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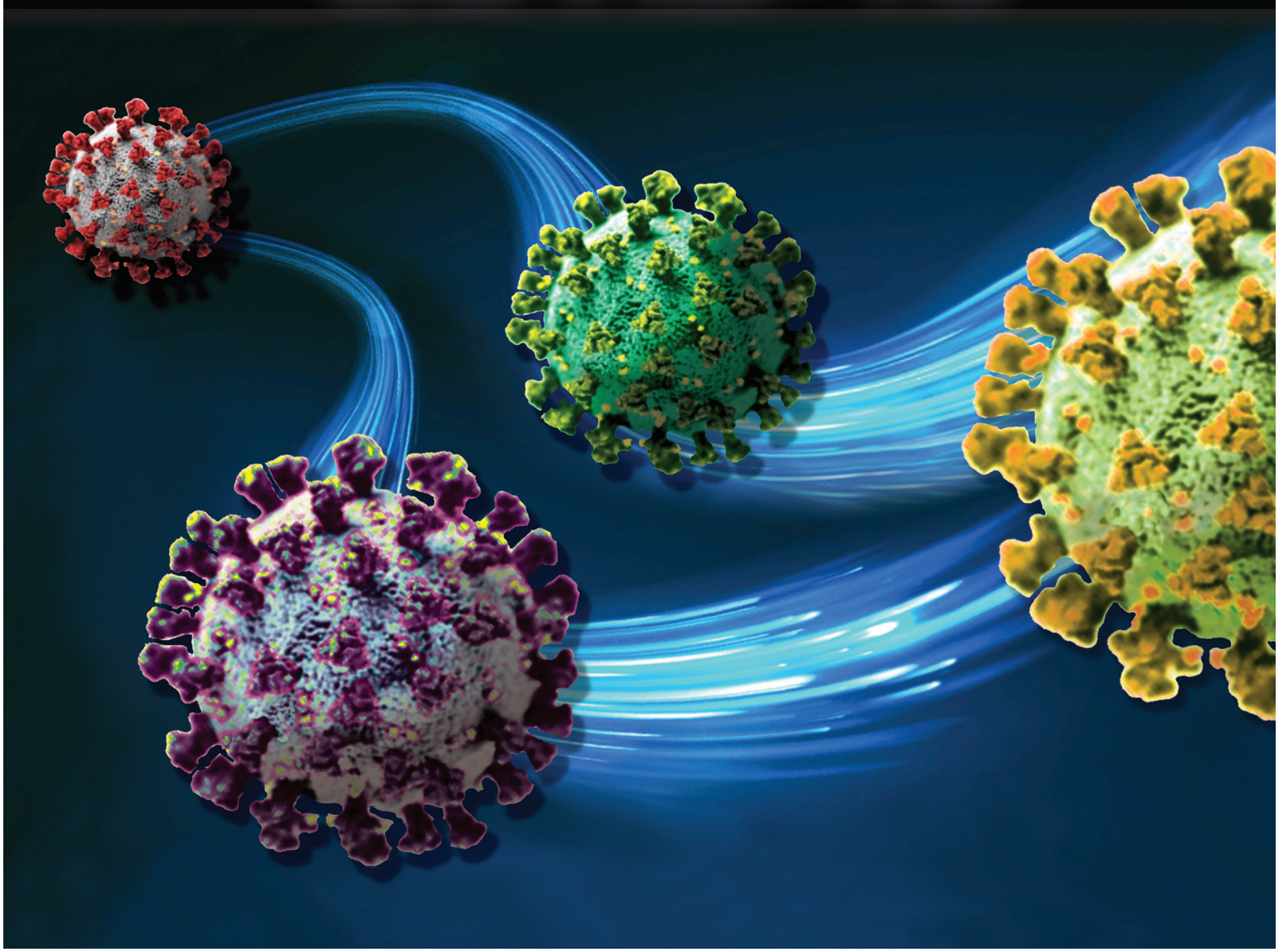
Fall July-September 2022

Navigating COVID-19



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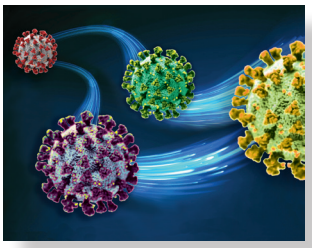

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Note from the Editor...

For almost three years, the world has tried its best to navigate the COVID-19 pandemic. From Alpha to Delta, Omicron to Deltacron, variants seem to develop quicker than we can track. However, one thing remains steadfast. The precautions implemented early on still provide significant defense against widespread transmission. Circumstances are a bit different now. We have several vaccinations available to help combat severe illness, as the world braces itself for a potential new wave of a new variant.

Timing of this issue seems appropriate. In this second COVID-19 volume of *The Medical Journal*, we re-visit the topic of the coronavirus, specifically from the lens of the military medical community, which includes its support to the civilian medical healthcare sector. We hope you find it informative and beneficial.

The Medical Journal accepts submissions year round. Email submissions to usarmy.jbsa.medical-coe.list.amedd-journal@army.mil. Submission guidelines are included in each issue of the journal. To find out more information about the journal and view electronic issues online, log on to our website: https://medcoe.army.mil/the-medical-journal.

The Medical Journal has a current call for submissions focusing on military veterinary medicine. You can view the call for submissions on the journal's website, and be sure to share with friends and colleagues. Submission deadline is 31 August, 2022.

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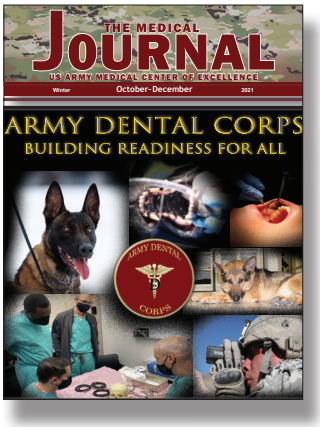

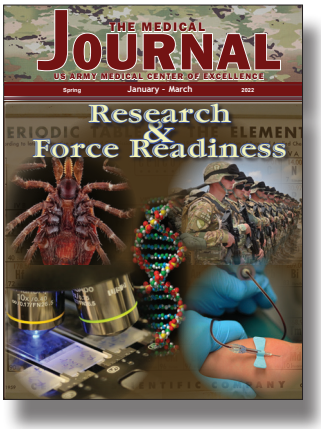

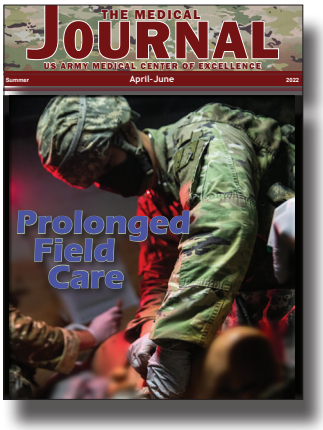

Task Force Contain: A Descriptive Analysis of Brigade Combat Team COVID-19 Operations

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Abstract

Background: In March 2020, a Fort Carson brigade combat team established Task Force (TF) Contain in response to the Coronavirus Disease 2019 (COVID-19) pandemic. We offer a descriptive analysis of the TF Contain execution.

Methods: This study comprises a descriptive analysis of the design and execution of COVID-19 response by an infantry brigade combat team. Specific analyses include patient flow and mitigation measures; task organization; and definition of commander decision points as associated with separate lines of effort.

Results: TF Contain defined separate teams to address each component of the COVID-19 response, each assigned to subordinate battalions. Team Trace augmented the installation medical activity tracing interviews and data collection. Team Isolation provided lodging and life support; whereas, Team Transportation provided movement assets for soldiers requiring restriction of movement related to COVID-19. Team Clean executed disinfection operations at geographic locations determined to be associated with transmission events. Team Oversight enforced standards of mask wear and social distancing throughout the installation. Team Overflow analyzed installation infrastructure for contingency planning in the event more facilities became necessary for soldiers in isolation or quarantine. Finally, Team Testing augmented medical department activity (MEDDAC) medical manpower to staff providers and medics for support testing operations.

Conclusions: Few personnel assigned to this organization had pre-existing experience or training related to infectious disease prevention or epidemiology. Nevertheless, this organization demonstrated the capacity of the military decision-making and operations processes to build robust procedures in response to public health threats.

