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Improving patient and clinician safety during COVID-19 through rapidly adaptive simulation and a randomised controlled trial: a study protocol

Leigh V Evans,[1] Jessica M Ray ,[1,2] James W Bonz,[1] Melissa Joseph,[1] Jeffrey N Gerwin,[1] James D Dziura,[1] Arjun K Venkatesh,[1] Ambrose H Wong [1]

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[1]Department of Emergency Medicine, Yale School of Medicine, New Haven, Connecticut, USA
[2]Department of Health Outcomes & Biomedical Informatics, University of Florida College of Medicine, Gainesville, Florida, USA

Correspondence to
Dr Ambrose H Wong;
wongambrose@gmail.com

ABSTRACT

Introduction COVID-19 required healthcare systems to iteratively adapt for safe and up-to-date care as knowledge of the disease rapidly evolved. Rates of COVID-19 infections continue to fluctuate and patients without COVID-19 increasingly return to the emergency department (ED) for care. This leads to new challenges and threats to patient and clinician safety as suspected patients with COVID-19 need to be quickly detected and isolated among other patients with non-COVID-19-related illnesses. At the front lines, emergency physicians also face continued personal safety concerns and increased work burden, which heighten stress and anxiety, especially given the prolonged course of the pandemic. Burnout, already a serious concern for emergency physicians due to the cumulative stresses of their daily practice, may present as a longer-term outcome of these acute stressors.

Methods and analysis We will implement a rapidly adaptive simulation-based approach to understand and improve physician preparedness while decreasing physician stress and anxiety. First, we will conduct semi-structured qualitative interviews and human factor observations to determine the challenges and facilitators of COVID-19 preparedness and mitigation of physician stress. Next, we will conduct a randomised controlled trial to test the effectiveness of a simulation preparedness intervention on physician physiological stress as measured by decreased heart rate variability on shift and anxiety as measured by the State-Trait Anxiety Inventory.

Ethics and dissemination The protocol was reviewed and approved by the Agency for Healthcare Research and Quality for funding, and ethics approval was obtained from the Yale University Human Investigation Committee in 2020 (HIC# 2000029370 and 2000029372). To support ongoing efforts to address clinician stress and preparedness, we will strategically disseminate the simulation intervention to areas most impacted by COVID-19. Using a virtual telesimulation and webinar format, the dissemination efforts will provide hands-on learning for ED and hospital administrators as well as simulation educators.

Trial registration number NCT04614844.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Continued adaptation of virtual simulation scenarios will facilitate translation of rapidly changing COVID-19 guidelines and protocols.
⇒ Diversity of acquired qualitative and quantitative data across our study aims to capture physiological measures, self-reported surveys of stress/anxiety, and semistructured qualitative interviews that will allow for triangulation and verification of results.
⇒ Our incorporation of front-line staff's direct experiences will allow our intervention to benefit from rapidly gained real-world knowledge and skills.
⇒ Our clinical sites are located in the same healthcare system potentially limiting generalisability.

INTRODUCTION

The sustained course of the COVID-19 pandemic requires healthcare systems to be rapidly responsive. In recent months, the tide of patients with COVID-19 has started to ebb, and governmental mandates on travel restrictions, social distancing, and masking have started to relax.[1] Healthcare systems have started to resume elective procedures and non-COVID-19 operations as spikes in infection pass and financial recuperation efforts begin. Yet, additional waves of infections are anticipated in the future as vaccination efforts are yet to be completed and new variants may continue to emerge.[2] In the emergency department (ED), operational challenges have arisen from a culmination of a rebound in urgent medical needs of patients without COVID-19 due to exacerbations of neglected existing chronic conditions along with intermediate-term COVID-19 infection complications, reinfections, or breakthrough infections.[3] Recently, newer system-based failures have further stressed care delivery, including disruptions in the medical supply chain[4] and critical shortages in the healthcare workforce.[5] These considerations highlight the challenges of an extended response curve and fluctuating demands for care delivery. Thus, rapid system responsiveness is

needed to continue the safe management of patients with COVID-19 in addition to the return of usual clinical ED volumes prior to the pandemic.

