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Progress in the Pursuit of a COVID-19 Vaccine

Richard Simoneaux

Steven L. Shafer, MD *Editor-in-Chief*

ince the complete sequencing of the genome for SARS-CoV-2 in January 2020, there has been an unprecedented scientific effort to translate that knowledge into a usable vaccine for large-scale immunization. Vaccination represents our best hope to bring the pandemic to an end and return to pre-pandemic activity and life. In this column, we will present updates for four of the more promising vaccine candidates: BNT162b1/BNT162b2 from Pfizer and BioNTech, mRNA-1273 from

Moderna, Ad26.COV2.S (also called JNJ-78436735) from Janssen, and AZD1222 from AstraZeneca and Oxford University.

In a recent news article in *Nature*, Gaebler and Nussenzweig highlighted the similarity between the vaccine development and the steps required for producing other novel drugs and biologics (*Nature* 2020;586:501-2). Initial preclinical studies evaluate candidate vaccines using *in vitro* methods such as molecular or cellular assays. Subsequent preclinical *Continued on page* 8



ASA Survey Results: Top Regulatory Concerns

Catlin Nalley

n July, the ASA Monitor conducted an email survey that polled readers on their top perceived challenges facing anesthesiology today. You shared your greatest concerns and offered some innovative solutions to those challenges.

This third installment of a four-part series dissecting the survey results focuses on payment and regulatory concerns.

Patient care and health care regulations go hand in hand, so anesthesiologists must stay abreast of the latest guidelines and regulations while also making their voices heard to advocate for themselves and their patients. Our readers' main regulatory concerns included payment, The Joint Commission guidelines, and changing/conflicting regulations.

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An Anti-Anxiety Initiative – The 'COVID Cart'

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he COVID-19 pandemic is a oncein-a-lifetime event that has greatly disrupted every aspect of our lives. When the volume of COVID-19 patients initially spiked in spring 2020 in the United States, many hospitals and clinics had to shut down elective surgeries and procedures. The reason for this shutdown was threefold: 1) insufficient information on the severity and infectivity of the virus; 2) lack of adequate screening and testing capability; and 3) the need to preserve personal protective equipment (PPE), which was in short supply due to disruptions in global supply chains secondary to overwhelming demand. As our knowledge of COVID-19 has increased and our understanding of risk mitigation

has grown, steps have been taken in order to help balance the medical needs of patients while simultaneously protecting anesthesiologists and other perioperative staff. The "COVID Cart" is a major step forward in the improvement and streamlining of the processes involving the medical care of COVID patients. Its effects on anxiety and satisfaction in health care practitioners cannot be overstated.

Meeting the challenges

Anesthesiologists face unique challenges when dealing with COVID-19 patients. We are involved in facilitating surgeries, perioperative and OR management, intubating patients, ICU coverage, sedation for Continued on page 18

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'COVID Cart'

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various procedures, and many more tasks that bring us in close contact with infected COVID-19 patients. As one physician in Chicago stated, "You're basically right next to the nuclear reactor [when intubating a patient]" (asamonitor.pub/2JVfzd3).

There was and continues to be a lot of anxiety surrounding COVID-19. The challenges are exacerbated by fear, misinformation, distrust of the government, politicization of prescribed interventions, and the need to constantly balance the perceived risk to oneself versus the demands of one's job. Other confounders include the evolution of our scientific knowledge pertaining to COVID-19, the ever-changing status of PPE supplies, and the constant revisions of protocols for taking care of COVID-afflicted patients. At the Medical University of South Carolina (MUSC), our leaders moved quickly to secure PPE and implemented protocols and staffing models that would allow for care of COVID-19 patients while maximizing the safety of staff.

Despite everyone's best efforts, anxiety and uncertainty about COVID-19 remained incredibly high. One of the greatest sources of apprehension for the staff stemmed from putting on and taking off, or the "donning and doffing," of PPE for COVID-19 cases. Another challenge was the procurement and storage of intraoperative supplies. In order to minimize potential contamination of reusable and unused anesthesia supplies, COVID-19exclusive ORs were stripped down to bare essentials, potentially complicating the availability of necessary equipment related to airway management, line placement, and other basic tasks.