Introduction

In December 2019, a cluster of pneumonia cases occurred in Wuhan, China.[1-3] This respiratory illness spread, achieving global reach in the following months. In February 2020, the World Health Organization designated the cause of the illness to be coronavirus disease 2019 (COVID-19).[4]

In March 2020, 2nd Infantry Brigade Combat Team (BCT), 4th Infantry Division established Task Force (TF) Contain in response to the COVID-19 pandemic.[5] The mission of this red cycle tasking was to minimize the spread and mitigate the effects of the disease on Fort Carson as well as the greater Colorado Springs, CO, civilian community. This mission was very unique for an infantry brigade combat team ordinarily tasked with very different mission sets related to fires and maneuver in combat. Few of the brigade's key leaders had experience with public health and public health responses, but TF Contain was successful due to the integration of medical expertise with the operations staff and process.

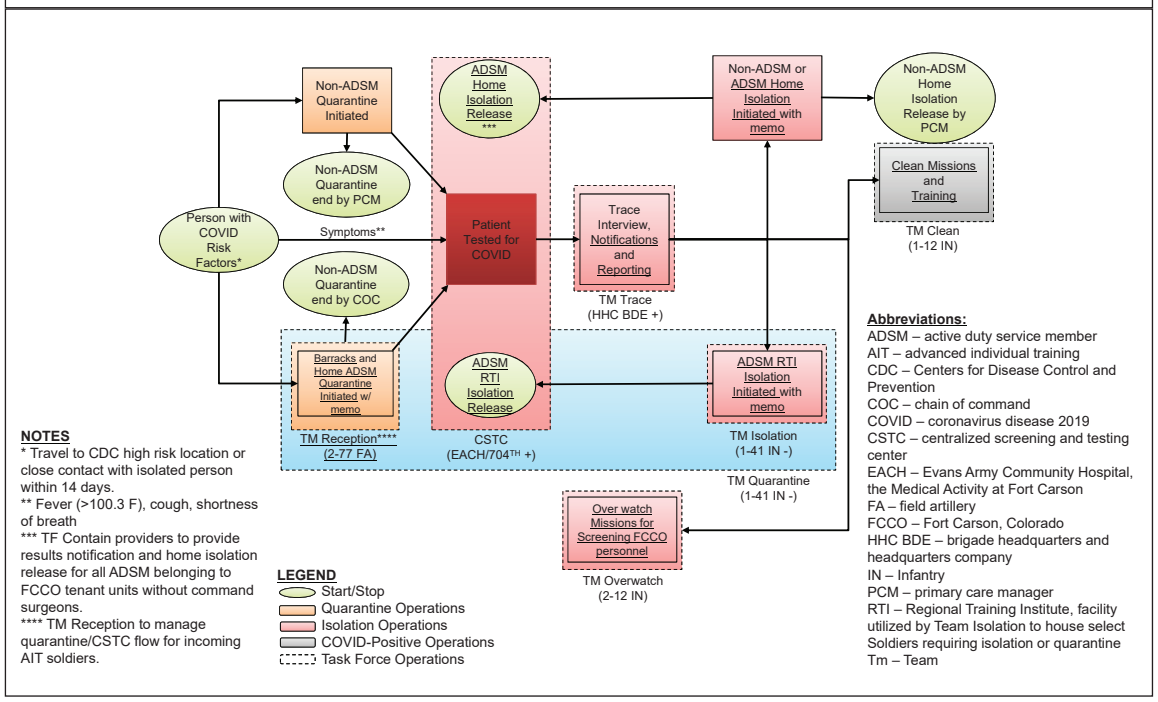
This paper offers a descriptive analysis of the Fort Carson TF Contain execution during the initial phase of the pandemic. The target audience is healthcare personnel assigned to brigade combat teams or other non-medical Forces Command Units. The intent is to empower these

individuals to understand how to leverage the organization of these combat-oriented units to achieve a public health response.

Methods

Study Design & Setting: The study was a descriptive analysis of TF Contain operations on Fort Carson, CO during the initial phase of the pandemic spanning 16 March through 31 May 2020. The analyses encompassed aspects of public health policy, organizational structure, and overall mission execution. It did not include any patient-level data or outcomes. The intent of the study was strictly performance improvement, hence did not meet criteria for research requiring institutional review board oversight.

Figure 1. Task Force Contain operations overview.



Interventions: TF Contain interventions focused on the command, clinical, and public health actions required to mitigate and suppress the spread of COVID-19 throughout the installation. As an installation task force, this focus included work to identify and close any capability gaps for tenant units unable to execute required actions in response to COVID-19 with organic assets. These actions included quarantine for persons with any COVID-related exposures. Exposures included recent travel to high risk locations as defined by the Centers for Disease Control and Prevention (CDC).[6] Alternatively, we considered persons at risk for infection who experienced close contact with confirmed COVID-positive cases; close contact initially defined as greater than 6 minutes of interactions within less than 6 feet.[7]

Individuals developing symptoms consistent with COVID-19 infection (including fever, cough, shortness of breath[1,2,8]) required a distinct set of actions. These included movement to the installation medical department activity (MEDDAC) for diagnostic screening and testing if indicated per the treating provider. Upon testing, these individuals became persons under investigation (PUIs)[9] and subsequently required restriction of movement in the form of isolation. Isolated persons required a deliberate process for isolation release to ensure symptom improvement and minimize risk of ongoing infectivity.

Finally, interventions included public health measures to mitigate and suppress disease spread. This included identification of persons whose contacts suggest they be at risk for or causing further disease spread. These efforts further included identification of locations associated with apparent COVID-19 transmission events. Identification of all of these targets relied upon the timely and accurate conduct of trace interviews.[10-12]

Resourcing Requirements: Utilizing lessons learned from COVID-19 response efforts at other locations, TF Contain identified multiple key requirements for the installation COVID-19 response. These requirements included space for quarantine and isolation of personnel considered high risk, measures to mitigate spread in public places and key facilities, cleaning of locations where the virus was likely to spread, and support to health care facilities. The latter support took the form of both provider augmentation for clinical care and testing delivery as well as trace interviews, all of which required coordination of proper training. TF Contain also identified a need to conduct contingency planning for increased transmission rates and safely transport personnel as soldiers began to move between bases.

Measurements: The 4th Infantry Division, together with the installation MEDDAC, collected a myriad of data

which informed the progress and activity of the task force. This included a personnel tracking document for reporting to higher headquarters the numbers of soldiers and dependents who were on quarantine, isolation pending test results, isolation with a positive COVID-19 status, and finally recovered from any of these COVID-related duty statuses. Both the task force and division monitored and tracked trends in these numbers. The principal staff proponents for these analyses were the intelligence staff cells. These staffs also regularly collated and summarized local and national COVID-19 data from the Johns Hopkins University Coronavirus Resource Center website (https://coronavirus.jhu.edu/us-map)[13,14] and tracking data provided by the *New York Times* on its website (https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html).[15]

The collected data further enabled model-based projections of disease trajectory to inform planning for disease mitigation efforts. Challenges related to these modelling efforts included limitations in existing data to populate model assumptions about disease spread and the existence of dozens of products with different model structures and assumptions invariably leading to broad variance in infection incidence estimates. The CDC forecast website simultaneously presenting source data from multiple models allowed the TF Contain staff to best present projections while accounting for the uncertainty in those projections to commanders.[16]

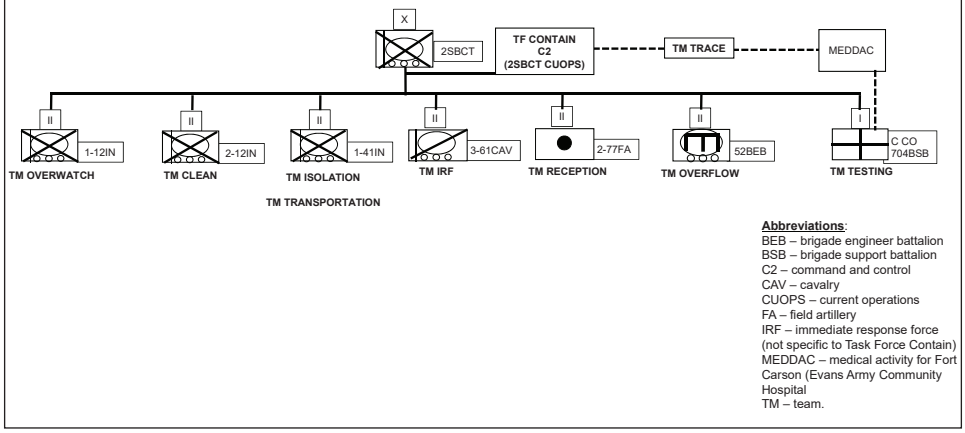
Outcomes: The end state for TF Contain's efforts was to preserve the medical readiness of the fighting force. This end state required considerations related to both active duty service members (ADSMs) but also non-ADSMs, whose interactions with soldiers had important implications for disease spread. Such non-ADSMs included dependents, retirees, Department of Defense (DOD) civilians, contractors. The TF was also mindful of the fact a sharply increasing rate of infection could lead to civilian leaders reaching out for medical expertise, equipment, and facilities from the military. The possibility of a requirement of Defense Support of Civil Authorities (DSCA) operations featured in all TF Contain planning efforts.