An extended pandemic response heightens healthcare worker stress and anxiety, leading to negative effects on patient safety. Healthcare workers have faced enormous pressure during the pandemic due to increased work burden, uncertainty, and risk of infection.[6–9] Burnout, already a serious concern for emergency physicians due to the cumulative stresses of their daily practice, may present as a longer-term outcome of these acute stressors.[10] A recent survey of emergency physicians demonstrated a prevalence of burnout as high as 61% nationally.[11] These high rates of burnout were further linked with depression, decreased career satisfaction, and suboptimal care. Specific downstream effects on patient safety included medical errors, increased waiting times, and decrease in patient satisfaction as a result of clinician stress and burnout.[12 13] In a recent editorial, we highlight the potentially deleterious effects of the pandemic response on the already strained mental health of front-line healthcare workers, especially those working in the ED.[14] Early reports from the COVID-19 outbreak in China indicated over 71% of healthcare workers surveyed reported symptoms of distress, while nearly 45% reported acute anxiety and depression.[8] As the pandemic stretches on, attention has shifted to restoring normal life, yet for the front-line workers, this pandemic is far from finished. Challenges and inconsistencies to the adoption of ever-changing guidelines have led to healthcare workers feeling unequipped to keep up to date with medication availability, care delivery, and team coordination.[6] In order to protect our workforce during the current and future high-stress surge times, there exists an urgent need to develop support systems to prepare these workers in developing both clinical and emotional resilience.[15]

Burnout develops from repeated exposure to acute stress and manifests in changes to physiological measures. Increasing evidence suggests a link between physiological measures of stress and emotional exhaustion subscales of burnout.[16] During acute stress events, healthcare workers may experience activation of the sympathetic nervous system resulting in key physiological changes.[17] Established markers of this stress response include a decrease in heart rate variability (HRV).[18] Low HRV has been observed in individuals presenting with burnout resulting from repeated or continuous stress exposure.[19] For 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.[19] Such low levels of HRV suggest sympathetic predominance, which may contribute to the adverse health effects associated with clinical burnout.[16 19 20]

Immersive simulation technology holds the potential to help mitigate the negative effects of healthcare workers' stress and overcome challenges to system responsiveness arising from COVID-19.[21] The military and aviation sectors were pioneers in targeting system performance and safety through the use of simulation, a burgeoning technical field that applies experiential techniques for the purposes of practice, learning, evaluation, testing, or insight into systems or human actions.[22] Simulation addresses complex operational challenges, including improvement of individual and team performance, as well as adaptive systems development to detect and prevent fatal errors and system failures.[23] In the healthcare sector, simulation is used for educating, training, and assessing expertise[24] through the recreation of clinical environments using a wide array of technologies ranging from high-fidelity mannequins to virtual reality.[25] However, simulation techniques can also be leveraged to identify latent safety threats, test new protocols and patient pathways, and improve the execution of complex medical procedures.[26 27] As knowledge builds and recommendations evolve during the outbreak, simulation can engage clinicians in the iterative testing and redeployment of new clinical strategies, equipment, bed use, and workflows.[28] In addition, simulation has shown significant benefits in decreasing occupational strain and enhancing healthcare workers' adaptive coping mechanisms during high-risk situations of patient care.[29 30] Active participation in team preparation, developing competency in new procedures, and providing feedback into care protocols support both protocol adoption and worker stress, anxiety and burnout outcomes.[14] These benefits may be crucial to help establish healthcare worker resilience through increased competence and preparedness as the COVID-19 pandemic stretches on.[31]

There is a critical need to learn how best to mitigate healthcare worker stress and facilitate system responsiveness in the next phases of the current pandemic. Thus, we aim

> Aim 1: To identify factors that influence system responsiveness, hazards, clinician stress and burnout, and adoption of COVID-19 care delivery protocols through qualitative interviews with clinicians and structured field observations during the care of critically ill patients with COVID-19.
>
> Aim 2: To assess the efficacy of an innovative simulation intervention, COVID-19 Responsive Intervention: Systems Improvement Simulations (CRI:SIS), on physician stress and anxiety during the COVID-19 pandemic through a multisite, randomised clinical trial assessing changes in HRV as a physiological measure of stress and State-Trait Anxiety Inventory (STAI) as a measure of physician anxiety.

