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Improving clinician burnout factors during emergency care of COVID-19 through rapidly adaptive simulation and a randomized control trial

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IMPROVING CLINICIAN BURNOUT FACTORS DURING EMERGENCY CARE OF COVID-19 THROUGH RAPIDLY ADAPTIVE SIMULATION AND A RANDOMIZED CONTROL TRIAL

by

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ABSTRACT

Background

In March of 2020, the novel coronavirus 2019 (COVID-19) pandemic required healthcare systems to be rapidly responsive to adapt hospital guidelines for the most up-to-date care and safety protocols as knowledge of the disease rapidly evolved. Rates of COVID-19 infections continue to fluctuate, and non-COVID-19 patients have now returned to the emergency department for care. This increase in patient volume leads to new challenges and threats to patient and clinician safety as suspected COVID-19 patients need to be quickly detected and isolated amongst other patients with non-COVID-19 related illnesses. In addition, emergency physicians face continued personal safety concerns and increased work burden on the front lines, heightening stress and anxiety. Burnout is a serious concern for emergency physicians due to the cumulative pressures of their daily practice, even under non-pandemic circumstances. Given the prolonged course of the pandemic, burnout may likely present as a longer-term outcome of these acute stressors.

Methods

A rapidly adaptive simulation-based approach was implemented to understand and improve physician preparedness while decreasing physician stress and anxiety. A randomized control trial was conducted to test the effectiveness of a simulation preparedness intervention on physician physiologic stress as measured by decreased heart rate variability on shift and anxiety as measured by the State-Trait Anxiety Inventory.

Outcomes

Front-line EM physicians participated in a simulation-based educational intervention aimed to facilitate the adoption of protocols and treatment algorithms. Four virtual simulation scenarios highlighted the care pathways a practitioner might implement when managing a COVID-19 positive patient. A debriefing session followed each scenario to interactively analyze the learners' management decisions. The discussion focused on the most current hospital protocols so that any gaps in knowledge could be successfully addressed. The scenarios were iteratively updated, and the debriefing emphasis changed to deliver the newest clinical guidance and operational procedures as they evolved while continuing to highlight the aspects of care that remained challenging. Ongoing analysis of the physiological data is still being conducted.

Next-Steps:

Mixed model analysis of physiologic and self-report measures of stress and anxiety will be used to determine if this virtual simulation intervention improves

adherence to guidelines and protocols in the clinical setting and its impact on physicians while on shift. The next steps include further dissemination and objective feedback from institutions that may adopt this learning intervention.

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LIST OF ABBREVIATIONS

CRI:SIS.....COVID-19 Responsive Intervention: Systems Improvement Simulations

ECG.....Electrocardiogram

ED.....Emergency Department

EM.....Emergency Medicine

HRV.....Heart Rate Variability

PGY.....Post-Graduate Year

PPE.....Personal Protective Equipment

RIP.....Respiratory Inductance Plethysmography

RMSSD.....Root Mean Square Standard Deviation

S-Anxiety.....State Anxiety

SRC.....Saint Raphael Campus

STAI.....State-Trait Anxiety Inventory

T-Anxiety.....Trait Anxiety

YCMS.....Yale Center for Medical Simulation

YNHH.....Yale-New Haven Hospital

INTRODUCTION

In March of 2020, emergency departments began seeing surging volumes of patients due to the novel coronavirus disease 2019 (COVID-19). At that time, patients were treated within the existing framework of respiratory illness that had been trusted and commonly applied by both emergency physicians and intensivists for decades. However, as the number of cases exponentially increased (Figure 1), it became apparent that this novel disease required a wholly different approach.

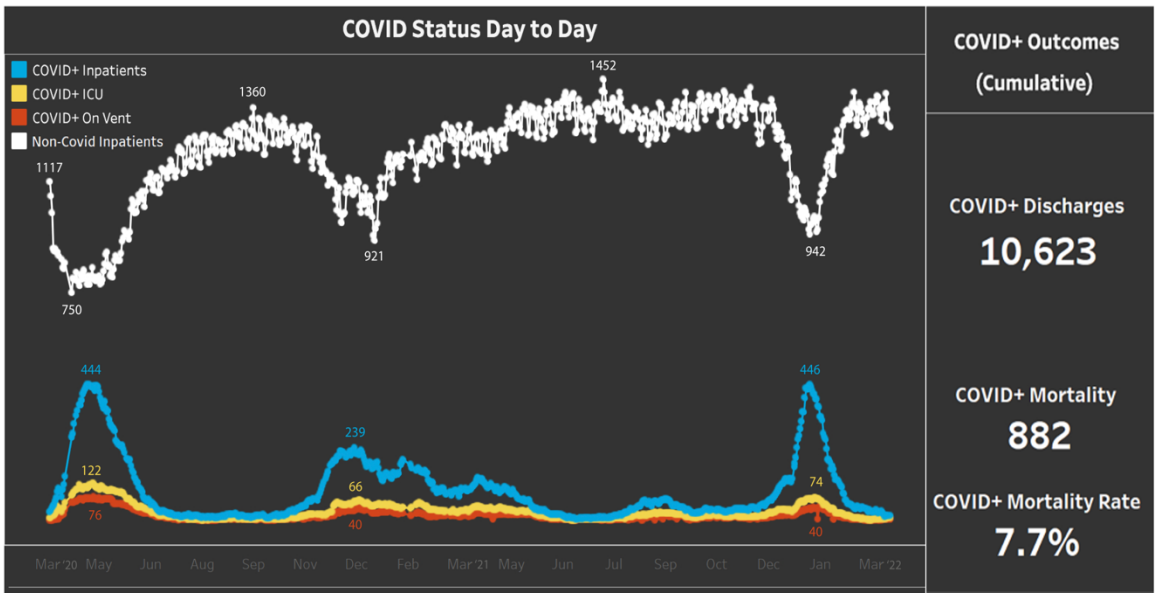

Figure 1. Census of COVID-19 positive patients at Yale-New Haven Hospital from March 2020 through March 2022. Data points and plots are adapted from Yale New Haven Health's System Incident Management Dashboard.[1]

In an effort to minimize both short and long-term risks to clinicians and patients, hospital administrators developed protocols to standardize system components. Guidelines on how to triage these patients, where to place them within the department,

withdrawal of care when appropriate, team structure, communication modalities, prevention and mitigation of in-hospital viral transmission, and personal protection were rapidly implemented and rapidly evolving. The medical management of the patients continued to change as more data were gathered and outcomes were observed in other countries such as China and Italy.[2,3] As the availability of supplies, medications, and workforce resources frequently fluctuated throughout this crisis, there was a clear need for the rapid adoption of these new changes to clinical care in order to ensure both provider and patient safety.[4] The adoption of new clinical guidelines into practice is already challenging, and clinicians additionally needed to adhere to barrier precautions and system processes meant to prevent transmission and intra-hospital spread.[5,6]

Daily changes and weekly updates from both the Yale-New Haven Hospital and emergency department (ED) administrations provided ongoing guidance on the evolving COVID-19 protocols. Directed at the entire hospital staff, they were distributed through passive and unidirectional communication pathways, such as email. These notifications not only included guideline additions but often changed previously announced protocols. This dissemination approach of the evolving guidelines was high volume and confusing, further contributing to the difficulty of implementation at the bedside.

The novelty of the disease with the wide variety of COVID-19 patient presentations and barrage of constantly evolving clinical knowledge exacerbated system challenges and physician stressors throughout the COVID-19 pandemic.[5,6] This highlighted the need for a structured implementation plan to mitigate the impact of uncertainty on physician stress in rapidly changing operations and guidelines.

Clinician Burnout

The syndrome of burnout is a serious concern for emergency physicians. The high prevalence of burnout in emergency physicians, due to the cumulative stresses of their daily practice, is associated with adverse psychosocial and health outcomes.[7] A survey of emergency physicians, published in 2015, demonstrated a prevalence of burnout as high as 61% nationally.[8] These high rates of burnout were further linked with depression, decreased career satisfaction, and suboptimal care. The consequences of provider burnout to the healthcare system include decreased staff attrition and downstream effects on patient safety such as increased medical errors, extended patient waiting times, decreased quality of patient care, and a decrease in patient satisfaction.[9-11]

With the onset of COVID-19 pandemic, burnout may precipitate as a longer-term outcome of the acute stressors accompanying the care of COVID-19 patients.[12] On the front lines, emergency physicians face enormous pressure from continued personal safety concerns such as the risk of infection, increased work burden, and general uncertainty–all are known factors that heighten stress and anxiety.[5, 6, 13-18] Preliminary work has highlighted potentially deleterious effects of the pandemic response on the already strained mental health of frontline healthcare workers, especially those working in the ED.[19] Early reports from the COVID-19 outbreak in China indicated that over 71% of healthcare workers surveyed reported symptoms of distress, while nearly 45% reported acute anxiety and depression.[17]

The headline news of the unfortunate death of Dr. Lorna Breen brought the issue of provider burnout into the national spotlight. Dr. Breen, the former ED medical director of New York-Presbyterian Allen Hospital, committed suicide after succumbing to the adverse psychological effects of combating COVID-19 during the height of the first wave of the pandemic. If not addressed, EM physician burnout will continue–making it critical that the factors leading to burnout are addressed, and the mental health of frontline workers is supported.