Analysis: As a strictly conceptual descriptive analysis for performance improvement purposes, this paper does not report patient-level of epidemiological data for outcomes. Instead, it focuses upon the systems-based solutions employed by the 2nd BCT of the 4th Infantry Division to implement an installation COVID-19 response. Methods of analysis and collation of results included narrative summaries and graphical depictions of these operations.

Results

TF Contain first defined a framework for the primary missions encompassing the installation COVID-19 response. This framework conceptually began with a member of the Fort Carson community potentially exposed to COVID-19 and subsequently proceeded to outline all of the measures required as a result of the exposure (Figure 1). In this construct, green ovals represent start and stop nodes, orange rectangles represent quarantine actions, red rectangles represent isolation actions, and black rectangles represent actions in response to the identification of positive COVID-19 patients. Areas enclosed in dashed rectangles represent actions taken as part of TF Contain operations. The red area enclosed in dashed rectangles specifically represents actions taken at the installation medical activity testing center. The blue area enclosed in a dashed rectangle specifically represents actions by Team Quarantine as part of TF Contain. These measures broadly included processes related to quarantine of exposed asymptomatic persons, isolation of symptomatic persons with unknown or pending COVID-19 status, and isolation and treatment of COVID-positive patients. It further entailed environment or installation actions taken in response to COVID-19 positive cases to prevent further spread of the virus.

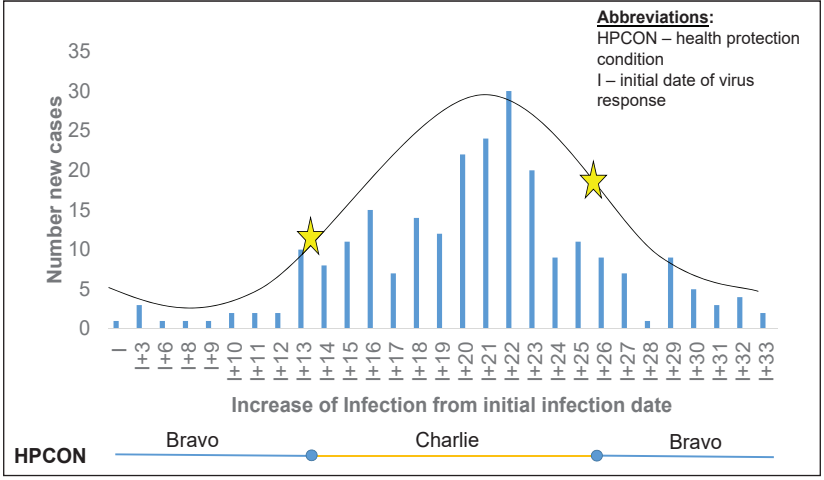
Figure 2. Task Force Contain task organization.



The infantry brigade combat team comprising TF Contain allocated separate battalions to specific teams to execute each of these processes (Figure 2). This diagram depicts each of the 7 battalions comprising the 2nd Infantry Brigade Combat Team assigned to 4th Infantry Division as depicted using military symbology per Army Doctrine Publication

1-02 Terms and Military Symbols. Solid lines represent organic command relationships. Dashed lines represent coordination between formations. Assigning responsibility to discrete pieces of the public health response to individual battalions achieved unity of command. To the extent possible, we assigned task and purpose to each battalion most aligned with their mission essential task list. Of course, each organization had to grapple with missions falling well outside their area of expertise.

Figure 3. Health protection condition status as a function of infection incidence.



Finally, to continue advancing the public health response in light of the evolving epidemiology of the virus, we defined discrete lines of effort for the command team. These lines of effort helped leaders visualize activities and define sequential decision points associated with the activities of each team. The epidemiological picture of COVID-19 spread on the installation as measured by the curve depicting COVID-19 incidence drove progress through the decision points across each of these lines of effort (Figure 3).

This figure depicts decisions for each line of effort aligned with the current epidemiological status on the installation (Figure 3). The horizontal axis represents time measured in days, starting with a conceptual initial date (I). The vertical axis represents the number of new COVID-19 cases in a particular day. Each blue bar represents a data point regarding numbers of infections. The black line represents a trend line. The stars represent conceptual dates aligning with decision points for the commander related to COVID-19.

Decisions points also aligned with separate lines of effort associated with each of the TF Contain teams over the passage of time as indicated by the horizontal axis (Figure 4). Each triangle represents a decision point. Dashed lines represent those pending decisions; green represents decisions with execution ongoing; yellow represents decisions for which resource shortfalls exist; and red represents decisions approved but not yet implemented. The remainder of this section discusses TF Contain components and teams in greater detail.

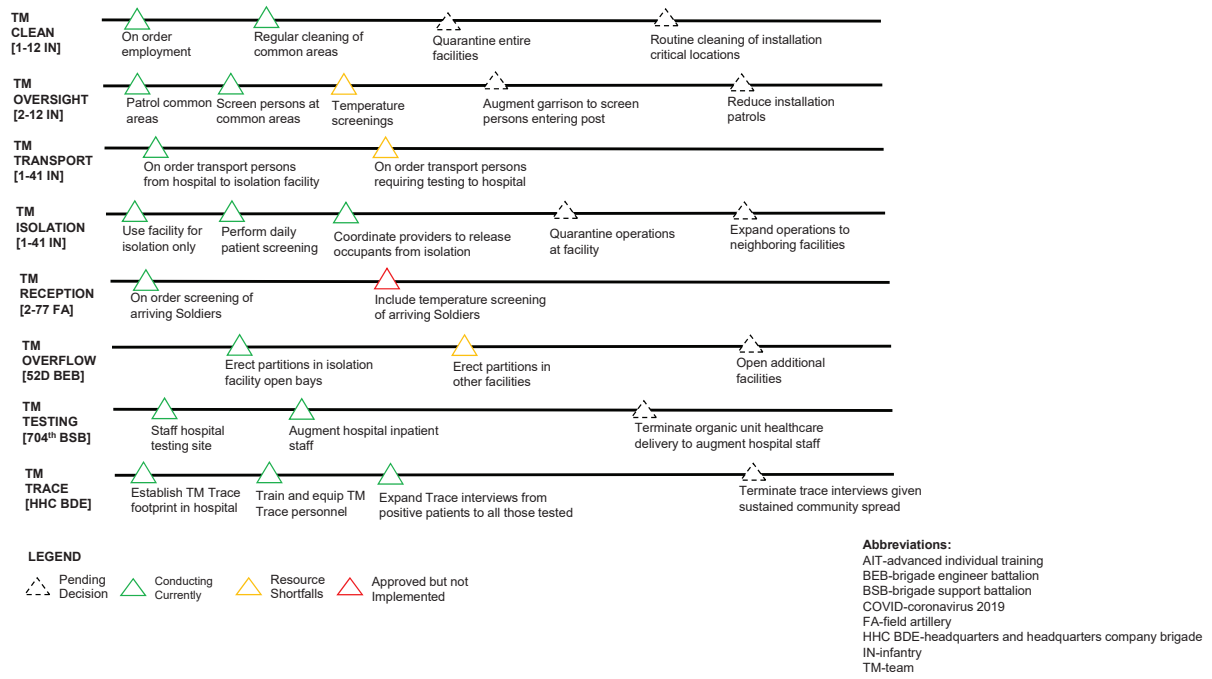
TF Contain Headquarters: TF Contain immediately established a current operations (CUOPS) cell to manage the various teams executing missions. This cell included liaison officers (LNOs) from subordinate units to quickly convey updates from each team. Regular communication with the installation CUOPS and these subordinate unit LNOs ensured synchronization across all elements in support of the installation COVID-19 response. This is where the TF Contain surgeon cell maintained a physical presence during operations while simultaneously allocating medical manpower to planning to ensure widest possible dissemination of advice and expertise across the entire enterprise.