METHODS AND ANALYSIS

Our overarching goal for the proposed project is to test and implement a simulation intervention (CRI:SIS) that relieves emergency physician stress and improves system responsiveness during COVID-19. To accomplish this goal, we will use a multipronged mixed-methods

approach[32] at two clinical sites of a tertiary care, urban academic hospital to (1) identify facilitators, barriers, and unintended safety risks and hazards in the adoption of new COVID-19 guidelines and checklists affecting clinician stress and system responsiveness and (2) assess the impact of CRI:SIS as a simulation preparedness intervention through a randomised clinical trial on changes in clinician stress and anxiety as measured by HRV during the care of patients with COVID-19 and post-shift ratings of the STAI,[33] a commonly used measure of trait and state anxiety in clinical settings to diagnose anxiety and in research as an indicator of participant distress.

Patient and public involvement

There were no funds or time allocated for patient and public involvement as the main focus was on healthcare worker wellness and preparedness. However, we have invited patient advocates to help us develop our dissemination strategy so that it is designed to improve the public good.

Aim 1 methods: qualitative assessment of system responsiveness

Aim design and rationale

In the first phase of our work, we will conduct in-depth interviews with emergency physicians to explore the facilitators and barriers to the adoption of COVID-19 guidelines into practice amidst a changed healthcare sector landscape. Using a sociotechnical systems framework,[34] we will also conduct detailed field observations in the ED to describe guideline and checklist use at the bedside and identify potential unintended systems consequences of guideline adoption including risks and hazards to patient and clinician safety. In response to the COVID-19 pandemic, local task force teams have iteratively designed and implemented a series of new guidelines, clinical decision pathways, and companion checklists to support both patient and clinician safety and ensure compliance with standards of care. However, rapid changes in knowledge of COVID-19 disease processes and presentations as well as resource availability require frequent updates to these practice guidelines. While daily updates from local task force teams are delivered via email and print materials, the rate and systemic adoption of these protocols are still unknown.

Participants and setting

In months 1–6 of the study period, beginning in January 2021, we will recruit ED healthcare providers (attendings, residents, nurses and technicians) with experience treating COVID-19 (and suspected COVID-19) patients as participants in 30–45 min qualitative interviews. Eligible participants shall include all providers having worked at least one clinical shift caring for patients with COVID-19 since March 2020. All participants will be targeted via email and recruitment fliers with QR codes that will be posted in the ED. Participation will be on a voluntary basis. Observations will be conducted at the Yale-New Haven Health (YNHH) ED, situated in a busy, 1541-bed, urban, tertiary care referral academic hospital in New Haven, Connecticut, USA. Both resident and attending physicians actively working at the YNHH ED will be enrolled as part of the system observations. Participants will provide verbal consent at the time of recruitment and scheduling for interviews and/or observations.

Qualitative interviews with resident and attending physicians will be based on normalisation process theory (NPT),[35] a sociological theory that identifies, characterises, and explains key mechanisms that promote and inhibit the implementation, embedding and integration of new health innovations, technologies and clinical practices. Quality experts have increasingly used NPT to inform feasibility studies and adoption evaluation of complex healthcare interventions.[36] Interview topics (table 1A) will organise around the four core constructs within NPT to explore barriers and facilitators of guideline adoption as well as factors contributing to clinician stress and burnout. All interviews will be audio recorded and professionally transcribed weekly for analysis.

Field observations in the ED will be conducted on a biweekly basis for randomised 8-hour blocks throughout the baseline study period. Observers will further assess the adoption of COVID-19 clinical care guidelines by completing one or more of four established guideline checklists. Using a sociotechnical systems framework, we will use field notes to capture systems features related to guideline use and care provision (table 1B). A human factor expert and a trained research associate will double code a subset of observations to assess inter-rater reliability. We will calculate a Cohen's kappa for inter-rater reliability.

Outcomes

From Aim 1, we will obtain qualitative data on preparedness, adoption of COVID-19 care guidelines, and perceived risks and hazards to clinician and patient safety through qualitative interviews with emergency physicians and human factors observations of ED physician shifts. These data will inform the refinement of CRI:SIS to ensure that we embed information that will improve preparedness and mitigate stress during clinical care for our participants.