As governmental mandates on travel restrictions and social distancing relaxed, experts warned of a "second wave" of infections.[20, 21] The resulting wave, catalyzed by the Delta-variant, presented an extended response curve and fluctuating operational demands for COVID-19 care, especially as hospitals resumed elective procedures and non-COVID-19 operations. New threats to patient and clinician safety emerged within the emergency department, where suspected COVID-19 patients needed to be quickly detected and isolated amongst other patients returning with non-COVID-19 related illnesses.[22] However, with limited hospital boarding capacities, and a resurgence in COVID-19 positive cases, patients were no longer being isolated and frequently placed in beds located in the hallways of the ED. This imposed a new and significant risk of infection for both patients and providers in the ED.

Additional waves of infections are anticipated in the future as vaccination efforts are yet to be completed and new variants may continue to emerge.[21] An extended pandemic response will perpetuate heightened levels of healthcare worker stress and anxiety, ultimately leading to adverse effects on patient safety and care. Challenges and

inconsistencies in adopting the changing guidelines have made healthcare workers feel unequipped to keep up to date with medication availability, care delivery, and team coordination.[5] Therefore, to protect the healthcare workforce during the peak surges and potential high-stress surges in the future, there was an urgent need to develop a comprehensive support system to prepare frontline workers in developing both clinical and emotional resilience.[23]

Burnout Physiology

Burnout develops from repeated exposure to acute stress and manifests in changes to physiologic measures. Evidence also suggests a link between physiologic measures of stress and emotional exhaustion subscales of burnout.[24] Burnout has been characterized by stress-related dysregulation of the sympathetic and parasympathetic nervous system.[25] During acute stress events, healthcare workers may experience the activation of the sympathetic nervous system, commonly known as the fight-or-flight response, resulting in fundamental physiological changes.[26] Established physiologic markers of an acute stress response include a decrease in heart rate variability (HRV)–the measure of the interval variations between each heartbeat caused by fluctuations in cardiac sympathetic and parasympathetic activity.[25, 28] Modulation of sympathetic activity tends to increase heart rate and thus reduces the amount of time beat-to-beat (lower HRV), while modulation of parasympathetic activity decreases heart rate, allowing for variability between beats (higher HRV).

Low HRV, and accordingly high sympathetic activity, has been observed in individuals presenting with burnout resulting from repeated or continuous stress exposure.[28] For healthcare workers presenting with clinical burnout, measures of HRV have been shown to be lower than both workers with non-clinical burnout and healthy individuals with no burnout symptomology.[28] These low levels of HRV suggest sympathetic predominance (and therefore low parasympathetic activity–responsible for governing anabolic and recovery activities), which may contribute to the adverse health effects associated with clinical burnout such as the increased risk for cardiovascular disease.[24, 25, 28]

Medical Simulation

Immersive simulation technology is well-positioned to mitigate negative effects of healthcare worker stress and overcome challenges to system responsiveness arising from COVID-19, such as providing support for implementing rapid protocol changes. Simulation is a burgeoning technical field pioneered by the military that applies experiential techniques for the purposes of practice, learning, evaluation, testing, and insight into systems and human actions.[29] Simulation has been shown to address complex operational challenges, individual and team performance improvement, and adaptive systems development to detect and prevent fatal errors and system failures.[30]

In the healthcare sector, medical simulation provides the opportunity for standardized practice for high-stakes events,[17] and is currently used for educating, training, and assessing expertise[31] through the re-creation of clinical environments by

utilizing a wide array of technologies ranging from high-fidelity mannequins to virtual reality.[31]

Simulation techniques can be leveraged to test new protocols and patient pathways and improve the execution of complex medical procedures.[33, 34] Simulation has already shown significant benefits in decreasing occupational strain and enhancing healthcare workers' adaptive coping mechanisms during high-risk patient care situations.[35, 36]

There is precedent for using simulation training to educate and inform clinical practice during previous novel health crises such as the 2009 SARS and 2013 Ebola epidemics.[37] Moreover, prior work has demonstrated that health workers participating in simulations of high-risk clinical situations can provide feedback that improves protocol implementation and identifies latent safety threats.[38, 39]

As knowledge of the COVID-19 virus is accumulated, and recommendations evolve over the course of the current pandemic, simulation can engage clinicians in the iterative testing and re-deployment of new clinical strategies, equipment, system processes, and workflows.[40] Developing competency in these new procedures will support protocol adoption and improve worker stress, anxiety, and burnout outcomes.[19] These benefits will be crucial to help establish healthcare worker resilience through increased competence and preparedness as the COVID-19 pandemic stretches on.[41]

Aims and Objectives

The rapidly changing hospital policies and protocols and the intense and challenging work of caring for an influx of severely ill patients created new stressors on hospital personnel. Uncertainty surrounding the availability of protective equipment and the risk for infection further exacerbated the stressful clinical environment resulting in higher levels of physician burnout.[41] Therefore, there is a critical need to learn how best to mitigate healthcare worker stress and facilitate system responsiveness in future phases of the pandemic.

This project aimed to assess the impact of simulation-based preparedness and training on physiologic stress and anxiety in emergency department physicians during the care of COVID-19 patients through a multi-site, prospective randomized clinical trial. Changes in heart rate variability (HRV) as physiologic measure of stress and State-Trait Anxiety Inventory (STAI) as a measure of physician post-shift anxiety were both used to evaluate the efficacy of simulation intervention. This project implemented the innovative COVID-19 Responsive Intervention: Systems Improvement Simulations (CRI:SIS), a novel simulation-based training and quality improvement intervention developed by the faculty of Yale Center for Medical Simulation (YCMS). In the age of COVID-19, public lockdown and social distancing measures to combat viral transmission have altered operations in many training centers. In response to these operational challenges, CRI:SIS was developed to be an adaptive simulation program that allows for transition along a continuum from in-person simulation to fully remote virtual tele-simulation complying with social restriction guidelines. CRI:SIS is unique in utilizing a rapid cycle

implementation and evaluation design in a novel virtual tele-simulation intervention format. The simulation scenarios focus on mitigating physician anxiety and stress, improving frontline provider preparedness, and accelerating the adoption of quality improvement initiatives promoting safety culture.

The rapidly evolving knowledge regarding COVID-19 places pressure on healthcare administrators to disseminate guidelines reflecting the most up-to-date information to their frontline providers. The rapidity of the changes in guidelines may have unintended consequences when implemented at the bedside and lead to confusion and variable adoption due to shifting expectations and procedures. Educating clinicians in preparedness will result in improved patient and clinician safety during COVID-19.

METHODS

A two-arm prospective randomized control trial was conducted across two clinical sites. The primary outcome was to measure the changes in HRV as a physiologic measure of stress during the clinical care of COVID-19 patients over the course of a standard shift in the ED, and a secondary outcome of measuring physician State-Trait anxiety post-shift with the STAI survey. The intervention was comprised of a packaged set of immersive simulations that were previously developed based on qualitative data from staff participants and guidance issued by the departmental COVID-19 ED Task Force. These scenarios were delivered as just-in-time simulations to prepare emergency physicians working subsequent clinical shifts with the intended outcome of lowering their anxiety and stress levels when caring for acutely ill COVID-19 patients.

Campus Sites

The two Yale-New Haven Hospital campuses utilized in this study are geographically and structurally unique academic ED sites: (1) the York Street Campus is the tertiary care referral center with four resuscitation bays, 56 beds, and average adult volumes of 100,000 visits per year; and (2) the St. Raphael Campus, is an urban community hospital with two resuscitation bays, 35 beds, and approximately 65,000 visits per year.

Recruitment

Eligible participants were enrolled across a ten-month period starting in January 2021. The target participant demographic were frontline EM physicians–residents, fellows, and attending physicians working full-time and actively treating acutely ill COVID-19 (and suspected COVID-19) in the emergency departments at either Yale-New Haven Hospital York Street or Saint Raphael Campuses. Participants worked an average of 45-50 hours per week (4-5 shifts per week) for resident physicians and 26 hours per week (3-4 shifts per week) for attending physicians. Physicians working within a capturable window and who did not fall within the exclusion criteria were recruited via email one to three weeks prior to their participation. Exclusion criteria included the use of beta-blockers and antiarrhythmic medication, active thyroid dysfunction, and pregnancy.

