CRNA/anesthesia expert were recruited by Dr. McMurray to participate in the Nurse Approved Value Analysis of the McMurray Enhanced Airway (MEA). The Certified Registered Nurse Anesthetists Experts agreed to complete a brief onboarding survey, a one-hour interview, the Nurse Expert Quality Standard Index (NEQSI)®, and consent to use their information and name. The onboarding survey gathered demographic information, and participants signed consents to participate and authorize recording and use of the interviews. Each Focus Group session used a Zoom platform for a one-hour

interview of the CRNA Experts about the Usability, Safety, and Preference domains associated with use of the McMurray Enhanced Airway (MEA). Nurse Approved identified five CRNA experts to participate in the value analysis.

A mix method approach was chosen to provide in-depth, valid, reliable, credible qualitative and quantitative data for rigorous results using focus groups and survey questions.¹ The sample of five highly experienced Nurse Anesthesiologists/CRNAs were selected to develop in-depth assertions about how the MEA works in practice.² The sample size was small but provided a deep reach into the practice of using the MEA device. Of the five selected CRNA Experts, the group had cumulative experience of 97 years (mean 19.4 yrs.; range 2-26 yrs.) as practicing Nurse Anesthesiologists. In the prior month, the CRNA Experts spent an average of 30.4 hours per week in the operating room and completed an average of 19 surgeries (range 12-21) in atypical week. The CRNA Experts reported that 10-75% of their surgical cases per week presented special ventilation challenges specifically related to sleep apnea, obesity, and facial surgeries. All CRNA Experts used the MEA tool at least three times a week and often in more than a third of their cases. Other devices used to ventilate patients for surgery included patient positioning, oral pharyngeal airway (OPA) also known as an oral airway, nasal pharyngeal airway (NPA) also known as a nasal airway, Laryngeal Mask Airway (LMA), and endotracheal tube (ETT). (See below for a table summarizing the CRNA Experts experience).

Leaders of the focus group sessions were Dr. Roxanne McMurray, DNP, APRN, CRNA, founder of McMurray Medical Group LLC; Rebecca Love, MS, RN, NP, FIEL, Chief of Innovation for Nurse Approved LLC; and Nancy Hanrahan, Ph.D., RN FAAN, Chief Scientist of Nurse Approved LLC. The focus groups were divided into 3 sessions to accommodate the CRNA Experts busy schedules. Surveys were taken before and after the focus groups.

INTERVIEW QUESTIONS

1. “Tell us how you Use the MEA”
 - a. Name the patient conditions that work best for the MEA use.
 - b. What criteria do you use to choose the MEA?
 - c. What do you like about the MEA?
 - d. What don't you like about the MEA?
 - e. Describe how the MEA saves you time.
 - f. What patient benefits do you notice by using the MEA?
 - g. What are the facility benefits of using the MEA?
2. “Tell us about Safety and the MEA”
 - a. Describe a case where you had a failure of ventilation. Would the MEA have been helpful, or was the MEA helpful? How?
 - b. Name three significant patient outcomes you achieved using the MEA.
 - c. Name potential adverse effects using the MEA.
 - d. If you could change one thing about the MEA, what might it be?
3. Preference. Tell us how the MEA compares with other airway devices?
 - a. Name three features about the MEA that you appreciate.
 - b. Would you recommend the MEA to colleagues?
 - c. With ventilation and airway challenges, how does the MEA compare with other airway devices to improve

airway outcomes?

The Zoom meetings were transcribed, and video recordings were made and distributed to Dr. Roxanne McMurray. Below are key comments by the Nurse Anesthetist Experts in the domains of Usability, Safety, and Preference.

TABLE OF CRNA BACKGROUNDS & EXPERTISE

ONBOARDING SURVEY OF CRNA EXPERTS FOR THE MCMURRAY ENHANCED AIRWAY REVIEW										
ID	TITLE	STATE	ZIP	Years as a RN	Years as a CRNA	In the past month, how many hours in a typical 40-hour work week have you spent in the operating room as a CRNA	How many surgeries do you complete in a typical 40 work week?	Estimate the percent of your surgical cases per week that present special ventilation challenges	How likely are you to use the MEA to ventilate patients for surgery?	Other devices used
1	CRNA	MN	55387	9	5	25	12	75%	A few times a week	OPA LMA
2	CRNA	SC	29926	22	22	40	20	30%	A few times a week	Nasal Cannula OPA NPA LMA ETT
3	CRNA	IA	51601	2	46	25	21	15%	A few times a week	Nasal Cannula LMA ETT
4	CRNA	MN	56387	26	17	30	20	40%	A few times a week	Natural Airway Chin lift OPA NPA MEA LMA ETT Mask Ventilation
5	CRNA	MN	55330	14	7	32	20	10%	A few times a week	OPA NPA Patient positioning

USABILITY

Comments from Anesthesia Experts

+ "I won't do a case without having the MEA within hand's reach...Because it bails me out of unforeseen situations. Whether it's in OB, whether it's in ER, whether it's in the CT scan room."