To ease provider anxiety and allow for greater clarity of mind while caring for COVID-19 patients, department members developed the concept of the



Figure 1

L&D COVID Supply Kits (Package in Autoclave Bags)

GENERAL SUPPLY KITS

- 1 Handful 4x4 gauze
- 2 Blue luer lock caps
- 2 Tegaderms
- 1 Eye tape (clear)

INDUCTION KIT

4 - 3 cc syringes

2 - 5 cc syringes

1 - 10 cc syringe

1 - 20 cc syringe

8 -Blunt tip needles

- I Tube tape (pink)
- 2 Strips chlorhexidine pads

A-LINE KIT (A&B)

(TAPE BAGS TOGETHER)

- A: 1 ALINE KIT 2
- B: (Autoclave bag)
 - 1 Wrist roll
 - 1 20G Arrow catheter
 - 1 Guidewire

SMALL SYRINGE KIT

- 2 3 cc syringes
- 2 5 cc syringes
- 2 10 cc syringes
- 6 Blunt tip needles
- 1 Set of black tip caps



I.V. KIT

Fentanyl

Propofol

- 1 Sterile I.V. kit
- 1 Flush syringe
- 1 Each: 18G and 20G I.V. catheter

Stickers stuck on outside of bag:

Lidocaine

Rocuronium

1 – Baxter Ext for I.V. hookup

(TAPE BAG to 1L plasmalyte bag)

1 - Injection port

OB TUBING KIT

3-10 drip tubing set

1 - Handful 4x4 gauze

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- 5 EKG pads
- 1 BP cuff (regular)
- 1 pulse oximeter adult
- 1 emesis bag
- 2 Gel lubricant caps
- 2 Small squarer chlorapreps

OB AIRWAY BAG

- 1 6.5 ETT with 14 Fr stylet, 10 cc syringe
- 1 Yellow OPA
- 1 26 Fr nasal trumpet
- 1 MAC 3 blade
- 1 Adult handle
- 1 18 Fr OGT
- 1 Esophageal temp probe
- 1 Nasal cannula

Figure 2

"COVID Cart" (Figure 1). The idea behind this cart was to simplify and protocolize the procurement of PPE and intraoperative supplies. By reducing the stress associated with these major perioperative steps, providers would then be free to fully concentrate on taking the best care of patients. The cart is a simple and commonly used OR metal shelving device kept immediately outside of our COVID ORs. Laminated instruction cards visually and textually list the order to "don" or "doff" the PPE inside the cart in accordance with WHO and CDC best practices. The cart also contains premade "grab & go" bags for common procedural needs using readily available hospital autoclave bags (Figure 2). These bags contain medications used for standard inductions, emergency/code scenarios, and emergency airways. The overarching concept was to remove the stress and anxiety related to securing all of these supplies individually. If asked to take care of a COVID-19 patient, each provider could simply walk to the COVID Cart, put on PPE, take the necessary "grab & go" bags, and quickly be confident that they had all the essential tools required to take care of the coming patient.

After the COVID Cart was assembled, department leaders embarked on an educational campaign. Numerous emails, videos, information pamphlets, and in-person demonstrations were conducted in order to both inform and familiarize the staff with this resource. The results and feedback were overwhelmingly positive. A quality improvement survey was conducted in June 2020 to gauge this response and to potentially help direct further utilization of such designated carts.

Results and discussion

Altogether, 56 anesthesiologists out of our department of 84 were asked to anonymously fill out a short survey regarding their anxiety regarding COVID patient care and their subjective feelings of safety



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while at work. We had 100% compliance with the survey, which was conducted over the course of two weeks.

