

TITLE PAGE

Improving patient and clinician safety during COVID-19 through a rapidly adaptive simulation intervention

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1. ABSTRACT

Purpose: **Aim 1:** Identify factors that influenced clinician stress and burnout through qualitative interviews during the care of COVID-19 patients; **Aim 2:** determine the efficacy of COVID-19 Responsive Intervention: Systems Improvement Simulations (CRI:SIS) to assess physician stress throughout clinical shifts during the care of COVID-19 patients; **Aim 3:** test a simulation-based process improvement strategy that informs COVID-19 care guideline updates.

Scope: Stressful work environments and burnout lead emergency medicine (EM) healthcare providers to leave their jobs. The future EM workforce will need to prioritize provider well-being to ensure optimal patient care.

Methods: 1) We conducted qualitative interviews with frontline workers during the COVID-19 pandemic. 2) We conducted a randomized prospective clinical trial testing CRI:SIS as a preparedness intervention on decreasing emergency physician stress by assessing changes in heart rate variability (HRV) and State-Trait Anxiety Inventory (STAI) during clinical shifts. 3) We tested a process improvement strategy through rapid cycle iterative loops of simulation-based testing of guidelines and design prototyping for Emergency Department (ED) administrators.

Results:

1) Qualitative interviews with healthcare providers resulted in rich responses related to the impact of COVID-19 on resident training and emotional well-being as well as helped identify factors outside of the emergency department that directly impacted provider emotional well-being. 2) HRV data resulted in a significant reduction in clinical stress immediately following CRI:SIS in the intervention group versus the control group. 3) Our process improvement strategy led administrators to make real-time recommendations for front-end workflow of a new ED clinical space.

Key Words: COVID-19 pandemic, Emergency Medicine, physician burnout, heart rate variability, simulation intervention

2. PURPOSE

During COVID-19, increasingly prevalent occupational stressors threaten safe, high-quality patient care and system responsiveness. (1, 2) 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 objective, we divided our study into three specific aims:

1. Identify factors that influenced system responsiveness, hazards, clinician stress and burnout, and adoption of COVID-19 care delivery protocols through qualitative interviews with clinicians with experience in the care of critically ill COVID-19 patients.
2. Assess the efficacy of our simulation intervention on physician stress and anxiety during the COVID-19 pandemic through a multi-site, randomized clinical trial assessing changes in heart rate variability as a physiologic measure of stress and State-Trait Anxiety Inventory as a measure of physician anxiety.
3. Test a simulation-based process improvement strategy that informs iterative refinement of COVID-19 care guideline updates and supports physician engagement in safety culture via focus group debriefings with emergency physicians.

3. SCOPE

Background

The extended response to the novel coronavirus 2019 (COVID-19) pandemic has increased clinician work burden and risk for infection while creating an environment of uncertainty, especially as the easing of government lockdown measures and potential additional surges of infection were expected in the near future. (3-6) Rapidly evolving care guidelines for patients result in continuous changes to implementation at the bedside, presenting the opportunity for unintended consequences and the introduction of latent safety threats.

Though much of the current attention in clinical research is focused on healthcare system preparedness, diagnostic testing, and medical treatment of patients with COVID-19, experts have increasingly raised concerns regarding the wellness of the front-line health workers who are directly diagnosing and managing critically ill patients during this pandemic.

Clinician exposure to acute occupational stress events can activate the sympathetic nervous system, resulting in key physiologic changes. Repeated or continuous stress exposure, leading to the syndrome of burnout in physicians, is also linked to increased medical errors, increased risk of patient safety incidents, extended patient waiting times, and decreased patient satisfaction. To address patient safety in the current pandemic, we must first address the safety needs of our clinicians caring for these patients. (7, 8) 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 patient-care conversations. Therefore, system responsiveness and clinician preparedness are needed to prevent safety threats for clinicians and patients. (8) If these needs are not met, COVID-19 presents an increased risk of infection, anxiety, and burnout for clinicians.