Recruited physicians were grouped by experience levels. Resident physicians with less than four post-graduate years (PGY) of ED experience (PGY 1-3) were designated to the junior group. Senior resident physicians, fellows, and attending physicians with more than four years of experience (PGY 4 and above) were designated to the senior group.

Incentives

All participants were compensated with a $25 gift card per shift, for a total of $100. Incentives were received upon the completion of their participation in the study. Additionally, all eligible participants received three hours of didactic credit for their participation in the training intervention.

Consent Process

All recruited physicians were given the opportunity to ask questions regarding the details of the study before either agreeing or declining to participate. They returned signed physical copies of consent forms that outlined the study's objectives, the safety risks of participating, and the requirements of the participants before beginning their participation.

Hexoskin

In order to collect physiologic data from the participants, Hexoskin Smart Shirts from Carre Technologies Inc (Hexoskin) were used. Hexoskin's "smart garments" have embedded textile sensors that allow for moment-by-moment cardiac and respiratory monitoring via continuous 1-lead electrocardiograph reporting and chest and abdominal respiratory inductance plethysmography (RIP) sensors (Figure 2). As a portable and non-invasive technology, Hexoskin Smart Shirts allow for the seamless capture of physiological measures of the wearer while on shift. Moment-by-moment heart rate recordings, captured via electrocardiogram (ECG), were necessary to calculate heart rate variability changes as measures of participant stress and anxiety levels during the care of patients with COVID-19 and suspected COVID-19.

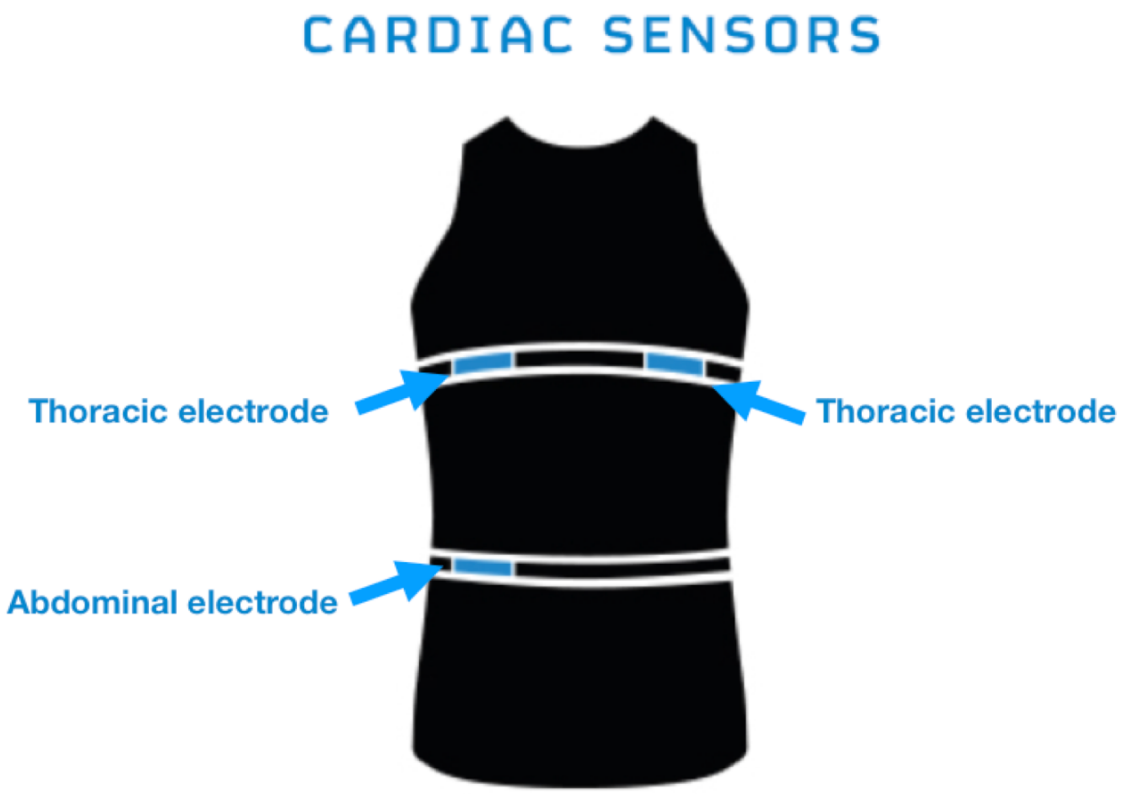

Figure 2. Location of cardiac sensors on the Hexoskin Smart Shirt.

The cardiac sensors (Figure 2) must be in direct contact with the participants' skin to get a clean reading. A water-soluble lubricant was applied to the sensors in order to enhance conductivity with the participants' skin.

The Hexoskin shirts have different designs and fit men and women (Figure 3), and each participant was correctly fitted with appropriately sized Hexoskin Smart Shirts before the baseline session. The Hexoskin shirts were worn underneath the participants' standard scrubs and needed to remain in place for the duration of their eight to ten-hour shift. Movement of the shirt may both interfere with the ECG reading and cause

discomfort to the participant. Every participant received a new Hexoskin shirt between the second and third data collection.

Figure 3. Hexoskin Smart Shirt. Men's Hexoskin Smart Shirt (A). Women's Hexoskin Smart Shirt (B).

Baseline Session

The purpose of the baseline session was two-fold. The first was to establish baseline physiologic measures at rest. Participants were asked to sit quietly for 10-minutes wearing the Hexoskin in order to record each individual's baseline heart rate and HRV at rest. The second was to administer the STAI survey. Following the capture of these baseline data, participants completed the 40-item STAI survey–a self-evaluation questionnaire that measured state-anxiety and trait-anxiety at the time of assessment. In

addition, a demographic survey was administered concurrently to provide basic characteristic information and confirm the participants' exclusion criteria statuses.

Data Collection

Each participant wore the Hexoskin smart shirt for data collection across four shifts in the ED. The participant was asked to arrive at their shift wearing the Hexoskin shirt underneath their standard scrub shirt. On the dates of data collection, a research team member was present shortly before the start of each participant's ED shift to confirm data capture and log shift start time on the recording. The team member would sync the Hexoskin Smart Device (Figure 4) to an iPad to begin recording the physiologic measures and visualize the ECG in real-time.

Figure 4. Hexoskin Smart Device. Hexoskin Smart Devices connect to the Hexoskin Smart Shirts and store the recorded physiologic data. The Hexoskin Smart Device can be paired via Bluetooth to visualize the data in real-time.

If there was a consistently readable ECG, the participant would be ready to begin their shift as usual. If there was not a readable ECG, the Hexoskin would need to be adjusted, and additional water-soluble lubricant would be applied to enhance conductivity. The Hexoskin shirt was worn for the entirety of an eight-to-ten-hour shift in the emergency department. Participants were asked to continue HRV data recording for 20 minutes following the end of the data collection shift to assess for return to baseline HRV before disconnecting the Hexoskin Smart Device. Following end-of-shift sign-out, a research

team member would note the end of shift time, administer a 20-item state subscale of the STAI, and conduct a written debriefing with the participant to capture qualitative data on perceived stressors experienced during the shift. This information was captured before the participant left the hospital while their recollection of events was fresh in their mind.

Randomization

Following the completion of the first two data collection shifts, participants were prospectively randomized to either the control or intervention arm of the study before scheduling the remaining two data collection sessions. Participants were divided into two groups based on experience level, junior (PGY 1-3) and senior (PGY 4 and above). Prior to the start of the clinical trial, numbered envelopes with random intervention and control designations were prepared by a statistician and evenly divided between the junior and senior groups. After the completion of two shifts, a corresponding envelope was opened by a research team member designating the participant to either the control or intervention arm. Participants were then notified of their grouping. Participants randomized into the intervention arm of the study were scheduled to participate in the training simulation. Participants randomized to the control arm proceeded to collect a third and fourth shift. Control participants completed four shift data collections with no additional intervention. These participants still had access to the regularly distributed COVID-19 Task Force updates, guidelines, weekly town hall meetings, and any in-service support that were available to all clinical staff as per standard operational practice in the ED department. Once participation was complete, all participants randomized to

the control arm were offered the opportunity to complete the simulation intervention for its educational benefit.

COVID-19 Responsive Intervention: Systems Improvement Simulations (CRI:SIS)

Participants randomized into the intervention arm of the study were notified of their designation and scheduled to conduct the virtual intervention with a YCMS instructor. Each participant completed the session one to five days prior to their next recorded clinical shift. The participants randomized to the intervention arm received CRI:SIS as a three-hour simulation session consisting of a prebrief and four scenarios followed by debriefing after each scenario. For each intervention, a senior and junior participant were paired. However, some senior physicians (PGY-4, fellows, and attendings) completed the intervention without a junior physician (PGY 1-3) present due to scheduling. An EM instructor served as the attending physician during simulation for any junior physician who was not matched with a senior physician.