Other efforts related to communication included maximization of telework to protect the force. This required early identification of personnel whose roles, responsibilities, equipment, and health made them ideal candidates for telework. It also required hasty implementation of a robust communications infrastructure. Hardware requirements included laptops with virtual private network capability and also equipment to facilitate video and audio projection. Software solutions for teleworking included the Defense Information Systems Agency Global Video Services for conferences and Sharepoint for collaborative work on products. Early publication of communication cards and battle rhythms proved equally important to maintaining accountability and productivity during remote working.

Team Trace: TF Contain implemented collective and coordinated disease mitigation actions by following a process analogous to targeting. Specifically, TF Contain utilized data gathered by Team Trace to select and prioritize these actions. This process ensured optimal allocation of manpower and resources to achieve the greatest impact in containing the spread of the virus.

MEDDAC Public Health authorities initially performed all trace interviews which collected the data to guide these actions and focused on COVID-positive patients. Early on, the installation experienced extensive delays in turnaround time for testing, sometimes ranging up

Figure 4. Task Force Contain lines of effort.



to 3 weeks or more. Given concerns regarding the time lapse between a patient testing and a patient subsequently being identified as a positive case, the Installation Senior Mission Commander ordered trace interviews for all patients at the time of testing. The resulting volume of interviews exceeded Public Health nursing capacity to perform these interviews. Consequently, TF Contain augmented their capability with additional personnel. These personnel comprised Team Trace.

The team required sufficient manning to sustain 24-hour operations at the MEDDAC. Activities included tracking personnel tested for COVID, performing trace interviews, and disseminating notifications. We selected branch nonessential soldiers for these roles given a deliberate effort to preserve medical combat power. These persons received formal training via approximately 4 hours of didactics led by Public Health nursing staff. They also completed online Health Insurance Portability and Accountability Act (HIPAA) training on Joint Knowledge Online. The Team Trace officer in charge performed validation before each member began shift work without direct supervision to ensure understanding and compliance with the team's standard operating procedures.

Team Trace members required a number of MEDDAC resources. These included MEDDAC badges, access to the Defense Health Agency (DHA) network, and DHA computers. Placing Team Trace members physically inside of the MEDDAC facilitated robust lines of communication between all sources of patient COVID-19 testing to track all patients tested. These sources included the outpatient Centralized Screening and Testing Center stood up by MEDDAC, the emergency department, and inpatient services. Direct interface between the TF Contain and MEDDAC commanders was imperative for timely completion of all notification requirements. Early engagement of Forces Command (FORSCOM) providers was similarly invaluable as these individuals served as links between FORSCOM and MEDDAC personnel and infrastructure.

Team Trace interview procedures included multiple interview and notification actions. Upon initial testing of patients for COVID-19, patients became PUIs. Team Trace utilized an interview tool based upon CDC interview guidance[17] and endorsed by MEDDAC Public Health to solicit all close contacts with the patient during the 48-hour period preceding first symptom onset or time of testing for asymptomatic patients. Team Trace then submitted notifications to the battalion chain of command (COC) for any ADSMs requiring duty status restrictions on the basis of these trace interviews. The report names utilized orange to indicate the need for quarantine, red to indicate the need for isolation without a confirmed positive test, and black to indicate a

COVID-19 positive result (Table 1).

Table 1. Team Trace reports.

Report	Situation
Orange 1	Non-ADSM who is a close contact with an ADSM has undergone testing. Notifies chain of command that ADSM requires quarantine.
Orange 2	Trace interview complete for non-ADSM identified by Orange 1.
Red 1	ADSM has undergone testing. Notifies chain of command that ADSM requires isolation.
Red 2	Trace interview complete for ADSM identified by Red 1.
Black 1	ADSM has tested positive for COVID-19.

ADSM: active duty service member

Upon receipt of these notifications, units performed their own trace interviews to supplement the Team Trace interviews. MEDDAC Public Health would perform Trace interviews after positive result of a COVID-19 test. Each of these interviews fed into a single database managed by Team Trace. In this manner, the interviews built upon another much like a running estimate. This iterative process was time and manpower intensive but ensured greater accuracy of information by compelling the patient to repeatedly recall the information regarding recent locations visited, activities, and close contacts.

Comprehensive capture and notifications of these duty status restrictions required Team Trace be able to interview non-ADSMs. This required careful coordination with the installation staff judge advocate to ensure compliance with all legal requirements. Ultimately, these authorities determined by virtue of the declaration of a public health emergency by the installation senior mission commander, Team Trace could conduct these interviews provided all interviews were voluntary, and Team Trace disclosed no personally identifiable information for persons other than soldiers assigned to each chain of command. The installation staff judge advocate coordinated with the department of public works and MEDDAC to post informational signs disclosing the use of trace interview data in this manner to protect the force and the public health by ensuring patients accessing installation healthcare are fully informed: "By entering this area, all individuals consent to any action taken pursuant to the commanding general's authority under DoD Instruction 6200.03, Public Health Emergency Management (PHEM) within the DoD. This includes, but is not limited to, medical screening/testing and contact tracing. All collected personal information will be disclosed only as necessary to safeguard public health and safety."

A Division Operations Research and Systems analyst built the database used to store all of this information. Following data entry, it was possible to use the database to perform link analysis to identify individuals at high risk of COVID-19 exposure or spread. This analysis provided Team Trace with information necessary to identify locations associated with high footfall of PUIs and COVID-19 positive persons for Team Oversight and Team Clean action.

Team Isolation: Team Isolation comprised an infantry battalion headquarters company to provide both medical and missions assets in support of isolation operations. The installation designated a facility specifically for use to house soldiers requiring restriction of movement that could not otherwise be accomplished at other locations on post. Examples of soldiers requiring use of this facility included those who reside in the barracks (meaning other soldiers in close proximity were at risk for exposure) and soldiers with household members at high risk for adverse outcomes from COVID-19 (e.g., household members with lung disease). This facility provided lodging for quarantine soldiers only as a last resort to preserve bed space.

Team Isolation established a tactical operations center in this facility. Their activities included twice daily evaluations and temperature checks of all patients in isolation by medics. When patients required medical care, Team Isolation medics facilitated telemedicine visits with TF Contain providers (e.g., the physician assistants assigned to the brigade). Team Isolation personnel ensured all patients in the isolation facility received meals three times per day. They attended to any other administrative requirements as necessary such as interfacing with patients' chain of command. Once isolated patients met medical criteria for release, TF Contain medics and providers would perform final evaluations and notifications of the soldiers' command teams.

Team Transportation: Team Transportation moved soldiers who did not have access to vehicles but required transportation related to COVID-19 response. This included transportation of soldiers from lodging on post to the MEDDAC for screening and possible testing. Transportation missions also included transportation of soldiers tested at the MEDDAC requiring restriction of movement in the designated isolation facility as necessary. These actions preserved availability of the MEDDAC ambulances for patients throughout the installation requiring emergency transportation. Planning for these missions required accounting for the 6 or more feet of separation between soldiers in each transportation platform and personal protective equipment (PPE) for drivers and medics to minimize disease spread. Transportation vehicles included busses and vans procured from the installation Army Field Support Battalion. Tactical vehicles served as a contingency option.

Team Clean: Team Clean performed disinfection operations throughout the installation. They postured to act on orders to perform clean missions during the entirety of the COVID-19 response. Areas for clean missions

derived from requests throughout the installation and analysis of areas on the installation experiencing high foot traffic of individuals becoming PUIs. This posture required the creation of 4 separate teams each comprised of 8 branch non-essential soldiers. Of these teams, 1 was always on 2-hour recall while the remainder were on 24-hour recall.

Regarding equipment, all Team Clean soldiers utilized PPE to include at a minimum procedure masks and gloves. Careful measurement and monitoring of PPE burn rates was imperative to guide procedures to ensure the sustainability of the enterprise. For example, single teams performed multiple missions throughout a day reusing the same PPE in lieu of activating multiple teams when possible. Shortages of many cleaning supplies during the pandemic occasionally required novel solutions. The Army Field Support Battalion on post stockpiled swimming pool bleach which ensured a robust supply of cleaning solution during the COVID-19 response.