Data analysis

Qualitative interviews will be analysed for emergent themes of adoption facilitators and barriers. We will use Dedoose (SocioCultural Research Consultants),[37] a collaborative qualitative software package, for thematic analysis and data organisation. We will start with a systematic, inductive approach through an initial round of open coding, then achieve consensus on major themes[38] through an iterative analytical process as more information is added after additional interviews using the constant comparative method from grounded theory.[39] Field notes will be analysed using a deductive coding method based on the sociotechnical systems approach.[34] Items marked as completed

Table 1 Sample interview topics

(A) Sample interview topics		(B) Sample field observation tasks	
Normalisation process theory construct	**Interview topic examples**	**System component**	**Field observation task examples**
Coherence	► Purpose/goals of guidelines. ► Provider's attitudes, beliefs, knowledge regarding treatment of patients with COVID-19.	Person (patient)	► Note levels of physical comfort and pain; describe provider contact with family. ► Describe patient communication and rapport with provider. ► Note any delays in treatment/care provision. ► Record chief complaints, differential diagnoses.
Relations	► Discuss care coordination among team members. ► Engagement of and feedback to leadership regarding guidelines and treatment.	Team (staff)	► Note the roles and responsibilities of all staff in the room. ► Describe teamwork and communication dynamics among staff. ► Physical and psychological well-being and safety.
Operations	► Potential formats for COVID-19 compliance checklists. ► Guideline impact on patients and staff safety. ► Applicability of guidelines to bedside care. ► Interactions with non-COVID care.	Tasks, tools and technology	► Taking history and performing physical exam. ► Record selection of tests, medications and treatments. ► Record all procedures conducted (airway and central venous access). ► Note the use of personal protective equipment, supplies, equipment and electronic health record.
Appraisal	► Effectiveness and success of the guidelines. ► Guideline alignment with best practices and current knowledge of COVID-19 treatment and care.	Environment and organisational conditions	► Evaluate usage of rooms and physical space. ► Measure staffing and worker morale. ► Record patient volume and acuity.

or deficient on the checklist during field observations will be aligned with observed system factors to identify critical system interactions impacting adoption. We will stop interviews and field observations when we reach data saturation, an accepted technique for ensuring richness of data in qualitative research.[40] We approximate that this will occur at 25–30 physician interviews and 75–80 hours of observations.

Aim 2 methods: effectiveness of a simulation preparedness intervention through a randomised control trial

Aim study design and rationale

Our innovative approach applies a fully adaptive simulation programme that can rapidly shift between remote virtual telesimulation and in-person modalities developed and implemented by our team. High-fidelity simulation activates participants' emotional or affective state and allows the development of necessary cognitive and psychomotor skills in clinical practice.[41] To achieve similar benefits, we created our virtual telesimulation technology with the goal of retaining as many cognitive and affective learning features of the live simulation environment as possible while adapting the simulation experience to a virtual videoconferencing platform.[42] This rapidly adaptive format allows us to maintain continuity of simulation delivery while responding to fluctuations in local public health restrictions, including business closures and social distancing. Applying this rapidly adaptive approach, CRI:SIS will address healthcare worker stress through preparedness and engagement. Experts have increasingly raised concerns regarding the wellness of the front-line health workers that are directly diagnosing and managing critically ill patients during this pandemic.[6] However, much of the current attention in clinical research is currently focused on healthcare system preparedness, diagnostic testing, and medical treatment of patients with COVID-19.[43] Our simulation scenarios embedded within CRI:SIS will focus on health worker preparedness to mitigate physician anxiety and stress as our main goal and use health worker physiological measures as our primary outcome of interest.

This section of our study will be a randomised controlled trial assessing the impact of CRI:SIS as a simulation-based preparedness intervention on physician stress levels through changes to HRV on shift while caring for patients with COVID-19 and post-shift anxiety as measured by STAI. In order to address patient safety in the current pandemic, we must first address the safety needs of our clinicians caring for these patients. Clinicians require support along a range of psychological needs, including basic safety through proper use of personal protective equipment (PPE), social support fostering teamwork, and preparedness for clinical challenges, including difficult