Pandemic Adaptation

At the onset of the pandemic, the YCMS program was rapidly transferred to an online format to adhere to guidelines regulating close personal contact.[43] The virtual format allowed for continued reach to learners while maintaining social distancing requirements. Leveraging this format, the team designed a new comprehensive simulation experience to better instruct the learner in the intricacies of the rapidly evolving COVID-

19 protocols. This simulation structure had the distinct advantage of being adaptable as new protocols emerged.

Intervention Setup

Intervention simulations were conducted and recorded via Zoom. Patient vital signs were programmed using Laerdal LLEAP simulation software and displayed to the participants through a simulated patient monitor (Figure 5). Participants were encouraged to access and utilize the Epic care pathways on their electronic devices during the simulations.

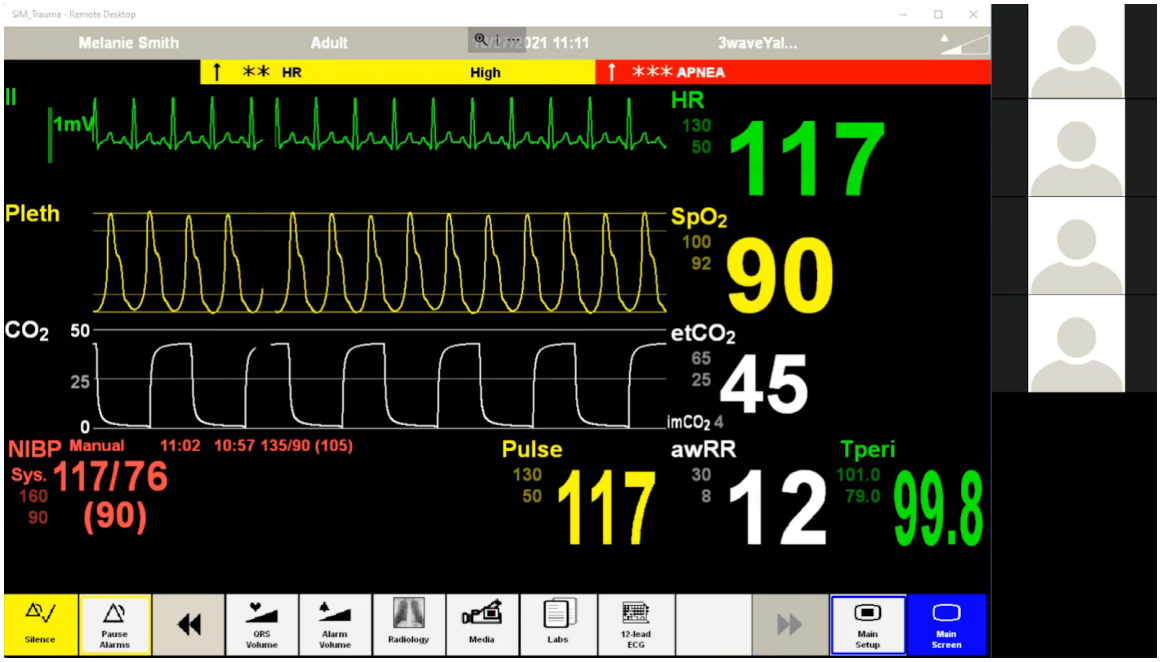

Figure 5. Screen share of virtual tele-simulation technology used in CRI:SIS. Simulated patient monitor programmed using Laderal LLEAP.

Scenario Design

CRI:SIS was created by board-certified emergency medicine simulation faculty and reviewed by the hospital's ED COVID-19 Task Force to ensure adherence to the most current guidelines. The scenarios were first piloted on EM faculty, and each scenario was individually refined through a modified Delphi process through multiple rounds of distillation.

Simulation Intervention.

Participants randomized to the intervention arm received CRI:SIS as a three-hour simulation session. The four intervention scenarios consisted of a series of COVID-19 related presentations with varying severity of illness that required the learner to triage the patient, decide on disposition, and provide appropriate treatment depending on the acuity level for each case. Specific critical actions were designed to have the emergency physician utilize the care pathways a practitioner might implement when managing a COVID-19 positive patient. Each scenario was followed by a debriefing session to interactively analyze the learners' management decisions so that they may reflect on actions and omissions. This discussion focused on the most current hospital protocols so that any gaps in knowledge could be successfully addressed.

Recommended critical actions for each scenario were updated at least biweekly or more frequently (as needed) when new recommendations to COVID-19 protocols occurred. In addition, patient presentations were continually modified to highlight potential pitfalls or challenges that commonly arose as the pandemic evolved. The

scenarios included in this session focused on four critical areas of COVID-19 patient care:

1) Airway management procedures in patients with COVID-19 increase the risk of viral transmission to personnel and rapid respiratory deterioration in infected patients.[14, 15]

2) New presenting symptoms and associated complications of COVID-19 (e.g., hypercoagulability, cardiovascular morbidity) makes accurate diagnosis and treatment of patients with suspected infection difficult.[7, 10, 16]

3) Caring for patients presenting with severe illness and poor prognosis adds emotional and cognitive strain to physicians as they initiate palliative care, discuss goals of care, or withdraw care in the ED.

4) Evaluating discharge criteria for COVID-19 positive patients.

Each scenario also addressed changes to normal ED team dynamics during COVID-19 care from social distancing and personal protective equipment (PPE) requirements (e.g., only allowing one staff member in the room at a time) through interactions with nursing and ancillary staff confederates during each scenario. The most up-to-date scenarios are described in detail in Appendix A.

Data Analyses

The descriptive statistics for the demographics of the physician population in both the intervention and control groups were derived from the self-reported survey collected

during the baseline session. The categorical data was reported as frequencies (percentages) and compared differences between the two groups using $\chi 2$. Continuous data was reported as the mean and standard deviation, and the differences between the intervention and control groups were tested using the two-sample t-test. A *p*-value of <0.05 was considered as significant.

The primary outcome of interest compared the change in HRV from baseline to the HRV during the treatment of acutely ill patients, as a measure of cumulative shift stress. HRV was assessed as the time-domain measure of root mean square standard deviation (RMSSD) of sequential R-R intervals. RMSSD is considered a measure of vagally mediated change and is more resistant to respiratory artifacts than other HRV measures (Figure 6).[44] HRV was analyzed using 5-minute periods. These HRV periods were captured at baseline, immediately following on-coming shift sign-out, on-shift medical patient responses, ahead of the end-of-shift sign-out, and post-shift. The primary outcome of interest was measured as the change from baseline to these 5-minute periods as a measure of cumulative shift stress. Additional analyses examined acute stress as changes in HRV at the presentation of acutely ill medical patients during the shift. Timing for the treatment of individual patients was captured by aligning Hexoskin timestamps with electronic timestamps from electronic health record review will allow for identification of COVID-19 positive and suspected COVID-19 medical patients. An increase in stress was indicated by a decrease in HRV from baseline. Changes in HRV were averaged over the two shift data collections to control for an anticipated shift-to-

shift and patient-to-patient variability in stress response due to patient acuity and workload.