Simulation, a technical field that applies experiential techniques to practice, learn, evaluate, and test systems or human actions provides a proven methodology for improving system responsiveness and process improvement. (9, 10) We developed and piloted a new rapidly adaptive simulation intervention to increase guideline adoption and preparedness for COVID-19 care delivery. Building upon this work, we developed and tested the COVID-19 Responsive Intervention: Systems Improvement Simulations (CRI:SIS), a simulation-based training and quality improvement intervention that minimized physician stress and improved system responsiveness.

Context

Aim 1

We conducted in-depth interviews with emergency physicians to explore the facilitators and barriers to adopting COVID-19 guidelines into practice amidst a changed healthcare sector landscape. In response to the COVID-19 pandemic, local task force teams iteratively designed and implemented a series of new guidelines, clinical decision pathways, and companion checklists to support patient and clinician safety and ensure compliance with standards of care. However, rapid changes in knowledge of COVID-19 disease processes and presentations and declining resource availability required frequent updates to these practice guidelines. Though daily updates from local task force teams are delivered via email and print materials, the rate of systemic adoption of these protocols was unknown.

Aim 2

During the pandemic, our team developed and piloted a COVID-19 simulation intervention designed to support preparedness for the clinical stressors physicians encountered caring for patients with COVID-19 in the ED. This randomized clinical trial focused on health worker preparedness to mitigate physician anxiety and stress. Our approach utilized our innovative adaptive simulation program that could rapidly shift between remote virtual telesimulation 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. To achieve similar benefits, we designed our virtual telesimulation platform to retain as many cognitive and affective learning features of the live simulation environment as possible while adapting the simulation experience to a virtual videoconferencing platform. This rapidly adaptive format allowed us to maintain the 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 aimed to mitigate healthcare worker stress through preparedness and engagement.

Aim 3

Change is difficult, especially in the healthcare setting. In March 2022, our tertiary care teaching hospital emergency department (ED) underwent a massive change in workflow with the construction of a new emergency care space (ECS), a temporary satellite structure to increase ED capacity. The ECS represented a large change in workflow, including a new physical space, a new front-end triage process, and a physician in the waiting room making triage decisions. In the first month, 35% of ED patients were seen in this space. Prior to opening, there was concern among staff about whether the change in operations would be successful.

To encourage a positive change mindset, we developed a simulation model to identify and clarify new policies, procedures, and logistics to improve the new workflow.

Participants and Setting

Aim 1

From January 2021 to October 2021, we recruited 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 included all providers having worked at least one clinical shift since March 2020 at either of the two Yale New Haven Health (YNHH) ED campuses. These two campuses are geographically and structurally unique academic ED sites: 1) York Street Campus, the tertiary care referral center 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. All participants were targeted via email, recruitment fliers posted in the ED, and in-person staff meetings. Participation was voluntary, and interviewees were compensated with a \$25 gift card for their time. Participants provided written consent at the time of recruitment and interview scheduling.

Aim 2

From January 2021 to December 2021, we recruited eligible resident or attending physicians actively treating acutely ill patients with COVID-19 (and suspected COVID-19) at either YNHH ED campus. Eligible participants worked full-time in one of these two EDs with an 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. Enrolled participants were divided into two groups based on experience level: *junior* (PGY1-3) and *senior* (PGY4+). Eligible participants were selected for recruitment based on proximity to working clinical shifts in the ED at either one of the two YNHH campuses and recruited via email and in person at staff meetings. All virtual tele-simulation interventions were hosted remotely via Zoom and conducted in a location of the participant's choosing. Participation was voluntary, and participants were compensated with a \$25 gift card per completed shift. Exclusion criteria included the use of beta blockers and antiarrhythmic medication, active thyroid dysfunction, and pregnancy. At the time of enrollment, participants signed a statement of written consent before proceeding with baseline data collection.