conversations regarding patient care.[14] If these needs are not met, COVID-19 presents increased risk of infection, anxiety and burnout for clinicians.[8 14] The syndrome of burnout in physicians increases risk of patient safety incidents, extends patient waiting times and reduces patient satisfaction.[44 45] Evidence suggests links between physiological measures of acute stress and the emotional exhaustion subscale of burnout.[16] During the pandemic, our team has developed and piloted a COVID-19 simulation intervention designed to support preparedness for the clinical stressors physicians will likely encounter caring for patients with COVID-19 in the ED. We aim to test CRI:SIS to determine its effect on mitigating physician stress through a two-arm randomised controlled trial at two clinical sites with a primary outcome of change in on-shift HRV as a physiological measure of stress and a secondary outcome of post-shift anxiety related to the care of patients with COVID-19 as measured by STAI,[33] a commonly used measure of trait and state anxiety in clinical settings to diagnose anxiety and in research as an indicator of participant distress.

Participants and setting

In months 3–12, we will recruit resident or attending physicians actively treating acutely ill patients with COVID-19 (and suspected COVID-19) at either of the two YNHH ED campuses. These two campuses are geographically and structurally unique academic ED sites: (1) York Street Campus, the tertiary care referral centre with four resuscitation bays, 56 beds, and average adult volumes of 100 000 visits per year; and (2) St. Raphael Campus, an urban community hospital with two resuscitation bays, 35 beds and 65 000 visits per year. Eligible participants shall be working full-time in one of these two EDs with an anticipated average of 26 hours/week (three to four shifts/week) for attending physicians and 45–50 hours/week (four to five shifts/week) for resident physicians. Eligible participants will be selected for recruitment based on proximity to working clinical shifts in the ED at either one of the two YNHH campuses and contacted via email. Participation will be on a voluntary basis. Exclusion criteria will include use of a beta blocker and/or antiarrhythmic medication, active thyroid dysfunction and pregnancy.

Protocol and randomisation

We will enroll eligible participants across a period of 12–15 months. At the time of enrolment, participants will completea written consent, then will be fitted with an appropriately sized Hexoskin smart shirt. Participants will be asked to sit quietly for a 5 min baseline session to capture each individual's baseline heart rate and HRV. The Hexoskin shirt contains three sensors to capture participant heart rate via ECG, respiratory rate, minute ventilation and movement/activity. This non-invasive technology will capture moment-by-moment physiological data necessary to calculate HRV changes as measures of stress during the care of patients with COVID-19 and suspected COVID-19. Following capture of these baseline data, participants will be asked to complete the 40-item STAI survey. All participants will wear a Hexoskin smart shirt underneath their standard scrub shirt for four consecutive shift data collections. Following the completion of the first two data collection shifts, participants will be randomised to either the control or intervention arm and scheduled for the remaining study sessions (two additional data collection shifts±the intervention session). Participants will be divided into two groups based on experience level, junior (PGY1-3) and senior (PGY4+). Prior to the start of the clinical trial, numbered envelopes with random intervention and control designations will be prepared by a statistician and evenly split into junior and senior groupings. After completion of two shifts, a corresponding envelope will be opened, designating the participant to either the control or intervention grouping. For participants randomised to the intervention arm, data collections will consist of two shifts prior to the intervention and two shifts following the intervention. A research assistant will be present at the start of each participant's shift to confirm data capture and log shift start time on the recording. Following end-of-shift sign-out, a research assistant will administer the 20-item state subscale of the STAI and conduct a debriefing of 5–10-min with the participant to capture qualitative data on perceived stressors experienced during the shift. Participants will be asked to continue HRV data recording for 20 min following the end of each data collection shift to assess for return to baseline HRV. The primary outcome of interest will compare the change in HRV from baseline to the last 5 min of the shift prior to sign-out as a measure of cumulative shift stress. Additionally, post-processing of the data will capture 5 min readings during the treatment of each acutely ill medical patient based on time logs of medical patient alerts as a measure of acute stress during the shift (figure 1).