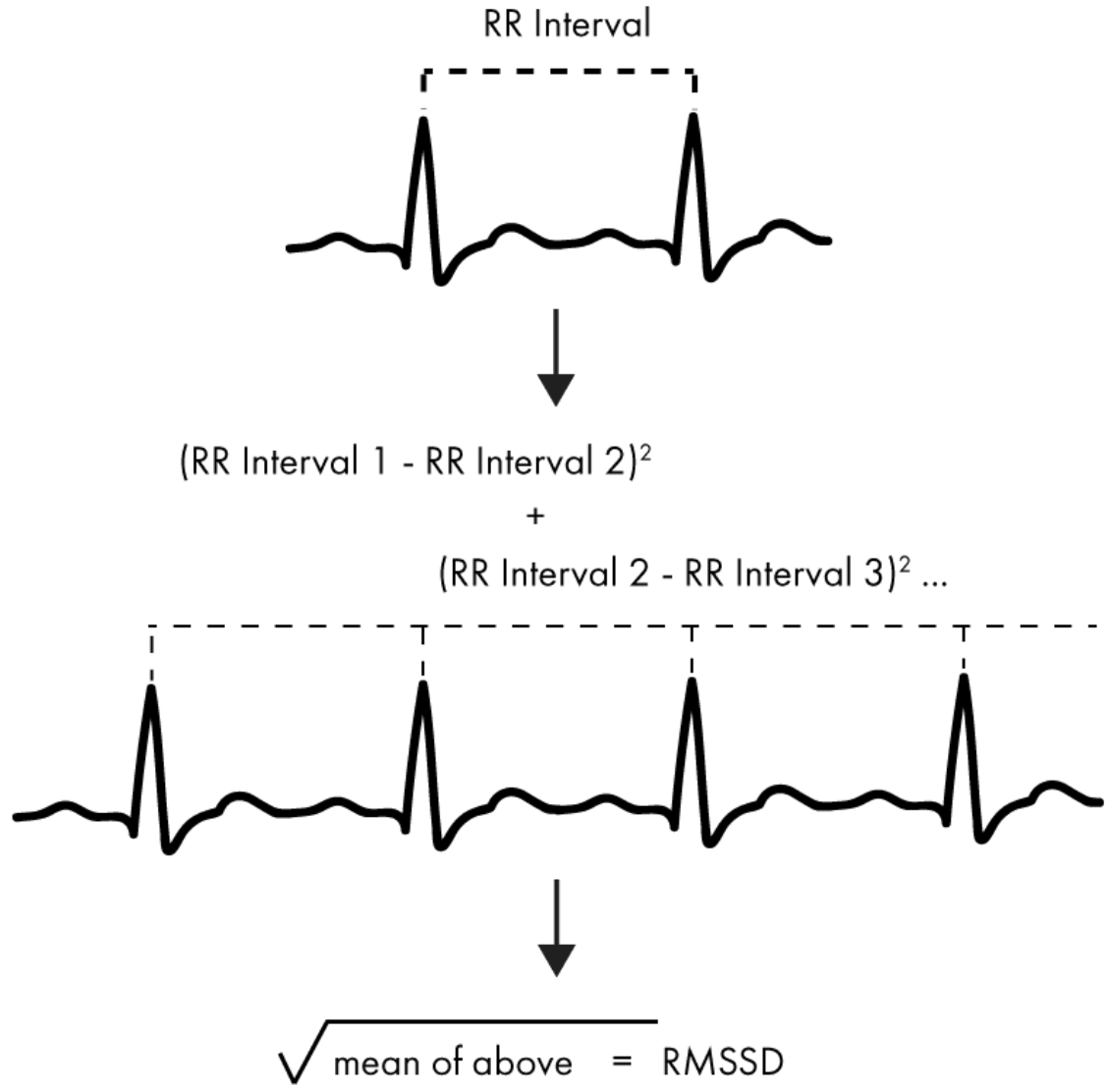

Figure 6. Root mean square standard seviation (RMSSD) for heart rate variability (HRV) calculation.

The secondary outcome of interest is the change in anxiety between the intervention and control conditions as measured by the STAI. The change in both the primary outcome of HRV and outcomes of STAI was assessed using repeated measures

mixed models. Baseline outcomes were included as a covariate. A random effect was included for the subject variable to accommodate for repeated measures. The least-squares means was used to describe HRV and other outcomes under each intervention. Changes in HRV were averaged over the two post-intervention shift data collections to control for an anticipated shift-to-shift and patient-to-patient variability in stress response due to patient acuity and workload. Linear contrasts with 95% confidence intervals were used to compare the outcomes between different interventions.

Note: Unfortunately, at the time of writing, only the demographic and STAI data have been reviewed and analyzed. The HRV data is currently being cleaned and pending further analysis as outlined above. Once the analysis of the HRV data is complete, mixed model can be used to determine the association between the completion of the intervention and changes in physician stress and anxiety measures.

Sample Size

Given an SD of 15ms in HRV,[44] and an estimated STAI score difference of 5.8 (SD=8), a sample size of 38 participants per group will provide 80% power at the two-sided 0.05 significance level to detect differences of 10.8ms, an effect reflecting clinically meaningful changes to stress in prior HRV studies.[28] This sample size was a conservative estimate with expected improvements in power (or detectable effect size) given the repeated post-randomization assessments. Nevertheless, the target enrollment of 42 participants per group and a minimum of 33 participants per group was set to accommodate a potential 10% loss to follow-up.

Data Processing

Post-processing of the HRV data was completed with Kubios HRV Premium software to validate the signal quality and mark ECG R-waves for analysis. Additionally, during the post-processing of the data five-minute readings during the treatment of each acutely ill medical patient will be captured based on time logs of medical patient alerts and electronic medical records (Figure 7). These select regions of interest from the processed data represent acute stress during the shift and will be used for the RMSSD of sequential R-R intervals and subsequent mixed model analysis.

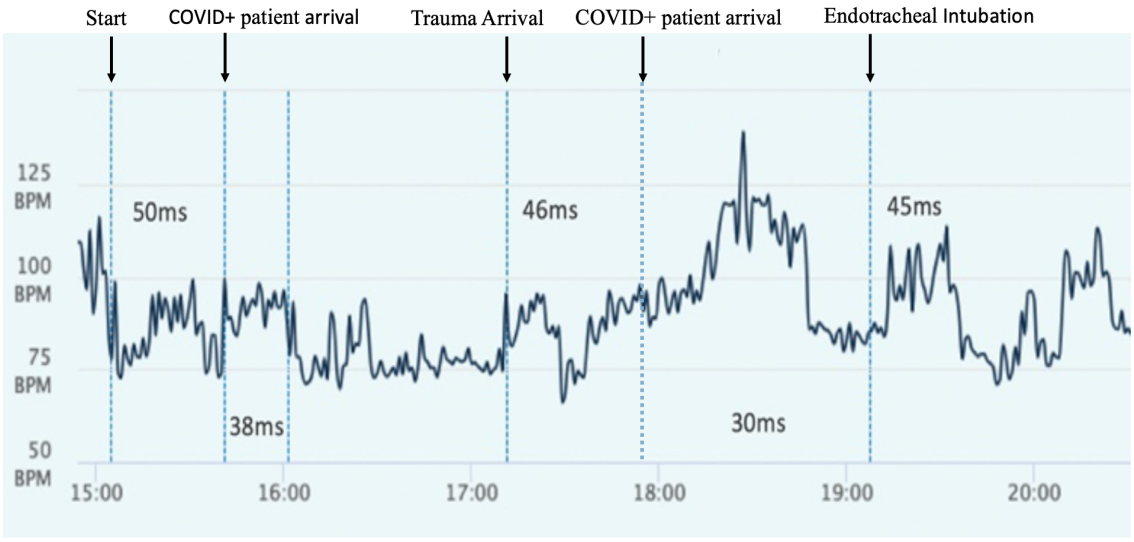

Figure 7. Physician heart rate and event-related heart rate variability (HRV) while working a standard emergency department shift during the COVID-19 pandemic.

RESULTS

Two primary factors are used to assess the impact of CRI:SIS as a simulation-based preparedness intervention for the clinical stressors physicians will likely encounter caring for COVID-19 patients in the ED. Physician stress levels, evaluated by the changes to heart rate variability (HRV) on shift, will measure the acute stress while caring for COVID-19. The STAI will measure participants' post-shift anxiety.

Recruitment Outcomes

A total of 81 participants were enrolled in the clinical trial; 41 were randomized to the control arm, and 40 were randomized to the Intervention arm of the study (Table 1). There was an equal distribution of seniors (21 control, 20 intervention) and juniors (20 control, 20 intervention) between the two arms of the study in order to control for the variation in clinical experience of the emergency physicians. Every enrolled participant passed all exclusion criteria evaluations, completed the baseline physiologic captures, completed the 40-item STAI survey during the baseline session, and completed four data collections wearing the Hexoskin throughout a standard shift in the ED. However, two participants were later excluded from analysis after failing to complete two or more post-shift STAI questionnaires.

Table 1. Demographic information of participating EM physicians.* Recorded via a self-reported questionnaire at the time of the baseline session. (N=81).