Aim 3

From March 2022 to September 2022, we recruited emergency nurses, advanced practice providers, and attending physicians scheduled to work in the new ECS at the YNHH York Street campus. Both clinician participants and administrative stakeholders were recruited to participate in each design session. Virtual simulations and design sessions were conducted via Zoom in a location of their choosing; however, participants finishing a clinical shift together would conduct the simulation as a group in a conference room. In situ simulations were conducted in person in the new ECS and the YNHH York Street emergency department. Enrollment was voluntary, and both simulation and session participation were compensated with a \$25 gift card for their time. Participants provided written consent at the time of recruitment and interview scheduling.

4. METHODS

Study Design

Aim 1

This qualitative study aimed to determine factors affecting system responsiveness and clinician stress during the COVID-19 pandemic. We conducted in-depth (30- to 45-minute) interviews with emergency department clinical staff with experience treating COVID-19 (and suspected COVID-19) patients. Qualitative interviews were based on normalization process theory (NPT), a sociological theory that identifies, characterizes, and explains fundamental mechanisms that promote and inhibit the implementation, embedding, and integration of new health innovations, technologies, and clinical practices. (11) Interview topics were organized around the four core constructs within NPT to explore barriers and facilitators of guideline adoption and factors contributing to clinician stress and burnout. Our research team consisted of an interprofessional group with expertise in psychology, human factors, systems engineering, and emergency medicine to provide a spectrum of perspectives and evaluate providers' experiences in the emergency department setting. The Yale University Institutional Review Board approved our study protocol.

Aim 2

We conducted a randomized controlled trial to test the effectiveness of our simulation-based preparedness intervention (CRI:SIS) in mitigating physician stress, physiological stress, and anxiety when caring for patients with COVID-19. All participants first completed a baseline session prior to the first data collection. After completing the first two data collections, participants were randomized to either the control or intervention arm. Participants randomized to the intervention arm completed a scheduled intervention session before completing two more data collections following the intervention. Participants randomized to the control arm participated in four shift data collections without additional intervention. However, these participants had access to the routinely distributed COVID-19 Task Force updates, guidelines, weekly town hall meetings, and any in-service support available to all clinical staff per standard operational practice in our local departments.

Aim 3

We designed a rapidly adapting simulation model to address the changes in departmental workflow with the opening of the new ECS. We conducted four cycles of simulations from February 2022 through August 2022. Each cycle consisted of four sessions: two virtual simulations conducted via Zoom and our novel platform, one in-situ simulation in the ED and new ECS, and one participatory design session with participants from the prior simulations, simulation faculty, and emergency department administrators from the ECS task force.

Data Collection

Aim 1

Through interviews with emergency physicians, we collected qualitative data on preparedness, adoption of COVID-19 care guidelines, and perceived risks and hazards to clinician and patient safety. All interviews were audio recorded and professionally transcribed for analysis.

We employed a systematic, inductive approach with initial open coding, followed by group consensus on major themes through an iterative analytic process using the constant comparative method as more information is added after each simulation session.

Aim 2

Participants were fitted with appropriately sized Hexoskin Smart Shirts (Carré Technologies Inc.) with physiologic sensors embedded within the textiles. These portable sensors allow continuous cardiorespiratory and activity monitoring via a one-lead electrocardiograph, two respiratory inductive plethysmography (RIP) sensors, and a three-axis accelerometer. This non-invasive technology captured moment-by-moment physiological heart rate data necessary to calculate heart rate variability (HRV) changes as measures of stress during the care of patients with COVID-19. (12, 13) All participants wore a Hexoskin smart shirt underneath their standard scrub shirt for four consecutive data collections. At the start of each participant's shift, a research assistant was present to confirm data capture. Following end-of-shift sign-out, a research assistant administered the 20-item state subscale of the STAI to capture state-anxiety data on perceived stressors experienced during the shift. (14)

Aim 3

Qualitative data was generated from debriefing focus groups held immediately after the simulation's completion, and they were transcribed from recorded audio files from each simulation. As described in the qualitative analysis in Aim 1, we used thematic analysis to evaluate and analyze the debriefing sessions. After completing all simulations, the research team compiled a thematic overview for presentation during the design session.