In collaboration with the installation Preventive Medicine Detachment, Team Clean also provided training to other units on the installation regarding cleaning procedures. This simultaneously ensured both standardization and quality control. To make this training more readily accessible to the installation at large, Team Clean recorded and published multiple open access educational videos regarding best practices for cleaning procedures.

Team Oversight: Team Oversight members performed screening operations outside of the MEDDAC footprint to expand the reach of screening capability and prevent the spread of COVID-19. The order of priority for these screening efforts was first employees of facilities with high foot traffic (e.g., post exchange, commissary) followed by random screenings of persons entering these facilities. Screening also included temperature measurements. Questions administered during screening solicited any history of symptoms or contact with PUIs or travel to high risk locations.

The other major component of Team Oversight activity was courtesy patrols throughout the installation. These patrols encouraged personnel to follow protective measures (e.g., wearing facemasks, maintaining 6 feet of distance at all times). Team Trace data again informed the locations prioritized for these activities. Collaboration with installation military police was important as these teams lacked legal authority to enforce individual compliance with specific actions.

Team Overflow: Team Overflow comprised the brigade engineer battalion leadership team and subject matter experts. This team identified and prepared additional isolation and quarantine spaces across the post. They conducted a review of buildings across the post to provide options for the senior commander for additional bed spaces. These spaces were available for a variety of uses ranging from housing personnel who arrived during the DoD stop-move order and were unable to find other accommodations, quarantining units prior to and after deployment, and providing additional options for treatment of patients had the need arisen. Subordinate companies also converted bay spaces into small rooms using plastic sheeting and wood partitions.

Team Testing: Physician assistants comprising the brigade providers augmented the installation MEDDAC to provide additional manpower in support of screening and testing of ADSMs and Tricare beneficiaries. The installation MEDDAC consolidated all outpatient screening and testing in a single center located at the MEDDAC: the Centralized Screening and Testing Center. The TF Contain Brigade Support Medical Company further augmented this facility with medics, and low density medical specialties (e.g., laboratory specialists). These personnel also ensured completion of all requisite requirements, in particular for ADSM tested prior to departure to include issuing the pertinent general order notifications of quarantine or isolation, discharge instructions, chain of command notification, and coordination with Team Transportation when necessary to move to the installation isolation facility.

Discussion

We present the response to the COVID-19 pandemic as operationalized by 2nd Infantry Brigade Combat Team (BCT), 4th Infantry Division on Fort Carson. Few of the personnel assigned to this organization had pre-existing experience or training related to infectious disease prevention or epidemiology. Nevertheless, this organization demonstrated the capacity of the military decision-making and operations processes to build robust procedures in response to unconventional threats.

Throughout the course of the TF Contain mission, the brigade staff held regular decision working groups with all subordinate units. During these groups, units and personnel associated with the mission nominated problem sets which were discussed with the larger audience, and a decision was either recommended at the moment or transitioned to a breakout group with specific stakeholders. This process saved immense amounts of time across the staff in both identifying decisions quickly and allowing personnel to work where they were needed most. Because TF Contain was supporting the broader Fort Carson community, the brigade arranged a standard decision board time with the senior installation

leadership to gain feedback and decisions on issues identified by TF Contain, but affecting the broader Fort Carson community.

Because of the significance of this mission for the post, the 4th Infantry Division G3 established a planning cell at the division level with a senior officer (O5) lead. This planner worked closely with the TF Contain staff and was instrumental in providing information, additional staff support, and other resources to TF Contain. The effectiveness of this structure is a testament to the importance of operational units viewing the public health response as a holistic responsibility for the entire organization rather than a responsibility solely of the medical community.

Our analysis has multiple limitations. First, as a descriptive analysis, it is incapable of demonstrating cause and effect. As such, it can only offer an anecdotal account of a public health response which appeared to achieve effective synchronization and implementation. That stated, a second major limitation is the lack of outcome measures. We lack comprehensive data regarding installation and surrounding community outcomes including infection rates and compliance with stipulated mitigation measures. This makes it difficult to speak to the efficacy of the measures outlined in this analysis, let alone more sophisticated measures such as cost-effectiveness.[18] Despite the absence of such data, we would argue our experience at least demonstrates a way brigade combat teams might tackle a public health crisis.

The experiences of TF Contain offer future brigade combat teams, in general, and infantry units in particular, a conceptual framework for the operationalization of a comprehensive public health response to an infectious disease. Ongoing worldwide population growth and globalization make it increasingly likely that future pandemics may be an evermore likely occurrence. US Army formations must be prepared to contend with similar infectious disease threats in the future.

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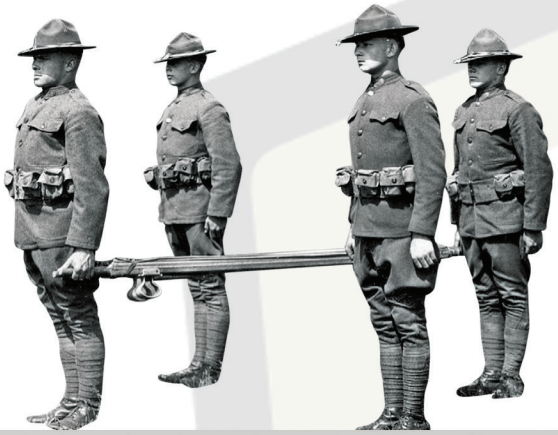

U.S. ARMY MEDICAL CENTER OF EXCELLENCE

BY: ADRIANE ASKINS NEIDINGER and NOLAN A. WATSON

A Descriptive Analysis of the Execution of the Expert Field Medical Badge Competition with Mitigation Measures during the COVID-19 Pandemic

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Abstract

Introduction: In September 2020, the 2nd Stryker Brigade Combat Team of the 4th Infantry Division at Fort Carson, CO, executed an Expert Field Medical Badge (EFMB) event, unique in its implementation of Coronavirus Disease 2019 (COVID-19) mitigation measures. We conducted a descriptive analysis of our experience to inform future EFMB events.

Methods: We planned and resourced the EFMB competition in accordance with the Army Medical Department Center and School Pamphlet 350-10. We additionally defined adjustments to each event based upon the installation's COVID-19 Health Protection Condition (B, B+, or C) to set conditions for us to execute training regardless of shifts in the public health posture. We further implemented mitigation measures to include a 72-hour restriction of movement for all candidates and cadre prior to competition start, strict use of face coverings, and two daily temperature and symptom screenings. We recorded numbers of candidates and cadre withdrawing from the competition each day and the reasons for withdrawal.

Results: Of the 66 evaluators, 179 support personnel, and 113 candidates, 2 personnel withdrew for reasons related to COVID-19 mitigation measures. A single cadre member entered a quarantine for the development of a sore throat during the competition. One candidate withdrew after disclosing failure to comply with the 72-hour restriction of movement prior to competition start. Another candidate withdrew prior to start due to an injury sustained during land navigation. Of the remaining 111 candidates, 22 (20%) earned the EFMB. Most failures occurred due to the Army Physical Fitness Test (APFT, 33) and land navigation (44).

Discussion: Our competition provides proof in principle that large-scale events to train individual skills such as EFMB are feasible in conjunction with COVID-19 public health measures. Our experience highlights the imperative of prior preparation of candidates in particular for the APFT and land navigation.

Introduction

The Expert Field Medical Badge (EFMB) is a special skill award recognizing exceptional competence and outstanding performance of field medical tasks. Soldiers eligible for the award broadly include officer and enlisted personnel with military occupational specialties (MOS) related to the provision of medical care. The Department of the Army first approved the award on 18 June 1965.[1] The award offers a vehicle by which to train and recognize excellence in the execution of individual skills related to the management of combat casualties.[2-5] Since the award's inception, the process of earning the award, the EFMB competition, has evolved to reflect changes in US Army fitness standards[6] and Tactical Combat Casualty Care guidelines.[7-9]

In December 2019, a cluster of pneumonia cases occurred in Wuhan, China.[10-12] This respiratory illness spread, achieving global reach in the following months. In February 2020, the World Health Organization designated the cause of this disease to be coronavirus disease 2019 (COVID-19).[13] The pandemic rapidly prompted a range of mitigation measures by the Department of Defense. These measures included widespread implementation of restriction of movement measures.[14]

Prior to the pandemic outbreak, the 2nd Stryker Brigade Combat Team of the 4th Infantry Division planned to execute an EFMB competition during September 2020. The virus response and associated restrictions posed unique challenges to the ongoing mission of the US Army to continue training for its wartime mission. Navigating these challenges required careful coordination between the EFMB Test Control Office (TCO) and the competition leadership. This coordination aimed to strike the appropriate balance between protection of the public health and execution of a robust training event to build and recognize individual excellence in field medical care. Among the measures adopted was a pilot hybrid decentralized validation construct.