+ *"It's just so simple and easy. It's not intrusive at all to the patient, whatsoever. No matter if they're a sleep apnea patient or a young adult and at the end of the case all of a sudden you need a little bit of extra sedation to get them under control and the airway becomes obstructed. Slip the MEA in, boom, you're doing fine and have a patent airway."*

+ *"I carry the MEA in my pocket because you never know when it might save someone's life! Recently, I used the MEA in ICU for a GI bleed. Upon arrival, the patient wasn't ventilating well, very ill. Since we couldn't intubate due to DNI order, I popped the MEA device in, hand ventilated them up, which allowed us to do the case to stop the bleed. The MEA allowed the patient to be discharged from the hospital and was instrumental in saving that man's life actually."*

+ *"The MEA revolutionized how we manage the airway without having to go further down our airway algorithm and keep patients in a safe place. I feel, the oral airways that we are so used to using, that we trained on initially, have their limitations. I especially find patients that have a very long chin to jawbone, I can't see behind the tongue, the MEA displaces tissue better. I'm able to utilize this in patients that I wouldn't be able to use an oral airway as effectively."*

+ *"It's so easy. Put it in your pocket to have it with and pull it out when needed. It's nice to have as a backup or even a first line. It's just so easy, as you wait to set up the other equipment like the GlideScope or other airway supplies."*

+ *"Algorithm for application of the MEA: If they're obstructing, start with opening the airway with a chin lift/ jaw thrust. Next, increase the oxygen level if the oxygen saturation is on the lower side based on their baseline round 90%- 94% SpO2. At that point, if they are still obstructing, use a device like an airway: an oral airway, nasal airway, or MEA to create a patent airway. If saturations are not maintained with oxygen and airway device, next apply positive pressure ventilation with the MEA and anesthesia circuit or Ambu bag or mask and anesthesia circuit or Ambu bag. The next step would be placing a LMA or intubating to support the airway."*

+ *"I think the MEA saves time especially when it's an unusual situation. But in any situation, it's time saving because you don't need another set of hands and you don't have to wait or delay anything. You may be the only person in the hospital with advanced airway skills. If you have to wait for somebody else to come to help, or delay a procedure, especially with a child...using the MEA can help make that hard decision. Keeping the patient in the ER versus going to the OR, using the MEA to keep the airway open, saves time and money-that's amazing, in my opinion."*

SAFETY

Comments from Anesthesia Experts

+ *"Facial Plastics and potential fires in the operating room or on the patient are higher under sedation/Monitor Anesthesia Care (MAC). The fire risk is especially high if there's a surgical procedure above the xiphoid or mid-nipple line and in close proximity to the surgeon's cautery with oxygen diffusion present. To minimize oxygen diffusion, we resort to placing a LMA or intubating. With the MEA, one can utilize a deep MAC and keep the fire risk still low, without having the oxygen near the cautery. The MEA keeps the oxygen closer to the lungs and not blowing around outside the mouth or nose. When you have something to burn (fuel), combustible oxygen, and an ignition source close together, the fire risk increases. Operating room fires are a low occurrence but a high liability payout."*

+ "For some procedures, the surgeons are right up by the airway with cautery. For fire safety reason, throughout the case we go on and off with the oxygen whenever cautery is used with a nasal cannula or oxygen mask. It is great to use the MEA to connect directly to the circuit to keep our oxygen flows from leaking into the surgical field...Using the MEA we cut O₂ leakage from 67% down to almost room air 21%. And it's awesome. The MEA can help to reduce the fire risk under MAC."

+ "I did an IRB approved study at my facility in the surgery center. We utilized 60+ MEAs and compared them to traditional oral pharyngeal or nasal pharyngeal airways at alleviating obstruction in two situations. One was with deep sedation and the other after deep extubation to facilitate room turnover. The PACU, RNs would be holding a lot of jaws to alleviate obstruction because people were deeply anesthetized. I noticed that they were often holding the jaw with an oral airway in place. I wanted to see if the McMurray airway would be better at opening the airway. We had the CRNAs fill out a survey whether the patient needed a jaw lift or not with the MEA. We had great results: It was significantly true for deep sedation and it was significant for deep extubation that the patient didn't need a jaw lift with the MEA. The CRNAs love the MEAs so much."