Characteristic: Measure	Control Group (N=41)	Intervention Group (N=40)	*P* value
Age in Years: Mean (standard deviation [SD])	34 (9)	37 (11)	0.22
Biological Identification: Female No. (%) of participants	19 (46)	26 (65)	0.09
Years of EM experience at time of enrollment: Mean (standard deviation [SD])	5 (7)	7 (9)	0.50
Years of EM experience at time of enrollment: No. (%) of participants			0.80
0-1	8 (20)	10 (25)	
2-3	12 (29)	9 (23)	
4-5	11 (27)	9 (23)	
6-10	2 (5)	1 (3)	
10+	8 (20)	11 (28)	
Caffeine (mg): Mean (standard deviation [SD])	191 (122)	186 (123)	0.84
Caffeine (mg): No. (%) of participants			0.25
The average cup of 8 oz Coffee contains 96 mg of caffeine.			
0	3 (7)	1 (3)	
1-192	23 (56)	28 (70)	
193-384	12 (29)	9 (23)	
385-576	3 (7)	2 (5)	
Exercise (minutes per week): Mean (standard deviation [SD])	127 (119)	128 (121)	0.95
Exercise (minutes per week): No. (%) of participants			0.32
<60	11 (26)	17 (41)	
60-120	15 (36)	8 (20)	
121-240	9 (21)	10 (24)	
240+	7 (17)	6 (15)	
Ethnicity: No. (%) of participants			0.25
Caucasian/White, non-Hispanic	23 (56)	26 (65)	
Black or African American	3 (7)	4 (10)	
Asian/Pacific Islander	10 (24)	4 (10)	
Hispanic	2 (5)	0	
Multiple ethnicity/other	1 (2)	4 (10)	
Prefer not to say	2 (5)	2 (5)	

* Some percentages in this table may not equal 100% due to rounding

Intervention Outcome

As shown in Figure 8, the rate of guideline changes followed a pattern mirroring the surges of COVID-19 infections and hospitalizations in the local region. Across the first four months of the pandemic response, daily emails were distributed to staff with reminders, guideline changes, and updates. The predominant themes of communication in

these early months included changes in patient care guidelines and PPE (Figure 8 & 9). Through the four separate simulations in the intervention, participants were able to apply and understand these changes through two principal mechanisms: Direct change to the scenario itself and the interactive debriefing after the conclusion of each simulation. Learning objectives for the scenarios largely centered around the proper use of PPE and changing patient care processes to align with protocol changes.

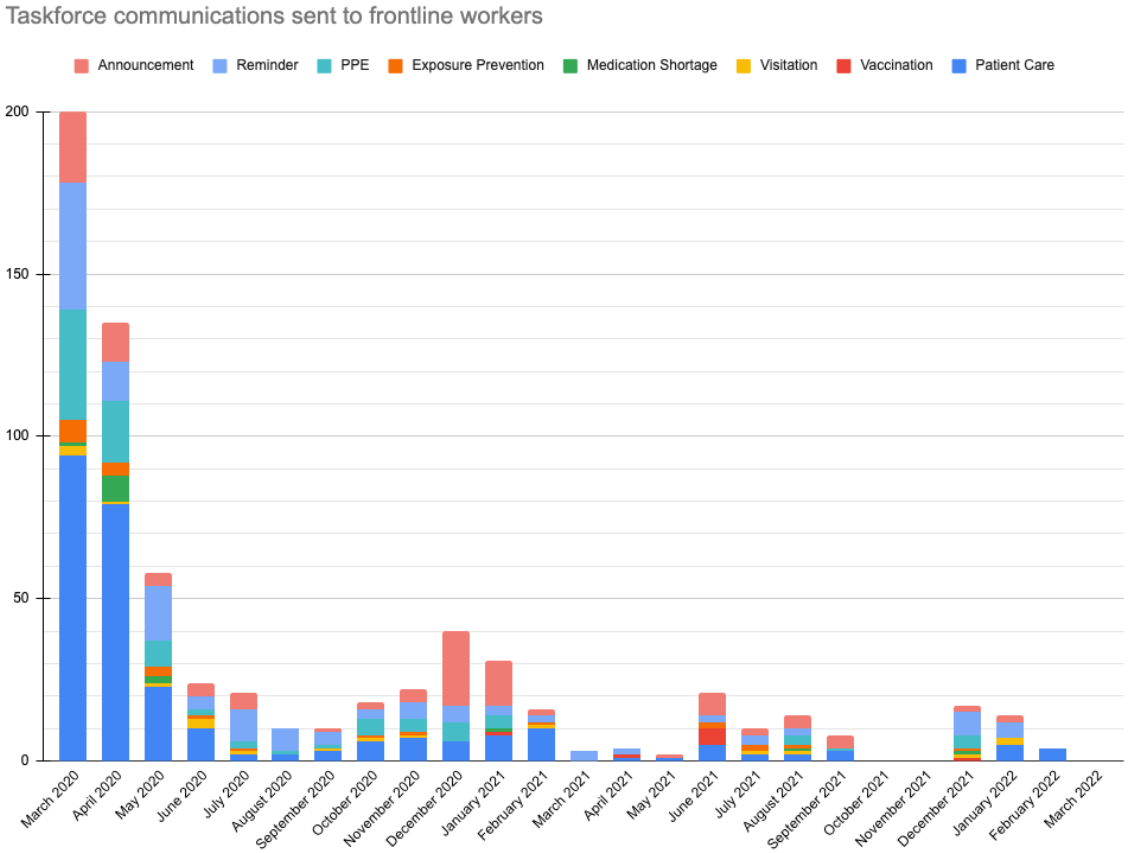

Figure 8. Taskforce communications sent to frontline workers. Number and types of clinical guideline changes, announcements, and updates sent by month between March 2020 and March 2022. Total updates sent via email to emergency department staff (N=1163).

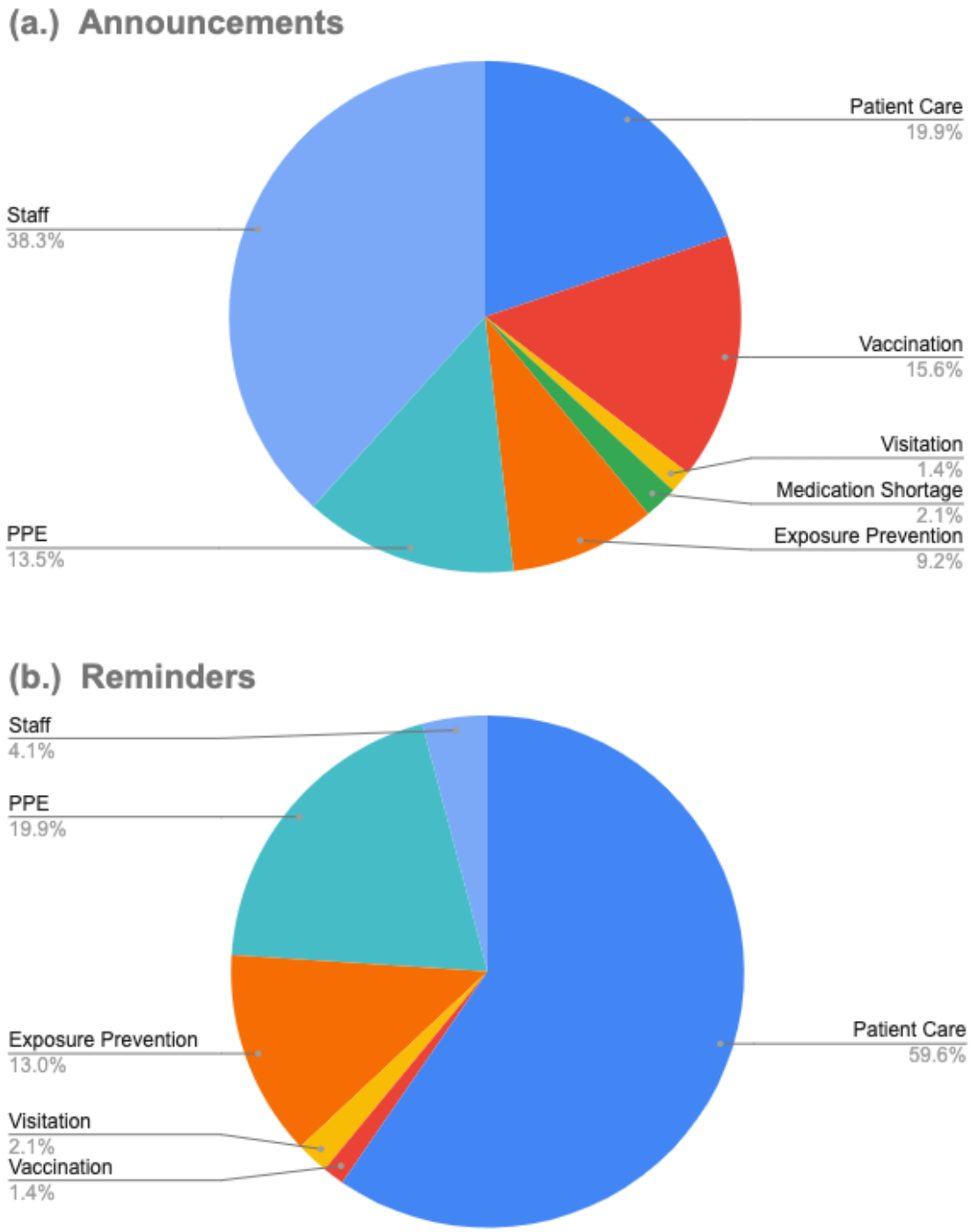

Figure 9. Categorical distribution of (a.) announcements and (b.) reminders sent by the YNHH administrative task force. Total announcements (N=141) and total reminders (N=146).