This paper comprises a descriptive analysis of these measures. It describes the EFMB competition components and requirements as established by the EFMB TCO. It then describes the mitigation measures specific to COVID-19 the competition leadership implemented. Finally, it describes the outcomes of the competition including candidate progression and health outcomes.

Methods

Study Setting & Design: The study setting was the EFMB competition location at Fort Carson, CO. Specifically, the EFMB competition took place at the installation's Wilderness Road Complex and surrounding training areas. This was a strictly descriptive analysis of our performance in planning, resourcing, and executing this event. Hence, we completed this analysis as a performance improvement project not requiring oversight by an institutional review board.

Population: Eligible candidates included military personnel with a medical MOS volunteering to participate in the competition. In accordance with the Army Medical Department (AMEDD) Center and School (C&S) Pamphlet 350-10, this includes Army officers assigned or detailed to the AMEDD or enrolled in medical training programs such as medical school. Eligible warrant officers include pilots with a special qualification identifier as an aeromedical evacuation pilot and assigned to an air ambulance unit. Finally, eligible enlisted personnel comprise soldiers with any medical MOS including all 68-series soldiers.[1]

All candidates had to submit documentation demonstrating they met a number of other eligibility criteria defined by the AMEDD C&S Pamphlet 350-10. These included a written recommendation by their unit commander, documentation of completion of a 12-mile forced ruck march in no more than 3 hours within 3 months of the final day of EFMB testing, and qualification as expert on their assigned weapon on a live-fire range within 12 months of the last day of EFMB testing. The pamphlet also requires all candidates have a current cardiopulmonary resuscitation certification valid through the final day of EFMB testing.[1] Exclusion criteria included any medical profiles prohibiting performance of any EFMB testing events and any administrative flags in accordance with Army Regulation 600-8-2.[15]

Recruitment principally occurred via 2 mechanisms. First, within Fort Carson, the EFMB competition leadership held monthly in-progress reviews attended by members of the Division Surgeon Section. During these meetings, coordination occurred with the senior leadership of all 4th Infantry Division subordinate units and Fort Carson tenant units to solicit estimates of numbers of eligible volunteers. In this manner, the EFMB competition leadership allocated the majority of slots. Additionally, the EFMB TCO posted details regarding dates, locations, and points of contact on the EFMB website (https://medcoe.army.mil/efmb), enabling units outside of Fort Carson to contact competition leadership to seek slots.

The other populations involved in the competition included cadre (evaluators) and support personnel. Prior award of the EFMB was a mandatory credential for evaluators serving on the test board, overall competition or combat testing lane (CTL) leadership, and for all graders on CTL 1 (medical lane). Support personnel requirements included both specialized (e.g., aid station personnel, field feeding team members) and branch nonessential soldiers (e.g, CTL lane support workers to help set up equipment, act as casualties, etc.)

Competition: Per AMEDD C&S Pamphlet 350-10, the EFMB competition requires successful completion of the Army physical fitness test (APFT, recently transitioned to the physical fitness assessment), a written test based on published Army medical doctrine and task standards, and successful completion of day and night land navigation courses. Following this, candidates must correctly execute a number of tasks divided into tactical combat casualty care, casualty evacuation, communication, and warrior skills. EFMB competition

leadership allocates these tasks across 3 CTLs in accordance with AMEDD C&S Pamphlet 350-10 (version dated 1 March 2019). Finally, the competition culminates with a 12-mile foot march with packed rucksack that includes the entirety of the EFMB packing list (Figure 1).

Figure 1. List of required Expert Field Medical Badge (EFMB) tasks.

APFT & Written Test
80% standard; Must answer 60/80 correctly
- 80% standard in each event, pass HT/WT
- 80 questions, 5 publications, 90 minutes

Land Navigation
Must get 3 of 4 navigation points within 3 hours (day and night)
- Day course will not exceed 4,500 meters
- Night course will not exceed 3,500 meters (Not self-correcting; has unique punch)

Tactical Combat Casualty Care
Must pass 12/15 tasks
- Perform a Combat Casualty Assessment
- Submit a TCCC Card
- Control bleeding using a tourniquet
- Triage casualties
- Control bleeding of a junctional wound using a hemostatic device
- Control bleeding using dressings
- Initiate a saline lock and intravenous infusion
- Initiate treatment for hypovolemic shock and prevent hypothermia
- Insert a nasopharyngeal airway
- Treat a penetrating chest wound
- Perform needle chest decompression
- Treat an open abdominal wound
- Treat an open head injury
- Immobilize a suspected fracture of the arm
- Treat lacerations, contusions, and extrusions of the eye

Casualty Evacuation Tasks
Must pass 8/10 tasks
- Establish a helicopter landing point
- Load casualties onto ground evacuation platform (M996, M997, M113, MEV M1133)
- Load casualties onto two different nonstandard vehicles (5-ton M1085, M1093, 2½ ton M1081) (2 ½ ton, 6x6, 5-ton 6x6 cargo truck)(1 ¼ ton, 4x4, M998)
- Extricate casualties from a vehicle
- Evacuate a casualty using a SKED litter
- Evacuate casualties using one-person carries or drags
- Evacuate casualties using two-person carries or drags
- Evacuate casualties using litter carries

Communication Tasks
Must pass 4/5 tasks
- Assemble and operate a SINCGARS/ SINCGARS (ASIP)
- Load (FH)/(COMSEC) data and conduct radio check using SINCGARS/ SINCGARS (ASIP)
- Prepare and transmit a MEDEVAC request (using secure mode radio)
- Submit CBRN 1 report
- Submit explosive hazard spot report

Warrior Skills Tasks
Must pass 10/13 tasks
- Protect yourself from chemical/biological contamination using your assigned protective mask
- Decontaminate yourself using RSDL
- Protect yourself from CBRN injury/ contamination with JSLIST chemical protective ensemble
- Perform self-aid for mild nerve agent poisoning
- Protect yourself from chemical or biological injury/contamination when removing MOPP using JSLIST chemical protective ensemble
- Store your assigned protective mask
- Disassemble, assemble, and perform a function check on a M4/M4A1 or M16 series carbine
- Disassemble , assemble, and perform a function check on a M9 pistol
- Correct malfunction of a M4 or M16 series rifle
- Move under direct fire
- React to indirect fire
- Move over, through, or around obstacles
- React to an UXO or possible IEE

Foot March
Must complete within 3 hours
- 12 miles with complete packing list

APFT: Army physical fitness test; ASIP: advanced system improvement program; CBRN: chemical, biological, radiological, nuclear; FH: frequency hop; HT: height; IEE: initial environmental evaluation; JSLST: joint service lightweight integrated suit technology; M (vehicles): medium tactical vehicle (e.g., M1087); M (weapons)-military: (e.g., military-9 pistol); MEDEVAC: medical evacuation; MEV: medical evacuation vehicle; MOPP: mission oriented protective posture; RSDL: reactive skin decontamination lotion; SINCGARS: single channel ground and airborne radio system; TCCC: tactical combat casualty care; UXO: unexploded ordinance; WT: weight

The EFMB competition leadership defined separate phases to organize execution of all required tasks in time and space as per Army doctrine.[16] Phase 0-I comprised all planning for the competition. Phase IIA spanned 1 week for establishment of all testing sites including the CTLs and cadre standardization. Standardization broadly refers to all efforts to ensure all cadre utilize identical interpretation of AMEDD C&S Pamphlet 350-10 standards for purposes of candidate instruction and grading.