Interventions

Aim 2

Participants randomized to the intervention arm received CRI:SIS after two shifts of HRV data collection as a block 3-hour simulation session 1 to 5 days before their next recorded clinical shift. CRI:SIS consisted of four intervention scenarios in which COVID-19-related presentations, with varying severity of illness, 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 in the ED. All scenarios were designed to address the 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. The scenarios included in the intervention focused on four critical areas of COVID-19 patient care and were administered consistently in the following order:

1. Comfort measures only COVID-19: A patient presenting with severe illness and poor prognosis requiring the provider to discuss goals of care or withdrawal of care in the ED.
2. Mild COVID-19: A COVID-19-positive patient meeting discharge criteria adapted to address vaccine hesitancy.
3. Moderate COVID-19: Management required calculating the COVID-19 Severity Index to determine the correct treatment, potential for clinical deterioration, and correct patient disposition.

4. Severe/life-threatening COVID-19: A patient with severe hypoxemia with a post-intubation elevation of PEEP leading to a pneumothorax. The provider must understand strategies to address severe hypoxemia and the associated complications.

Each scenario was followed by a debriefing session to interactively analyze the learners' management decisions. The recommended critical actions for each scenario were updated, and the scenario was adapted as new recommendations for COVID-19 protocols were implemented. For each intervention session, the most current hospital protocols were used to address any gaps in knowledge. Additionally, patient presentations were continually modified across sessions to highlight potential pitfalls or challenges that commonly arose as the pandemic evolved.

Aim 3

We implemented a simulation-based process improvement strategy that informed the iterative refinement of front-end workflow in the new ECS. As provider needs and challenges evolved and developed throughout the rollout, so did our simulation topics. The simulations for each cycle were structured as follows:

Cycle 1

Virtual Simulation Sessions 1 and 2 focused on front-end flow in advance of the opening of the new ECS space. The in-situ simulation session involved an unstable patient in the ECS - atrial fibrillation with rapid ventricular response (A-fib with RVR). The sessions focused on evaluating indoor route transfer time, monitoring, and equipment availability. The design session discussion focused on pre-opening protocol concerns, such as new triage protocols, physician relocation to triage, and transfer criteria to the main ED.

Cycle 2

Front-End Flow:

Virtual Simulation Sessions 1 and 2 focused on the challenges posed during the initial month of the ECS opening. The in-situ simulation session required management of a patient with anaphylaxis coding in the ECS, evaluation of outdoor route transfer time, management by the code response team, and communication between the ECS and main ED. The design session discussion focused on addressing post-opening challenges, such as updated triage guidelines and establishing a procedure room in the ECS.

Cycle 3

Virtual Simulation Sessions 1 and 2 focused on the workflow, load balancing, use of specialized rooms, and burnout of the APPs working in the new ECS space. The in situ simulation session was a postictal patient in the ECS based on safety concerns and identifying best practices in transfer routes, ECS care, and handoff. The design session discussion focused on barriers to APP workflow and solutions to improve morale.

Cycle 4

Virtual Simulation Sessions 1 and 2 focused on ECS in-patient admissions. Due to a recent national outbreak, the in-situ simulation session was designed to treat a patient with monkeypox, implementing pathways, isolation, reporting, and treatment for emerging infectious disease. The design session discussion focused primarily on the concern of ED crowding, especially the

responsibilities of the charge nurse, the movement of patients between the ECS and the main ED, and patient handoff around the time of staff changeover.

Measures

Aim 1

To identify factors that influence system responsiveness, hazards, clinician stress and burnout, and adoption of COVID-19 care delivery protocols, interview transcripts were analyzed for emergent themes of adoption facilitators and barriers. We used Dedoose (SocioCultural Research Consultants), a collaborative qualitative software package, for thematic analysis and data organization. In order to create the code book, the coding team utilized a systematic, inductive approach. After an initial round of blinded open coding, additional codes were identified and integrated with existing codes through group discussions. As more information was added with additional interviews, an iterative analytic process achieved a consensus on major themes. This data informed the refinement of CRI:SIS to ensure that we embedded information to improve preparedness and mitigate stress during clinical care for our participants.