Simulation intervention

Participants randomised to the intervention arm will receive CRI:SIS as a 3-hour simulation session. This session will include three scenarios focused on three critical areas of care for patients with COVID-19: (1) airway management procedures in patients with COVID-19 given increased risk of viral transmission to personnel and rapid respiratory deterioration in infected patients[46 47]; (2) new presenting symptoms and associated complications of COVID-19 (eg, hypercoagulability and cardiovascular morbidity), making accurate diagnosis and treatment of patients with suspected infection difficult[48–50]; and (3) caring for patients presenting with severe illness and poor prognosis adding emotional and cognitive strain to physicians as they initiate palliative care, discuss goals of care or withdraw care in the ED. In addition, all three scenarios will address negative effects on team performance during COVID-19 care from social distancing and PPE requirements through interactions with nursing and ancillary staff confederates during each scenario. We will refine

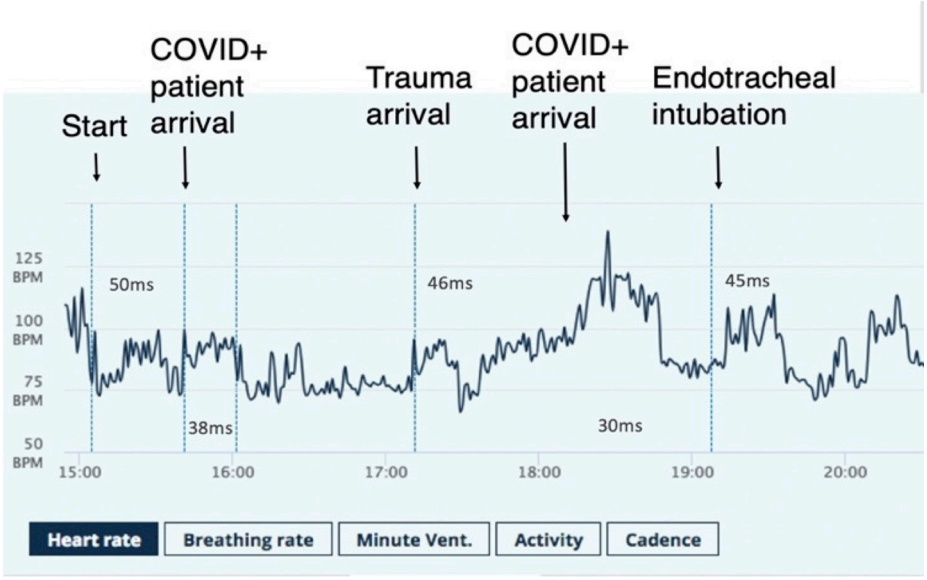

Figure 1 Example of heart rate and event-related heart rate variability during emergency department physician shift. BPM, beats per minute.

our simulation scenarios from our pilot programme to reflect qualitative data obtained in the first phase of the project. Each participant will complete all three scenarios within a 3-hour block between 1 and 5 days prior to a clinical shift. This simulation session will be offered on Tuesdays to clinicians, educators, and administrators recruited from outside institutions who are experiencing a surge in COVID-19 presentations in their geographical region (see Ethics and dissemination section).

Control

Participants randomised to the control arm will participate in four shift data collections, with no additional intervention. These participants will have access to the routinely distributed COVID-19 Task Force updates, guidelines, weekly town hall meetings, and any in-service support that would routinely be available to all clinical staff as per standard operational practice in our local departments. Once enrolment is complete, all participants randomised to the control arm will be offered the opportunity to complete the simulation intervention.

Outcomes

We have previously developed a rapid cycle implementation and evaluation of a novel virtual tele-simulation intervention to improve patient and clinician safety during COVID-19. If proven successful, CRI:SIS is readily scalable and applicable at other institutions to improve and evaluate the responsiveness of healthcare delivery systems and healthcare professionals to the COVID-19 pandemic.

Data analysis

Data processing of HRV will be completed with Vivosense software to validate signal quality and mark ECG R-waves for analysis. HRV, our primary outcome of interest, will be 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 artefact than other HRV measures.[51] We will analyse HRV using a short-term period of 5 min. These HRV periods will be captured at baseline, immediately following oncoming shift sign-out, during on-shift medical patient responses, ahead of the end-of-shift shift sign-out and post-shift. The primary outcome of interest will be measured as the change from baseline to the 5 min period prior to end-of-shift shift sign-out as a measure of cumulative shift stress. Additional analyses will examine acute stress as changes in HRV at the presentation of acutely ill medical patients during the shift. Timing for the treatment of individual patients will be captured by aligning Hexoskin timestamps with electronic timestamps of medical alerts from the ED's electronic paging system. Electronic health record review will allow for the identification of COVID-19-positive and suspected COVID-19 medical patients. An increase in stress will be assessed as a decrease in HRV from baseline. Changes in HRV will be 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. Our second outcome of interest is the change in anxiety between the intervention and control conditions as measured by the STAI. We will assess change in both primary outcomes of HRV and STAI using repeated measures mixed models. Baseline measures will be included as a covariate. A random effect will be included for the subject variable to accommodate for repeated measures. Least squares means will be used to describe HRV and other outcomes under each intervention. Changes in HRV will be 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% CIs will be used to compare