Resource limitations were emphasized in the early stages of scenario development, including medication shortages. The simulationist emphasized these points during the simulation and addressed them specifically in the debriefings. For example, if the learner noted they would don PPE prior to entering the patient's room, the instructor would ask them to explicitly state what materials they were donning and how they were doing so. Likewise, if the learner ordered a medication that was in shortage or unavailable, the instructor would inform them that they needed to specify the order for an alternative. During the debriefing, these points of emphasis and change in hospital protocols were highlighted so the learner understood their applicability.

As resources stabilized and scientific knowledge rapidly progressed, clinical guidelines for patient care shifted to incorporate new medication and treatment protocols. With this shift, the learning objectives were adapted to deemphasize PPE, which was now well-practiced, and added objectives to introduce protocols for risk stratifying patients, maneuvers and modalities for improving oxygenation, thresholds for mechanical ventilation, and guidelines for inpatient or outpatient referral for monoclonal antibody treatment. As vaccinations became more widely available, the mild scenario was refined to include conversations addressing vaccine hesitancy in the ED.

The tailored debriefing following the intervention was fundamental to addressing protocol changes, misunderstandings, and nuance. Beyond the learning points of each scenario, the participants learned how to use the COVID-19 Patient Management Pathway embedded within the electronic health record. The pathway, when used correctly, should aid the clinician in making the correct protocol and management

decisions. This improved understanding of the pathway enhanced the learners' ability to apply it to their future patients.

Heart Rate Variability Outcomes

All participant HRV data has been collected and cataloged. The data is currently in the process of being cleaned in order to be further analyzed as described above. The results will be used in mixed model analysis. Unfortunately, these results are still in progress at the time of submission.

State-Trait Anxiety Outcomes

Average trait anxiety (T-Anxiety) and average state anxiety (S-Anxiety) scores were measured for all participants at baseline (Table 2). Average state anxiety scores were measured after each shift, with the intervention arm of the study having received the educational simulation between shifts two and three. These measures will primarily be used in mixed model analysis. The analysis is still in progress at the time of submission.

However, preliminary t-test analysis was conducted to compare the S-Anxiety scores calculated from the 20-item state subscale administered immediately post-shift. Mean scores from data collections one and two and data collections three and four between the intervention and control arms of the study were compared to evaluate the changes in S-Anxiety. Out of a total score of 80 points, indicating the highest level of anxiety, the Intervention arm scored 34.6 points with an average change of 0.24 points– found to be not statistically significant (p=0.84) (Table 3). There was also no statistical

difference (p=0.84) in the change in the S-Anxiety scores of the control group (Table 3), which was the anticipated result. When comparing the mean S-Anxiety scores from data collections three and four of the intervention and control arms of the study, no significant difference was found (p= 0.52) (Table 4).

Table 2. Baseline S-Anxiety and T-Anxiety STAI scores.

STAI Measure	Control Baseline Score (SD)	Intervention Baseline Score (SD)
S-Anxiety	**32.8 (8.4)**	**34.6 (9.9)**
Junior	34.1 (8.3)	34.3 (10.2)
Senior	31.5 (8.5)	35 (9.9)
T-Anxiety	38.2 (10.1)	38.7 (11.6)
Junior	40.8 (11.5)	41.5 (10.7)
Senior	35.6 (7.9)	36.1 (12)

Table 3. S-Anxiety scores.

Group	S-Anxiety Shift 1 & 2 (SD)	S-Anxiety Shift 3 & 4 (SD)	ΔS-Anxiety (SD)	P-value
Control	34.3 (9.1)	34.6 (10.7)	0.24 (7.4)	0.84
Junior	35.9 (8)	35.8 (7.8)	-0.08 (7.2)	0.96
Senior	32.8 (10)	33.4 (13.1)	0.55 (7.7)	0.75
Intervention	36.8 (9.3)	36.1 (9.9)	-0.72 (6.8)	0.51
Junior	37.4 (6.5)	38.4 (7.1)	1.03 (6.5)	0.50
Senior	36.2 (11.5)	33.9 (11.7)	-2.38 (6.9)	0.14

Table 4. Comparison of S-Anxiety score between the Control and Intervention arms.

STAI Measure	Control	Intervention	P-value
S-Anxiety: Shifts 3 & 4 (SD)	34.6 (10.7)	36.1 (9.9)	0.52
ΔS-Anxiety (SD)	0.24 (7.4)	-0.72 (6.8)	0.55

DISCUSSION

The expected sustained course of the novel COVID-19 pandemic required healthcare systems to be rapidly responsive. As a response to the influx of information and pandemic guideline changes that impacted the ability of frontline clinicians to provide best-practice care to COVID-19 positive (and suspected COVID-19 patients), the YMCS team created a simulation-based educational intervention for emergency physicians to facilitate the adoption of new protocols and treatment algorithms. Healthcare systems have resumed elective procedures and non-COVID-19 operations as the initial crisis passed. In the ED, operational challenges have come from the culmination of a rebound in urgent medical needs of non-COVID-19 patients due to exacerbations of neglected existing chronic conditions and intermediate-term COVID-19 infection complications, re-infections, or breakthrough infections that presented in extremis.[45] Researchers are warning of a fast-spreading third wave of COVID-19 spawned from the heavily mutated Omicron-variant. This global public health alert warns that the new variant may spark new waves of infection or exacerbate ongoing rises being driven by Delta, continuing to extend the pandemic response.[47]

With an extended response curve and fluctuating demands for care delivery, continued system responsiveness is needed to provide safe management of COVID-19 patients during the anticipated return of standard pre-pandemic clinical ED volumes. This need highlights the innovative adaptability of CRI:SIS as an educational and training

intervention. The iteratively updated scenarios deliver the most recent guidance while continuing to highlight the aspects of care that remained challenging.

Simulation provides a unique experience for participants to reflect and better understand the framework for their clinical decision-making. CRI:SIS consists of an adaptive virtual simulation-based learning experience that updates with an evolving health crisis and directly immerses the learner in scenarios that address the challenges of constantly changing guidelines. It further empowered the learner to accurately apply the integrated, up-to-date clinical decision tool available to them to remain current with a continually evolving landscape.

The objective was to (1) lower levels of anxiety and stress in emergency physicians caring for acutely ill COVID-19 patients and (2) rapidly develop and adapt simulation-based scenarios that provide education and continuous process improvement of clinician COVID-19 preparedness. The analysis is ongoing to conclude whether there is a significant difference in physiologic measures and an overall decrease in stress and anxiety.

Initial feedback from participants has been overwhelmingly positive. Anecdotal evidence based on participant reporting indicated the skills acquired from the intervention training were beneficial and subsequently applied in practice when caring for COVID-positive patients in the ED.

Once completed, the outcomes of the current work will address the needs of clinicians in the current COVID-19 pandemic and provide a blueprint for achieving

system readiness and incorporate lessons learned from the COVID-19 pandemic into future system responses.

Innovation

The use of a rapidly adaptive simulation format is innovative: this will be the first study to apply a fully adaptive simulation program that can rapidly shift between remote virtual tele-simulation and in-person modalities. High-fidelity simulation activates participants' emotional or affective states and allows the development of necessary cognitive and psychomotor skills in clinical practice.[47] To achieve similar benefits, the virtual tele-simulation technology (Figure 5) was designed to retain as many cognitive and affective learning features of the live simulation environment as possible when adapting the simulation experience to a virtual video conferencing platform. This format still allows for real-time vital signs, patient interactions, team coordination, and psychomotor skills while complying with changing requirements for social distancing.[48-50] Utilizing virtual tele-simulation allowed the study to maintain continuity of simulation delivery while responding to public health restrictions.

Furthermore, the focus on ED physician stress and burnout is innovative: Experts have increasingly raised concerns regarding the wellness of frontline health workers who directly diagnose and manage critically ill patients during the pandemic.[4] However, much of the current attention in clinical research is focused on healthcare system preparedness, diagnostic testing, and medical treatment of COVID-19 patients.[51] This study brings to

light the harmful psychological impact of the pandemic on ED physicians and the potential downstream impact on patient safety and care quality.[19]

Iterative Improvement

The intervention scenarios focused on the greatest concerns of clinicians and the most significant changes to standard practice at the time of administering. These scenarios targeted protocols and proper use of PPE, airway management, ventilation strategies, anticipated complications, and subsequent interventions.

During the initial phases of clinical care, COVID-19 patients were often critically ill and profoundly hypoxemic. Therefore, the management strategies focused on protecting the clinician and staff while trying to rapidly stabilize critically ill patients. This meant early intubation and mechanical ventilation. However, as the understanding of the physiology of COVID-19 patients evolved, so did the guidelines put forth by the hospital and emergency department. Moreover, as clinicians became adept at specific protocols, it became less important to highlight this information within the constructed scenarios.