Subsequent sub-phases within phase II represent validation efforts. This particular EFMB event represented a pilot decentralized validation methodology. Historically, the Fort Sam Houston TCO performed all validation activities in person. During this event, the TCO provided remote education to all Fort Carson test board members regarding the process of performing validation. The test board then performed its own internal validation followed by observation by the TCO of these validation processes. The intent was successful execution of these validation procedures would set conditions for subsequent EFMB events to validate remotely without the physical presence of the TCO. Specifically, phase IIB allocated approximately 3 days for the test board internal to Fort Carson to validate all lanes and cadre standardization. Phase IIC then allocated another 4 days for the TCO representatives to validate these processes. The TCO did have physical presence during Phase IIB to ensure proper execution.

The arrival of candidates marked the beginning of Phase III. Phase IIIA spanned approximately 1 week and entailed providing all candidates demonstrations, instructions, and the ability to train all required tasks as part of the EFMB competition. This phase achieved candidate standardization under the supervision of the test board. Finally, Phase IIIB represented EFMB testing which begins with the APFT and culminates with the 12-mile ruck march no more than 144 hours after the start of testing. Following completion of this phase, recovery operations (Phase IV) commenced (Figure 2).

Data Collection: As part of the EFMB competition, our host unit's brigade support battalion (BSB) established a brigade support area (BSA) in the competition area of operations. This action enabled the BSB to train their own sustainment and mission command mission essential tasks. The BSA included a tactical operations center (TOC). The TOC processed accountability reports each morning prior to initiation of training and each evening upon the conclusion of training. These reports included details regarding candidate performance on all events and any adverse events such as injuries or illnesses. This information allowed the EFMB leadership to track the reasons for each candidate's termination from training as candidates progressed through the competition.

COVID-19 Mitigation Measures: The execution of this competition during the COVID-19 pandemic and the corresponding risk mitigation measures made this event unique. COVID-19 mitigation measures were at the discretion of the local test board and leadership of the host unit and installation rather than the TCO based out of Fort Sam Houston, TX. Mitigation measures prior to competition start included a 72-hour restriction of movement

Figure 2. Fort Carson 2020 Expert Field Medical Badge (EFMB) timeline of events.

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
30	31 (Phase IIA) LANE SETUP AND CADRE STANDARDIZATION	1	2	3	4 **(DONSA)**	5
6	7 (Phase IIB) TEST BOARD VALIDATION **(Labor Day)**	8 (Phase IIC) TEST CONTROL OFFICE OIC/NCOIC VALIDATION Intro Briefing:0800 TOC: 0900 W/T: 1000 Land Nav: 1400	9 CTL 1: 08-12 APFT: 13-15	10 CTL 2: 0800 Forced March: 1300	11 CTL 3: 0800 Make-Up: 1300	12
13 (Phase IIIA)	14 STANDARDIZATION WEEK **Inprocessing** Student Layouts EFMB introduction Counseling	15 **CTL Standardization** 1st PLT CTL 2 2nd PLT CTL 3 3rd PLT CTL 1	16 **CTL Standardization** 1st PLT CTL 3 2nd PLT CTL 1 3rd PLT CTL 2	17 **Day/Night Land Navigation Standardization** All PLTs Land Navigation	18 **CTL Round Robin** **W/T Study Hall** All PLTs TCO Brief	19 (Phase IIIB) **APFT** All PLTs APFT **Written Test** All PLTs Written Test
20 (Phase IIIB)	21 TESTING WEEK **Day/Night Land Navigation** All PLTs Land Navigation	22 **CTL Testing** 1st PLT CTL 2 2nd PLT CTL 3 3rd PLT CTL 1	23 **CTL Testing** 1st PLT CTL 3 2nd PLT CTL 1 3rd PLT CTL 2	24 **CTL Testing** **W/T Re-Test** **PCCs for Ruck** **TCCC (TABLE VIII) Re-Test**	25 **12 Mile Road March** All PLTs Road March **EFMB Graduation** All PLTs Graduation (Phase IV) RECOVERY OPS	26

APFT: Army physical fitness test; CTL: combat testing lane; DONSA: day of no scheduled activity; NAV: navigation; NCOIC: non-commissioned officer in charge; OIC: officer in charge; OPS: operations; PCC: pre-combat check; PLT: platoon; TCCC: tactical combat casualty care; TOC: tactical operations center; WT: written test

for all candidates and cadre during which these soldiers resided in their domicile. This prevented contact with any personnel not participating in the competition with the intent of creating a bubble for the competition.

Upon arrival to the competition, all cadre and candidates alike signed a counseling form attesting their understanding and willingness to comply with all COVID-19 mitigation measures during the competition. These included wear of face coverings at all times by all candidates and evaluators. The only exception to this requirement was candidates did not require face coverings during actual execution of testing events requiring physical exertion such as the APFT or CTLs. Candidate lodging utilized bays filled to no more than 50% capacity to ensure spacing between bunks of at least 6 feet at all times. The test board added to the EFMB packing list the requirement that each candidate bring at least 3 washable cloth face coverings. The EFMB OIC and NCOIC further coordinated with the host unit brigade support battalion (BSB) to resource at least 1 individual bottle of hand sanitizer per candidate bunk.

The EFMB cadre defined and rehearsed battle drills related to the management of symptomatic competition participants. All cadre and candidates agreed via the counseling statements to immediately notify their leadership should they develop any symptoms consistent with COVID-19 including but not limited to fever, cough, chills, or body aches.[10,11] Failure to comply with these instructions were grounds for immediate administrative removal from the course by the test board. Each morning and evening, CTL OICs would perform temperature screening and solicit the presence of any symptoms from each of their assigned cadre, and the cadre in charge of monitoring the participants (platoon sergeants) would do the same for all candidates. Should any individual screen positive or identify him or herself as having symptoms consistent with COVID-19 infection, we immediately isolated them from all other participants in a separate and empty building. We subsequently called for transportation assets based at the installation medical activity to move these patients to the hospital for further evaluation and testing.[17] None of these participants returned to the competition regardless of the results of this work-up.

In addition to these overarching competition mitigation measures, we also defined and implemented mitigation measures specific to each EFMB event. We built a sequential series of mitigation measures, from least to most restrictive, based upon the installation Health Protection

Condition (HPCON).[17] In brief, this ranges from HPCON 0 (normal baseline) to HPCON D (severe disease threat (Table 1). Our focus was to define mitigation measures for HPCON B and C conditions, reasoning less restrictive postures would not require significant changes to event execution; whereas, a more restrictive posture would preclude the competition altogether (Appendices 2-5).

Data Analysis: Data from the TOC daily reports allowed analysis of candidate sequential progression through each stage of EFMB training. This allowed us to quantify incidence of COVID-related illnesses, non-COVID-related illnesses, injuries, event failures, any other reason candidates did not progress to the next phase. We used descriptive statistics to characterize this candidate flow.

Table 1. Health Protection Condition (HPCON) statuses and operational implications.

HPCON	Situation	Operational Implications
0	Normal	Normal operations. Maintain standard health precautions (e.g., hand hygiene, diet, exercise)
A	Report of unusual health risk or disease	Communicate risk and symptoms of health threat to public; review public health plans and training.
B	Outbreak or heightened exposure risk	Strict hygiene to include no hand shaking and regular sanitation of common use items; restriction of movement for exposed persons.
C	High morbidity epidemic or contamination	Aggressive social distancing, limit access to installation, and cancel public gatherings.
D	High mortality epidemic or contamination	Public Health emergency declaration, shelter in place indoors, regular mass decontamination missions.

Results

Fort Carson was at HPCON B+ for the entirety of the EFMB competition. Cadre comprised 66 evaluators, and support personnel comprised 179 additional soldiers. There were no illnesses or injuries precluding participation by any cadre or support personnel for the duration of the competition. A single cadre member developed a sore throat during the validation phase of the competition, prompting the removal of this cadre member for medical evaluation and a 14-day quarantine. Subsequent work-up revealed no actionable diagnosis. In particular, the cadre member was negative for COVID-19 infection. No other cadre or support personnel developed any infectious symptoms during the competition.

During standardization, 113 candidates in-processed to start training. The first day of the competition, one candidate without symptoms disclosed he did not fully comply with the 72-hour restriction of movement, prompting an administrative drop from the course. A second soldier experienced a fall from height during night land navigation, resulting in a myriad of soft tissue injuries not requiring intervention or long-term follow up but prompting the candidate to withdraw from the competition.