Aim 2

Evidence suggests links between physiological measures of acute stress and the emotional exhaustion subscale of burnout. We used smart shirts to evaluate physiologic stress by measuring participant heart rate, HRV, and activity levels, such as cadence. Anxiety was assessed using STAI, a commonly used measure of trait and state anxiety in clinical settings to diagnose anxiety and in research as an indicator of participant distress. The primary outcome of interest compared the change in HRV and STAI pre-intervention and post-intervention. For HRV, we targeted 5-minute windows at the end of the shift before sign-out as a measure of cumulative shift stress. All STAI surveys were administered immediately after the completion of the shift. A baseline session captured each individual's resting heart rate, and a 40-item STAI survey evaluated their baseline state and trait anxiety.

Aim 3

The opening of the ECS presented several changes to the front-end workflow in the emergency department. To evaluate the effectiveness of these changes, we designed a virtual platform simulating the stressors of the front-end triage of a large emergency department. In addition to changes in workflow, the opening of the ECS included an entirely new treatment space, which was not contiguous with the main emergency department. The in-situ simulations addressed the new treatment space's physical, geographical, and resource challenges. Design sessions were aimed to address healthcare workers' concerns directly with the task force regarding the new workflow. Additionally, these sessions served to develop the content for the next round of simulations.

We used subjective surveys to evaluate participant perceptions of the simulations at two different time points during the study. To gauge immediate feedback after each simulation, we used a 23-item survey, which provided information on teamwork, cohesion, organizational perceptions, and insights related to the simulation. After each cycle, a second nine-item survey was conducted to provide a generalized interpretation of the overall experience.

Limitations

Aim 1

This aim faced several limitations. First, participation was voluntary, and several clinicians did not respond to the study request or ultimately chose not to participate. The larger proportion of physicians compared to nurses and technicians who were interviewed, as well as the absence of additional support staff who work in the ED, such as environmental services workers, secretaries, chaplains, and social workers, may have had different experiences than those who chose not to participate in our study and so biased our findings. Second, interviews took place throughout the pandemic, and memory processing and decay over time could affect the recall of the event and the emotions surrounding the event. Therefore, individual interviews may have been subject to recall bias, or significant events ongoing at the time of the interview could have affected the recollection of the experience. Last, this study was conducted at select sites in a single regional healthcare system; thus, generalizability may be limited.

Aim 2

Our primary limitation for this aim was artifacts during physiologic data collection. We implemented a standardized protocol during data collection with wearable smart garments to assess the quality of data capture at the start of a session. However, throughout an 8-hour clinical shift, the signal quality can degrade. The prevalence of artifacts in recordings posed a dilemma regarding window selection and whether to use one representative window or sample the entire shift, which would have limited our participant pool. A second limitation we faced was collecting data via ED field observations. In compliance with local university, hospital, and ED guidelines, research staff were trained on methods to minimize risk exposure, including proper donning and doffing of personal protective equipment and protocols for social distancing during any data collection in the ED. However, we could not complete field observations, because embedding non-clinical research staff in the ED presented the potential risk of exposure to research staff.

Aim 3

One potential limitation was a lack of buy-in and participation by stakeholders in a time of high work and social demands. Furthermore, because feedback was reported to administrative leadership, some individuals might have been hesitant to voice their true feelings regarding questions on safety culture and support. Though administrative leadership aligned their decision making with our simulation findings throughout the study period, we could not directly implement any changes and ultimately could only provide recommendations for changes.

5. RESULTS

Principal Findings

We identified safety barriers to adopting COVID-19 guidelines in the emergency department, assessed the impact of a simulation-based preparedness intervention on physician stress and anxiety, and tested a simulation-based process improvement strategy to increase emergency department safety culture during COVID-19.