+ "We had a patient that was a post cervical spine surgery that had some swelling in the recovery room. Since the patient was in a hard collar you cannot manipulate the neck to do airway management and also the surgeon did not want us to manipulate the neck and risk putting the patient through a redo surgery. However, the patient was not breathing well and obstructing their airway. We were contemplating intubation. So, we put the MEA device in, the patient was able to breathe with ease and we didn't have to manipulate their head and neck or remove the hard collar. The MEA was another save!"

PREFERENCE

Comments from Anesthesia Experts

+ "I think the biggest advantage of the MEA is for deep MAC. People ask for them. People call for them. They get upset when someone takes the last one."

+ "I like the fit of the nasal pharyngeal airway, and that's why I like the MEA because it's longer like the nasal pharyngeal. It goes farther back than the oral airway. The oral airway, all it does is curve and pull the tongue forward and out of the way. But if the oral airway is not exactly the right size, the airway still obstructs. The oral airway doesn't create a conduit like the MEA to open the airway to keep patients breathing."

+ "The problem is the nasal airway device is soft and when placed orally the patient can bite it, swallow or inhale it. I have heard of patients inhaling the nasal airway...it can be life threatening. With the MEA we have this nice bite block and flange. You can connect the MEA with the circuit which you can't do with the nasal airway."

Added question: Is the number and the amount of medication that you give a patient using an MEA different from perhaps when using an LMA or ETT with general anesthesia?

+ "Yeah...we can run them as light as they'll tolerate to keep the airway in place under MAC anesthesia. We have a huge population of geriatric patients or just unhealthy patients overall that physiologically can tolerate MAC much better than they would tolerate a general anesthetic. The MEA is just the tool we need to keep them breathing and safe."

+ *“When the patient is hard to mask ventilate, attach the MEA to the circuit and ventilate. You don’t have to change anything other than attaching the circuit and applying positive pressure. If you can’t ventilate*

and I’m heading toward intubation, I would try using the MEA first. The MEA saves time and you don’t need another set of hands. “

Would you recommend the MEA to colleagues?

+ *“Absolutely. I have students use it a lot too, just to get them exposed to it early on in their career.”*

+ *“Everybody knows about putting the nasal airway in the mouth, so it is easy to understand its utility and how easy it is to use. We like that it has a connector to connect to the anesthesia circuit or Ambu bag to apply positive pressure ventilation. I really like to point that out to people.”*

NURSE EXPERT QUALITY STANDARD INDEX ©:MCMURRAY ENHANCED AIRWAY						
	CRNA 1	CRNA 2	CRNA 3	CRNA 4	CRNA 5	Score
The product satisfies a need I have in my airway expert role	Very Satisfied	Very Satisfied	Satisfied	Very Satisfied	Very Satisfied	20
This product would be an important airway tool for my daily responsibilities	Strongly agree	Agree	Agree	Strongly agree	Strongly agree	20
I feel confident my colleagues would understand the value in this product	Strongly agree	Strongly agree	Agree	Strongly agree	Strongly agree	20
The product benefits are easy to explain	Strongly agree	Strongly agree	Agree	Strongly agree	Strongly agree	20
It is easy to understand product use cases	Strongly agree	Strongly agree	Agree	Strongly agree	Strongly agree	20
I feel confident adding this product as part of my practice	Strongly agree	Strongly agree	Agree	Strongly agree	Strongly agree	20

NURSE EXPERT QUALITY STANDARD INDEX
©:MCMURRAY ENHANCED AIRWAY

	CRNA 1	CRNA 2	CRNA 3	CRNA 4	CRNA 5	Score
This product addresses risk and exposure associated with current airway aspects	Strongly agree	Strongly agree	Neutral	Strongly agree	Strongly agree	19
There are situations where this product would not be safe for use	Disagree	Agree	Disagree	Disagree	Disagree	20
I am worried about unforeseen risks associated with this product	Strongly disagree	Disagree	Disagree	Strongly disagree	Strongly disagree	20
This product is better than current options	Strongly agree	Agree	Neutral	Strongly agree	Strongly agree	20
I would like to be able to use this product in my daily practice	Strongly agree	Strongly agree	Neutral	Strongly agree	Strongly agree	18
I would recommend this product to my colleagues with confidence	Strongly agree	Strongly agree	Agree	Strongly agree	Strongly agree	20
The product pricing seems fair and reasonable	Agree	Strongly agree	Neutral	Agree	Agree	18
The design of the product is appealing	Strongly agree	Agree	Agree	Strongly agree	Strongly agree	20
					Total Score	295
NURSE EXPERT QUALITY STANDARD INDEX ©					Percentile	98%