For example, the proper use and disposal of PPE became routine practice, early intubation and mechanical ventilation became disfavored, maneuvers such as proning and sitting patients upright were recognized as beneficial, and high oxygen delivery modalities such as high flow nasal cannula were advocated. The department even relaxed a prior prohibition on junior trainees intubating. Clinicians began to recognize how some seemingly stable patients could rapidly decompensate, and algorithmic tools were created

to help predict this deterioration.[52] Beyond the improved understanding of the disease process itself, multiple other conditions changed over time. Clinicians became vaccinated, certain patient subgroups had an opportunity to become vaccinated, and the understanding of pharmacologic interventions improved.

The intervention was able to capture the fluidity of the practice landscape by continually updating the scenarios themselves and the focus points of the debriefings. In parallel, the YNHH ED administrative team created and continually launched an algorithmic tool embedded within the hospital's electronic health record. This tool, when used properly, guides the user through current policies and guidelines. As part of the debriefing, the learners were instructed how to use this clinical tool so they could continually stay up to date moving forward.

Safety Risks

Standard of care was maintained during the implementation of the CRI:SIS study. However, minor risks existed for both participants and research staff. The extended use of real-time physiologic measurement with Hexoskin introduced a risk of discomfort and skin irritation for participants. A range of shirt sizes was provided and tested prior to the baseline session to ensure the best fit and mitigate this risk. In order to maintain confidentiality, study data was de-identified using unique study participant identifiers. In addition to participant risks, embedding research staff in the ED presented a potential risk of exposure to the research staff. In compliance with university, hospital, and ED guidelines, all research staff underwent detailed infection prevention training on methods

to minimize risk exposure, including proper donning and doffing of personal protective equipment and protocols in the ED.

Limitations

The study faces several limitations. The most significant limitation is the natural variation in COVID-19 presentations. Having conducted data collections later in the time course of the pandemic, and with the increasing prevalence of vaccinated staff and patient populations in the region, there may be fewer COVID-19 positive patients encountered each shift–and those cases may also present with lower acuity. Furthermore, with the return of clinical ED volumes prior to the pandemic, and given the nature of emergency medicine, there would likely be a large number of non-COVID-19 clinical factors contributing to the cumulative stress of an ED shift. Therefore, a participant may have a particularly stressful shift, but that stress might not necessarily be attributed to caring for COVID-19 patients. These non-COVID-19 stressors may skew the results of the post-shift STAI substate survey scores.

A methodological limitation of the study was how labor-intensive it was to implement and apply the intervention to relevant clinicians. Three hours were allocated to complete the scenarios and debriefings with two learners enrolled per session. Educating many learners with a priority for quick implementation is logistically challenging. Given this time commitment for participation, an initial concern was a lack of buy-in during this time of high work and social demands. A voluntary recruitment strategy brings forth the potential limitation of a strong non-response bias from physicians who chose not to

participate. There may have been a potential bias for attending physicians uncomfortable with the tele-simulation format and not wanting to demonstrate a lack of technological knowledge in front of younger colleagues. Younger interns, who may have little to no COVID-19 experience, might find the intervention intimidating to expose their lack of training to senior colleagues.

As the pandemic evolved, clinician knowledge, skills, and experiences had rapidly advanced. The sheer rapidity of changes made to the treatment algorithm poses a possible methodological limitation. After just a few months, learners who completed the earlier scenarios would benefit from an update, although their enhanced understanding of the integrated electronic clinical decision tool may reduce confusion moving forward. Furthermore, with the changing landscape of participant experiences, the appropriateness of the intervention changed, meaning later participants faced different guidelines and concerns than early participants and therefore received different versions of the intervention. The evolution of stressors throughout the pandemic may have a confounding effect on the reporting of STAI scores.

Future Application

More work still needs to be done to determine whether this virtual simulation intervention improves adherence to guidelines and protocols in the clinical setting, as well as the decrease in physiologic and self-report measures of stress and anxiety of physicians during a shift in the ED.

For now, outcomes have only been assessed across two EDs within the same hospital system. However, if proven successful, CRI:SIS is readily scalable and applicable at other institutions to improve and evaluate the responsiveness of other healthcare delivery systems and healthcare professionals to the COVID-19 pandemic. The following steps would include tailored dissemination at additional sites across regions and objective feedback from institutions that may adopt this learning intervention.

The rapid dissemination of CRIS:SIS would be particularly crucial to alleviate the challenges frontline healthcare workers face as they continue to care for patients in a constantly changing environment. The goal would be to engage Emergency Medicine residency training program directors, simulation educators, and ED and hospital administrators across the United States. Participants would first observe the scenarios implemented within the clinical trial intervention. Specific scenarios targeting the institution's needs will then be selected and adapted to apply institutional-specific guidelines. The participating institution can then implement the scenario(s) in a similar virtual tele-simulation format to provide all frontline health workers with this educational training.

As the pandemic stretches on, attention will likely turn to restore normal life, yet COVID-19 is far from finished for the frontline workers. With the looming possibility of new variants and subsequent waves of the pandemic, rapid system responsiveness will

continue to be needed to provide the most up-to-date best practices and safe management of COVID-19 patients while simultaneously handling the return of pre-pandemic clinical ED volumes. COVID-19 has upended all aspects of regular quality improvement routines, and therefore innovative solutions were required to address safety issues due to the pandemic. The adaptability of CRI:SIS as a simulation-based continuous process improvement program will hopefully serve as the universal model for reducing burnout factors in ED physicians and increasing frontline health workers' preparedness for future COVID-19 pandemic threats.

APPENDIX

Appendix A. Simulation intervention cases.

Scenario	Objectives	Scenario Description
Scenario 1: Mild COVID-19 A 73-year-old patient with fever and mild tachycardia	● Recognize that the patient's severity of illness does not necessitate hospital admission ● Discharge from the emergency department (ED) with close follow-up	Respiratory rate (RR) <25 and spO_2 ≥94% on room air (RA). The exertional spO2 remains above 94%. **Critical actions** ● Order an outpatient COVID test, ● Contact the patient's primary care physician, ● Discuss the patient's expected course with return precautions
Scenario 2: Moderate progressing to severe COVID-19 A 58-year-old patient presenting with hypoxia initially responsive to supplemental oxygen requiring hospital admission	● Stratification between patients who are stable for admission to the floor vs. a higher level of care as determined by physiologic measures (degree of hypoxia, respiratory rate) ● Predicting deterioration using the Quick COVID-19 Severity Index (CQSI)[51] ● Increase utilization of HFNC ● Indications/ contraindications for ED proning. ● use and maximally allowed settings for BiPAP	RR <25, spO2 87% RA. Pulse oximetry improves to 94% on 4L nasal cannula (NC). The patient deteriorates over time in ED, prompting proning/reassessment for a higher level of care. **Critical actions** ● Appropriate workup (relevant labs, imaging) ● Appropriate therapeutics (acetaminophen, steroid, aspirin) ● Appropriate risk stratification (Quick COVID-19 Severity Index (QCSI) & arterial measurement of PaO_2/FiO_2 (P/F) ratio)

Scenario 3: Severe COVID-19 with emphasis on goals of care A 92-year-old patient with multiple comorbidities and severe COVID-19	● Presentation immediately suggests a high risk of death necessitating goals of care discussion ● This scenario intentionally provides for a variety of clinical management decisions ● Highlights hospital policy surrounding physicians conferring Do Not Resuscitate (DNR) and Do Not Intubate (DNI) orders	Critically ill elderly female with multiple comorbidities. **Critical Actions** ● The learner must engage in goals of care discussion with a family member to determine treatment pathway ● Hospital order sets for facilitating Comfort Measures Only (CMO) status ● The learner must follow the pathway for a severely ill COVID-19 patient (dependent on goals of care discussion)
Scenario 4: Severe COVID-19 requiring emergency intubation A critically ill 50-year-old patient requiring immediate intubation complicated by difficult anatomy necessitating a difficult airway algorithm. Ventilator management complicated by barotrauma	● Rapid planning of anticipated interventions, supplies, pharmacotherapy, and ancillary staff (i.e., respiratory therapy) ● Management of difficult airway in a patient with minimal oxygen reserve ● Ventilator management using ARDS Net ● Anticipating/managing barotrauma injury in high PEEP	Patient in extremis, with severe respiratory distress with Spo_2 in the 50s. The patient requires intubation and rapid escalation in ARDSnet ventilator management. Patient experiences tension pneumothorax which must be decompressed. **Critical Actions** ● The learner must work through a rescue device algorithm ● ARDS Net ventilator management ● Successfully diagnose and treat pneumothorax ● The learner must follow pathway for a severely ill COVID-19 patient

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