Aim 1

Through the coding of qualitative interviews, we determined factors affecting system responsiveness and clinician stress during the COVID-19 pandemic. We further identified the educational and personal impacts the COVID-19 pandemic had on the training and experiences of emergency medicine resident physicians and the external factors that impact physician well-being. We reached data saturation with 27 individuals to ensure the richness of data in qualitative research. Of those interviewed, 19 (70.4%) were women, and 24 (88.9%) had worked in the emergency department throughout the COVID-19 pandemic. Those interviewed were predominantly experienced healthcare workers with more than 4 years of experience (19 [70.4%]), and the majority of the participants interviewed were physicians (18 [66.7%]). Ten resident physician participants were included, representing six senior residents (PGY-3 or PGY-4) and four junior residents (PGY-1 or PGY-2).

Qualitative analysis identified three primary themes related to external factors affecting healthcare workers during the pandemic: (1) external and structural factors impacting emergency care; (2) resource limitations impacting care quality; (3) social emergency medicine and population needs during COVID-19. Three major recurring themes emerged during our analysis of the resident physician interviews: (1) novel educational experiences dampened by negative structural forces from the pandemic, (2) fracturing of social interactions and mitigation through ad-hoc support systems and community of practice, and (3) development of negative emotions and psychological trauma, including fear, resentment, and moral injury, causing lasting harm.

Aim 2

We successfully recruited and enrolled 82 participants and achieved a final sample size of 81, meeting our prespecified power requirements for mixed model analysis. (15) Data collection concluded after all enrolled participants completed four data collections and the simulation intervention. Overall, 41 participants were randomized to the control arm (20 juniors and 21 seniors), and 40 participants were randomized to the intervention arm (20 juniors and 20 seniors). Some participants were excluded from analyses due to ECG recordings not meeting our quality threshold of clearly identifiable R-R intervals (RRi) or technical errors during the capture process. After adjustment for data quality, 72 participants were determined to have ECG data with high enough quality to be used for analyses (89% retention). Of these remaining participants, 37 were in the control group (17 juniors and 20 seniors), and 35 were in the intervention group (16 juniors and 19 seniors).

Heart rate data were collected across 324 clinical shifts by 81 healthcare providers, meeting our target enrollment. After post-processing and evaluation of ECG data quality, 278 clinical shifts across 72 participants were determined to have data with high enough quality to be used for the mixed model regression analysis. HRV was assessed as the time-domain measure of root mean square standard deviation (RMSSD) of sequential RRi. ECG recordings were algorithmically converted, processed, and analyzed to calculate RMSSD using a novel algorithm called HRVEST, developed by our team. HRVEST is a noise-filtering and data-processing algorithm that successfully processed the enormous volumes of physiologic raw data generated by wearable smart garments and meets the specific needs of HRV analyses. HRVEST automatically processed the biometric data from 413 electrocardiogram (ECG) recordings in just over 15 minutes.

Using mixed-model regression with a fixed intercept for our selected windows showed that decreased stress (increased HRV) occurred in shifts immediately following CRI:SIS in the intervention group versus the control group denoted by RMSSD differences of 13.4347 ms ($p < 0.004$) and 12.5841 ms ($p < 0.040$) for Clinical Shifts #3 and #4, respectively. There were no statistical differences between the baseline measurements of the intervention and control groups for RMSSD or trait anxiety. There was also no significant difference found between groups in the self-reported post-shift state anxiety scores between intervention and control.

Aim 3

Post-simulation surveys indicate participants found the simulation sessions helpful in adjusting to the new workflow of the ECS. Transcript analysis of the four rounds of design sessions found several recurring themes: 1) Simulation sessions helped clarify new policies and procedures for the ECS. 2) Logistical challenges with the new ECS were identified through the simulation sessions and addressed during design sessions. 3) Overall perception of the ECS was improved after design sessions.