Safety is a subjective measure. We recognize that multiple factors play a role in an individual's sense of safety and that safety can be defined in many different ways. With that being said, department members collectively rated their safety at work on average as 7.08/10, and being informed about the latest COVID developments as 7.2/10. This bolstered the perception that MUSC leaders did a terrific job of keeping their employees informed and made extensive efforts to create a safe work environment, which is in contrast to the numerous publicized reports of workers calling out or resigning from their health care jobs due to a lack of communication or a perceived indifference by their employers as to personal safety and well-being.

Anxiety is defined as "a feeling of worry, nervousness, or unease, typically about an imminent event or something with an uncertain outcome" (asamonitor. pub/32z3AIx). It is a completely normal reaction that has evolved over time as the human psyche adapts to the ever-changing world. According to the Yerkes-Dodson Law there is an "inverted U-shaped" response curve when anxiety is transposed against performance (J Comp Neurol Psychol 1908;18:459-82). Retrospectively, a 43% reduction in anxiety was reported by staff in June 2020 compared with March 2020. While it is likely multifactorial, we hypothesize that the widespread

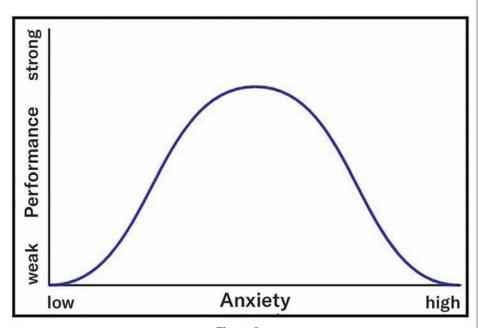


Figure 3

information and utilization of the COVID Cart contributed greatly to the reduction in anxiety. Removing the scramble and rush of being unprepared for surgical cases by utilizing the COVID Cart was thought to decrease the level of apprehension to a more manageable level and thus allow for the anesthesiologist's peak intraoperative performance, as predicted by the inverted U-shaped curve (Figure 3).

Thankfully, anesthesiologists are feeling subjectively safer and less anxious in regard to COVID-19 as time has passed. We must, however, remain vigilant in our practice as complacency and a false sense of security threaten to set in over time. We must continue to protect our patients, ourselves, and our coworkers as we lead the charge on perioperative safety. COVID-19 can surge at any given time, and the effects of a return to "normal" with increasing travel, return to non-essential work, and the opening of restaurants and entertainment venues remains to be seen. There is still the chance that you, a significant other, or patient become infected and have a devastating outcome as complications have been unpredictable and asymmetric, especially in the younger population. Until there is truly

herd immunity, an effective treatment, or a vaccine, the potential for infection or even reinfection remains a very real threat (Lancet Infect Dis October 2020).

COVID-19 has elicited significant anxiety among health care workers, but it has also highlighted the tremendous adaptability of anesthesiologists and perioperative staff. Tools such as the COVID Cart, with step-by-step instructions, labeled and available PPE, and "grab & go" bags have helped to reduce anxiety, increase efficiency, and kept the focus on high quality patient care with relentless personal safety. Anxiety regarding COVID-19 will likely never be completely eliminated, but these essential tools will help to temper those feelings and hopefully deter burnout and PTSD in high-risk physicians. Ultimately, instituting the COVID Cart at MUSC has benefitted quality improvement both anecdotally and by survey results with staff who feel safer, less anxious, and more empowered to provide excellent patient care with enhanced cost efficiency. We believe that a COVID Cart should be considered an essential as part of every center taking care of COVID-19-positive patients.

FAER and APSF Research Funding Opportunities

The Foundation for Anesthesia Education and Research (FAER) and Anesthesia Patient Safety Foundation (APSF) are accepting Letter of Intent submissions for the joint APSF and FAER Mentored Researching Training Grant from December 1, 2020, through January 1, 2021. FAER is accepting applications for Mentored Research Training Grants, Research in Education Grants, and Research Fellowship Grants from December 1, 2020, through February 15, 2021. For more information, visit www.asahq. org/faer/researchfunding.



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