SUMMARY

All the CRNA Experts were enthusiastic about the McMurray Enhanced Airway filling a gap in the tools they use to keep patients ventilated during surgery. They found the MEA intuitive, fast, and easy to use to maintain a patent airway and minimize respiratory distress. They described the MEA material as flexible and longer than the oral airway; thus, able to manage redundant distal pharyngeal tissue and maintain a patent airway. The other features the CRNA Experts liked were the cushioned bite block to avoid dental damage or severing the device, the flange to keep the device in place, and the interoperability of the MEA with a Manual Resuscitator/Ambu bag and other ventilation devices. Repeatedly, the CRNA Experts appreciated the time saving value of the MEA because their hands were free from chin lift/jaw thrust maneuvers. This feature was underscored as value added by the CRNA Experts who don't have a large staff to assist during procedures.

CRNA Experts reported value in the use of the MEA to create airway patency in deep sedation cases. A solution like the MEA for patients who are older, obese or who have apnea might avoid the more affordable ambulatory surgery procedures. The CRNA Experts reported that using the MEA resulted in faster operating room turnaround, shorter post-operative patient recovery, and reduced opioid use compared with the use of LMAs or intubation for general anesthesia. Other patient benefits that were reported by the CRNA Experts included lower risks associated with accessing and maintaining a patent airway, avoidance of surgical fires, and lower risk for dental damage, jaw pain and dislocation. CRNA Experts were enthusiastic about recommending the MEA to colleagues and report that colleagues liked that the MEA eliminated the need for chin lift or jaw thrust maneuvers, which often lead to clinician fatigue and provider hand pain.

There was a recommendation from the CRNA Experts that may require attention. Several CRNA Experts wanted smaller and larger sizes of the MEA to use for pediatric patients or patients with unusually large airways.

The CRNA Experts revealed five explicit patient-use cases where the MEA was a clear first-line choice of treatment over current available industry options or off-label products.

Patient Use Cases

- + Patients with a BMI greater than 25
- + Surgical cases with heavy facial hair, distorted facial or tissue structure of the face and neck
- + Patients with a history of Sleep Apnea
- + Patients who have signed a DNI (Do Not Intubate)
- + Patients in need of positive pressure ventilation (PPV), as the MEA easily attaches to the Ambu bag or anesthesia circuit.

These conclusions were made using qualitative and quantitative methods with expert Certified Registered Nurse Anesthetists and validated via the Nurse Expert Quality Index (NEQSI) survey. The MEA met the quality standards for the distinguished Nurse Approved Certification for Usability, Safety and Preference

and received a rating of 98.3% on the NEQSI. Thus, the MEA earns the distinguished Nurse Approved Certification of Usability, Safety and Preference. The Nurse Approved Certification of the MEA highlights the superior impact of the MEA.

The Nurse Approved Certification places the MEA at the top of industry validation by CRNA Experts who use this product in real world, front line patient cases. The MEA clearly demonstrates a superior impact to improve patient care and outcomes, prevents adverse events and deaths in a significant portion of the patient population who receive anesthetic procedures and/or has upper airway obstruction.

Results from the Nurse Approved Value Analysis adds validity to previous research and documentation of MEA use.

It is with great regard that Nurse Approved congratulates the entire McMurray Medical Group team, and their years of hard work and dedication to saving patient lives, and constantly improving airway management with the MEA design. The MEA fills the critical void in ventilation and oxygenation for patients with upper airway obstruction or positive pressure ventilation needs undergoing anesthetic procedures or during cardiopulmonary resuscitation. According to the value analysis results, the CRNA Experts interviewed and surveyed describe the MEA as a brilliant innovation that they believe impacts and improves patient outcomes and decreases injuries and death when used with patients with upper airway obstruction and poor ventilation undergoing anesthesia or cardiopulmonary resuscitation.

References:

1. Crick, J.M. Qualitative research in marketing: What can academics do better? *Journal of Strategic Marketing*. 2021;29(5):390-429.
2. Hyde, K. F. Recognizing deductive processes in qualitative research. *Qualitative Market Research: An International Journal*. 2000;3(2):82–90. <https://doi.org/10.1108/13522750010322089>.