The post-simulation survey data showed that 92% of respondents agreed that people support one another in the ED. This is also consistent with the data that 59% of participants agreed that people help each other when the ED environment gets busy. Around half (47%) believe activities are underway to improve patient safety, and 82% say they would speak up if they see something negatively affecting patient care. However, from an institutional perspective, only 28% believe that management provides a work climate that promotes patient safety, and over half cite the lack of coordination between hospital units.

The end-of-cycle survey was primarily conducted among registered nurses (N=10) and advanced practice practitioners (N=9), representing 19 of the 24 total participants. Of survey respondents, 70% agreed that they felt informed of their respective roles in the annex space, and 87% felt that they understood which patients should go to the annex space. Two thirds of the participants (67%) felt that simulation helped them better prepare for the task. Furthermore, 91% of the participants thought that the simulation was helpful in their learning process, and 83% felt that the Design Session with leadership was helpful. Additional results from this aim of the clinical trial are pending further analysis.

Discussion

Aim 1

The overarching goal for this aim, when we set out to interview healthcare workers regarding their experiences during the COVID-19 pandemic, was to identify facilitators, barriers, and unintended safety risks and hazards affecting clinician stress and system responsiveness in the approach to delivery of care during the active phases of the pandemic. Through semi-structured interviews of healthcare workers, we identified many factors external to the ED environment that impacted their experience and ability to care for patients at the bedside. During the COVID-19 pandemic, healthcare workers were forced to navigate a complex landscape of national policy, public opinion, and the effects of a global pandemic on their personal lives.

With the pandemic declared at an end, significant system challenges remain, and medical professionals are recognizing the need to strengthen the resilience of healthcare systems in the future.

Aim 2

The objective for this aim was to test the efficacy of our adaptive simulation-based intervention (CRI:SIS) and whether it could reduce physiologic stress in healthcare providers during the COVID-19 pandemic. As a simulation platform, it received successful iterative updates throughout the study as guidelines and best practices evolved. Our findings indicate that CRI:SIS participants demonstrated reduced physiologic stress as measured by increased heart rate variability in the intervention group compared to the control group. This means that an adaptive simulation intervention during medical crises that seriously impact public health may be a warranted approach in the future.

During this study, we also developed HRVST to address the logistical and data challenges of wearable technologies, particularly in a clinical trial to measure HRV as a marker of physiologic stress in emergency healthcare providers during the COVID-19 pandemic. When using these wearable smart garments, the dilemma was two-fold: (1) the volume of raw physiological data produced is enormous and is recorded in formats not easily portable in standard analytic software, and (2) the commensurate data analysis often requires proprietary software. Furthermore, throughout this study, we identified unique logistical challenges of working with these technologies and proposed solutions that may facilitate future use in broader contexts. With HRVEST, using wearable smart garments to monitor HRV over long periods becomes logistically and feasibly viable for future studies. We also see the potential for real-time feedback to prophylactically reduce emergency physician stress, like informing optimal break taking or short meditation sessions to lower heart rate. This could improve emotional well-being, clinical decision making, and patient outcomes.

Aim 3

Preliminary findings from the post-simulation survey indicate that participants generally believe that within an ER setting, peers will step up and assist one another while at the same time recognizing less-than-optimal functioning across the macro/organizational environment in which they work. The interesting counterpoint to this data is that management becomes more interested in patient safety after an adverse event occurs. This pattern indicates the opinion of management is reactive rather than proactive and may prioritize damage control to the organization and the patient.

The data from the end-of-cycle survey demonstrated positive views on our methodology, with the majority of the group feeling that simulation helped them be better prepared while being helpful. Furthermore, the design sessions, which provided the participants with opportunities to discuss challenges and opportunities with leadership, were very strongly supported. This includes evidence (at least from the subjective perspective) that simulation can be a welcomed and valuable learning tool. Our remaining findings for this aim are pending further investigation.