the outcomes between different interventions. Given an SD of 15 ms in HRV[51] and an estimated STAI score difference of 5.8 (SD=8), we found that a sample size of 38 per group will provide 80% power at the two-sided 0.05 significance level to detect differences of 10.8 ms, an effect reflecting clinically meaningful changes to stress in prior HRV studies.[20] This sample size is a conservative estimate as we expect improvements in power (or detectable effect size), given the repeated post-randomisation assessments. Nevertheless, we will enrol 42 participants per group to accommodate a potential 10% loss to follow-up.

ETHICS AND DISSEMINATION

All phases of the current study have been reviewed and approved by our institutional review board. Process improvement simulations and qualitative interviews were deemed exempt. Our clinical trial has been reviewed and approved. Standard of care will be maintained during implementation of the CRI:SIS study, but minimal risks do exist for both participants and research staff. The use of real-time physiological measurement through wearable device introduces a risk of minor discomfort for participants. To mitigate this, we provide a range of shirt sizes to ensure best fit. To maintain confidentiality, study data will be deidentified using unique study participant identifiers. In addition to participant risks, embedding non-clinical research staff in the ED presents a potential risk of exposure to the research staff. In compliance with local university, hospital, and ED guidelines, detailed plans for infection prevention will include research staff training on methods to minimise risk exposure, including proper donning and doffing of PPE and protocols for social distancing during observations. All observations will be conducted within an appropriate area to accurately capture visual and verbal information while minimising exposure risk.

There are no physical interventions in this study, so there is no risk of physical harm. Therefore, the investigators feel that additional monitoring by a data and safety monitoring board is not required. All adverse event forms will be completed by the principal investigator (LE), and the severity of the event and the relationship of the event to the study will be graded based on standard definitions. Adverse events, as well as any unanticipated problems or changes to the protocol that arise, will be reported within 48 hours to the Yale University Human Investigations Committee. The study team will apprise study personnel of all adverse events or unanticipated problems during monthly (more frequently as needed) study meetings. Additionally, a full report will be provided annually to the Yale University Human Investigations Committee and the funding agency programme officer. The effect of adverse events on the risk:benefit ratio of the study will be re-evaluated by the investigators with each event, with appropriate adjustments made to the protocol or consent forms if needed. Given the minimal risk of the study and intervention, the investigators do not anticipate the occurrence of any serious adverse events. At the time of publication of any manuscripts that arise from this research, the deidentified data for that manuscript will be made available to share for scholarly activities. Qualitative data will be shared as a deidentified Dedoose dataset, and quantitative data will be shared as a deidentified .csv file. Sharing of the data will require a data use agreement to be established between the requesting institution and Yale University. Data will be shared through secure file transfer.

COVID-19 has upended all aspects of normal quality improvement routines, and therefore innovative solutions are required to address safety issues due to the pandemic. Rapid dissemination is particularly crucial to alleviate challenges faced by front-line healthcare workers as they continue to care for patients in a constantly changing environment. We will immediately begin to disseminate our CRI:SIS simulation intervention for clinician preparedness to other institutions facing similar challenges while simultaneously collecting and analysing data throughout the 2-year study. We will engage emergency medicine residency training programme directors, simulation educators, and ED and hospital administrators across the USA. Participants will first observe the scenarios implemented within the clinical trial intervention. Specific scenarios targeting the institution's needs will then be selected and tailored to the institutional guidelines. Finally, we will facilitate the implementation of the scenario(s) in the virtual telesimulation format for the participant institution.

DISCUSSION

The proposed project will implement the CRI:SIS, a simulation-based training and quality improvement intervention that will minimise physician stress and improve system responsiveness. Medical simulation provides the opportunity for standardised practice for high-stakes events and the identification of latent safety threats.[8] We will develop a packaged set of immersive simulations based on qualitative data from staff participants and guidance from the departmental COVID-19 ED Task Force. These scenarios will then be delivered as just-in-time simulations to prepare physicians working within the subsequent week. Our objectives were to (1) identify factors associated with improved physician preparedness and adoption of guidelines, (2) lower levels of anxiety and stress in emergency physicians caring for acutely ill patients with COVID-19, and (3) rapidly disseminate simulation-based scenarios for COVID-19 preparedness to inform continued process improvement and detect latent patient safety threats at other hospital and institutions. In the age of COVID-19, public lockdown and social distancing measures to combat viral transmission have altered operations in many training centres. In response to these operational challenges, our team developed a rapidly adaptive simulation programme that allows for transition along a continuum from in-person simulation to fully remote

virtual telesimulation for delivery of our preparedness and threat detection programmes despite local restriction guidelines. We will couple this advancement with our prior work on simulation training techniques to mitigate clinician stress as measured by changes to HRV.[52]

Outcomes of the current work will both address the needs of clinicians in the current COVID-19 pandemic as well as provide a blueprint for achieving system readiness. If proven successful, the CRI:SIS rapidly adaptive simulation programme will be readily scalable and applicable at other institutions to improve and evaluate the responsiveness of healthcare delivery systems and healthcare professionals to the COVID-19 pandemic. Likewise, as a simulation-based continuous process improvement programme, CRI:SIS will provide a model for simulation-based preparedness to maintain readiness and incorporate lessons learnt from the COVID-19 pandemic into future system responses. We have initiated the qualitative interviews and started participant enrolment for the clinical trial as of November 2021 and plan to complete data collection for both aims of the project by Spring of 2022.

Our study does face several limitations. The most significant limitation is the natural variation in COVID-19 presentations. To mitigate this limitation, we will closely monitor local rates as well as capture rates of COVID-19-positive or suspected cases seen each shift by our participants. We may also face a lack of buy-in and participation in this time of high work and social demands. However, our pilot COVID-19 virtual telesimulation programme for resident physicians successfully enrolled 36 individual participants across a 4-week period with continued interest in additional simulation opportunities suggesting a demand for simulation preparedness programmes. A voluntary recruitment strategy brings forth the potential limitation of a non-response bias from physicians who chose not to participate. There may be a potential bias for attending physicians uncomfortable with the telesimulation 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. However, we suspect the desire to gain this information will outweigh those fears.

Additionally, we have developed a strong collaboration infrastructure in place with the ED administrative team and members of the ED COVID-19 Task Force in support of our proposed project. The ED COVID-19 Task Force has worked to develop a continuous improvement effort to respond to both feedback and system changes, which our study will further support. As the pandemic evolves, clinician knowledge, skills and experiences have rapidly advanced. We will address this changing landscape of participant experience both through an explanatory lens with our qualitative interviews as well as directly through our rapidly adaptive approach to our simulation scenarios incorporating both continuously updated guidelines and concerns. Finally, outcomes will only be assessed across two EDs in the same hospital. However, we plan for tailored dissemination at additional sites across regions. Assessment of dissemination will be guided by local sites and not strictly from the current study protocol.

Twitter Arjun K Venkatesh @arjunvenkatesh and Ambrose H Wong @ambrosehwong

Contributors JMR, AHW and LVE conceptualised and designed the overall protocol. LVE, JWB and MJ designed the simulation intervention. AKV and JDD advised on methodological and statistical design. JNG participated in overall planning and manuscript preparation. All authors provided critical review of the manuscript.

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Competing interests AHW reported receiving grants from Robert E. Leet and Clara Guthrie Patterson Trust Mentored Research Award and grants from NIH K23MH126366 outside the conduct of the study. JMR reported receiving grants from NIH R01MD014853 and American Medical Association Foundation outside the conduct of the study.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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ORCID iDs
Jessica M Ray http://orcid.org/0000-0003-3410-1507
Ambrose H Wong http://orcid.org/0000-0001-7471-1647

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