Conclusions

Aim 1

Frontline healthcare workers interviewed for this study identified a broad and complex array of factors external to the bedside and individual hospital systems that affected patient care, outcomes, and workplace dynamics. Front-line workers offer critical insights and observations on the greater healthcare system and the forces that indirectly affect patient care. They should be considered an essential component of provider support discussions and decision making. Results also suggest that emergency medicine resident physicians, in particular, faced unique experiences concerning their education, social support systems, and emotional states. Although the educational and social experiences were described as having both negative and positive impacts, the emotional experiences were largely negative. Residency program leadership may use these insights to improve resident preparation, wellness, and resilience in the face of future adverse events.

Aim 2

An adaptive simulation-based educational intervention was associated with decreased stress (increased HRV) compared to physician participants who did not receive the intervention. The HRV results may reflect a non-subjective measure of stress on physician participants more accurately than the self-reported assessment of anxiety (STAI).

Aim 3

Our simulation-based process improvement strategy effectively informed the iterative refinement of the front-end workflow of a new ECS and supported clinician engagement. Our recommendations were, in part, operationalized by the ED COVID-19 Task Force and ED administrative partners; however, the results related to these changes in front-end workflow are still being analyzed.

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6. List of Publications and Products

1. Evans LV, Ray JM, Bonz JW, Joseph M, Gerwin JN, Dziura JD, Venkatesh AK, Wong AH. Improving patient and clinician safety during COVID-19 through rapidly adaptive simulation and a randomised controlled trial: a study protocol. *BMJ Open*. 2022;12(5):e058980.
2. Gerwin JN, Boyce MW, Joseph M, Wong AH, Burseson W, & Evans LV. HRVEST: a novel data solution for using wearable smart technology to measure physiologic stress variables during a randomized clinical trial. *Frontiers in Computer Science*. 2024;6.
3. Gerwin J, Evans LV, Moylan T, Bonner S, Buck S. *Fusing Multi-Modal Wearable Data to Enhance Simulation-Based Education*. Presented at: The International Meeting on Simulation in Healthcare 2024; 2024 January 20-24; San Diego, CA.
4. Elyse F, Gerwin JN, Boyce MW, Joseph M, Wong AH, Evans LV. “A Steep Learning Curve”: Educational and Personal Impacts of the COVID-19 Pandemic on Emergency Medicine Resident Physicians. *BMJ Open*. 2024. (Submitted).
5. Evans LV. *An adaptive simulation Intervention decreases emergency department healthcare provider stress while caring for patients during the COVID-19 pandemic: A randomized clinical trial*. Presented at: The 27th Annual Society for Academic Emergency Medicine New England Regional Meeting; 2024 April 3; Worcester, MA.
6. Evans LV. *An adaptive simulation Intervention decreases emergency department healthcare provider stress while caring for patients during the COVID-19 pandemic: A randomized clinical trial*. Presented at: Society for Academic Emergency Medicine Annual Meeting; 2024 May 14-17; Phoenix, AZ.
7. Evans LV & Gerwin JN. *Reducing the Burdens of Healthcare Workers With Hexoskin*. Hexoskin. 2022 December 3. <https://www.youtube.com/watch?v=kskirZg3cJ8>
8. Evans LV, Wong AH, Joseph M, Gerwin JN, Buck S. *Improving patient and clinical safety during COVID-19 through a rapidly adaptive simulation intervention*. Yale School of Medicine Resident Research Showcase. 2022 October 19. New Haven, CT.
9. Joseph, M, Wong AH, Gerwin JN, Fults E, Alloco A, Ray JM, Evans LV. Societal and systemic influence on emergency department healthcare worker experiences during the COVID-19 pandemic. 2024 (In Progress)
10. An adaptive simulation Intervention decreases emergency department healthcare provider stress while caring for patients during the COVID-19 pandemic: A randomized clinical trial. 2024 (In Progress)

11. Buck S, Gerwin JN, Boyce, MW, Sun WW, Venkatesh A, Wong AH, Ikejiani S, Evans, LV. Prophylactic simulation: Improving change culture with an innovative, iterative simulation model. 2024. (In Progress)