The remaining 111 candidates initiated the EFMB testing phase. The events resulting in the most candidate failures were the APFT (33) and land navigation (44). Of the 34 candidates who started the CTLs, 25 (73.5%) successfully completed all 3 lanes. Ultimately, 22 candidates graduated and earned their EFMB (Figure 3).

Discussion

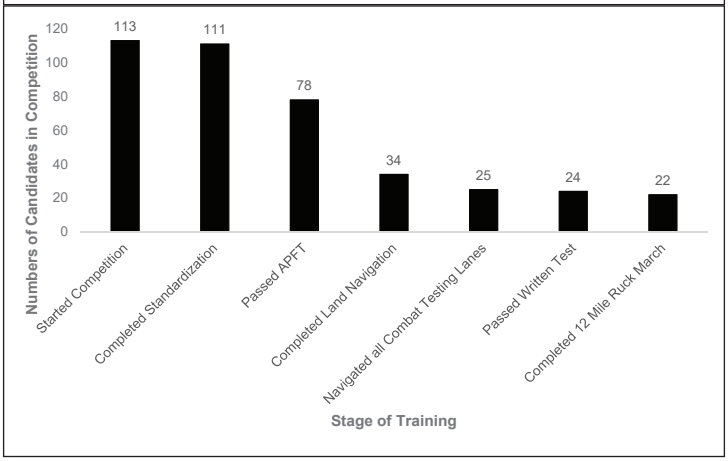
The EFMB represents an important vehicle by which the Army prioritizes individual critical medical task training, execution, and assessment. It ensures dissemination and training for best practices related to combat casualty care such as hemorrhage control,[3,4,18] patient assessment,[19-21] and safe analgesia administration.[7,22,23] While focused on combat medic (68W) tasks, the skills tested are broadly applicable to tactical combat casualty care competencies important for all soldiers in the Army Medical Department. The COVID-19 pandemic posed unprecedented challenges to training across the Army enterprise as leadership sought to balance the public health with military readiness. Our experience demonstrates proof in principle large training events such as EFMB are possible to execute in such circumstances through proper planning and judicious public health measures.

During the competition, only 2 soldiers experienced issues requiring removal in accordance with the COVID-19 mitigation measures. The aforementioned single cadre member, who entered a 14-day quarantine and subsequently testing negative for infection, and another candidate, who disclosed failure to comply with the restriction of movement as stipulated as a requirement to enter the competition. This incredibly low incidence of infectious symptoms suggests the mitigation measures put into place including social separation and mask wear were effective in minimizing disease spread. Simultaneously, the accommodations made to facilitate testing, such as no requirement for mask wear during the APFT and when testing on the CTLs, did not lead to a spike in infections.

Our experience also highlighted the feasibility of decentralized validation through use of remote communication tools with the Fort Sam Houston Test Control Office and local communication with the evaluators and lane leads. The successful hybrid decentralized validation set conditions for subsequent implementation of fully decentralized validation in later EFMB competitions. Most events and lanes experienced little to no challenges in either standardization or validation. One notable exception, however, was the land navigation lane, in which the physical presence of the TCO was invaluable for clarifying requirements. Our event was arguably

more complex than necessary given the use of the same land navigation course for both candidate standardization and subsequent testing. Based on our experience, we would strongly encourage future events strive to use a separate course for testing to avoid the nuanced complexities of adjusting points necessary to comply with all requirements of AMEDD C&S Pamphlet 350-10.

Figure 3. Candidate flow during the Fort Carson Expert Field Medical Badge Competition, fiscal year 2020. The vertical axis portrayed numbers of candidates. The horizontal axis portrays the sequential stages of training comprising the competition.



The overall pass rate for our competition was 20%. This modestly exceeded the average pass rate across all EFMB competitions during fiscal year 2020 (18%).[24] We attribute this success to widespread dissemination to units across Fort Carson of the importance of prior preparation to include preparation for the APFT, land navigation, ruck march, orientation to the CTL tasks, and written test studying. Furthermore, aggressive engagement in study hall by evaluators was pivotal for achieving candidate success on the Combat Testing Lanes. The vast majority of failures arose from the APFT and land navigation, highlighting the imperative of training for these events prior to arrival to the competition. Moreover, while it is not feasible to train APFT performance during a competition, future EFMB events might also consider building an additional day to practice land navigation.

Another factor we considered key to the success of the event was rigorous cadre standardization. During both test board and TCO validation, it was clear all evaluators had come to complete agreement on the standards for each graded task. This standardization was manifest in the fact there was not a single candidate rebuttal for a CTL task. This standardization not only makes grading easier but also likely contributes to increased proportions of candidates passing each event, given the instruction they received was presumably consistent across multiple evaluators and teaching sessions.

The literature would benefit from future studies related to large-scale individual training events such as this. Such literature would ideally describe experiences with COVID-19 mitigation measures. However, the literature would also benefit from a more robust data foundation related to the candidate flow, successes, and failures in these events in a more general sense. The existing medical literature related to these events is largely confined to anecdotal discussions of the training.[25] Future studies would ideally continue to outline the areas where candidates most struggle to highlight to medical leaders the ideal targets for individual training within their formations. The military and medical literature alike would further benefit from similar analyses for sister competitions such as the Expert Infantryman Badge (EIB) and Expert Soldier Badge (ESB).

The EFMB competition itself will and must also continue to evolve. As the Army shifts its focus from decades of counterinsurgency operations to the multi-domain operating concept, the competition should emphasize actions during mass casualty scenarios that will characterize large scale combat operations.[26] It should also continue to emphasize and build upon complex skills such as airway management known to be leading causes of casualty death on the battlefield.[27-28] Future competitions might also consider increasing incorporation of pediatric scenarios to continue expanding the skill set of candidates.[29-31]

There are important limitations to this analysis. First, we have no data related to the public health situation on Fort Carson, let alone the broader Colorado Springs area aside from the HPCON status. This makes it difficult to speak to whether the limited numbers of infectious symptoms observed during our competition represented a uniquely effective constellation of public health mitigation measures versus a population-based waning of infections in the surrounding area. We further cannot exclude the possibility of ascertainment bias: Cadre and candidates alike may have avoided notifying event leadership of symptoms in a desire to continue training. We attempted to minimize the risk of such lack of disclosure through our counseling statements instructing all participants to notify their leadership of any symptom development. Finally, while we present data regarding candidate flow through the competition so highlighting those events resulting in the most failures, we do

not have granular data to explain the reasons for failure Future studies might consider abstracting data from the EFMB grade sheets that lay out the specific criteria for failure during each event.

Appendices

Appendix 1. Non-combat testing lane COVID-19 mitigation measures.

Task	HPCON B	HPCON B+	HPCON C
Push-Ups	6 feet distance between candidates during event. Mats disinfected between each candidate.	12 feet of distance maintained between candidates during event.	
Sit-Ups	6 feet distance between candidates during event. Mats disinfected between each candidate. Feet secured using weighted pallets.	12 feet of distance maintained between candidates during event.	
2-Mile Run	30 person groups execute run spaced by 2 minutes.	20 person groups execute run spaced by 2 minutes.	10 person groups execute run spaced by 2 minutes.
12-Mile Ruck March	All Candidates begin at the start line with mask on. May remove mask once march initiated and 6+ feet distance between candidates achieved.	Candidates begin with mask on. Split candidates into 30 candidate groups with 10 minute start times in between each group. May remove mask once march initiated and 6+ feet distance between candidates achieved.	Candidates begin at the start line with mask on. Split candidates into 15 candidate groups with 15 minute start times in between each group. May remove mask once march initiated and 6+ feet distance between candidates achieved.
Written Test	All Candidates will wear a mask during the testing period. Each Candidate will have 6 feet apart from their desk. One pencil per use.		Split candidates into 50 candidate groups to maintain 12 feet of distance between candidates with 90 minute start times in between each group.
Land Navigation	Candidates to wear masks during transportation to and from Land Navigation site. Busses filled to 50% capacity to ensure increased social distancing.		

COVID-19: Coronavirus; HPCON: Health Protection Condition

Appendix 2. Combat testing lane 1 COVID-19 mitigation measures.

Task	HPCON B	HPCON B+	HPCON C
Disassemble, assemble, and perform a function check on a M-4 or M-16; Correct a malfunction of a M-4 or M-16	Cadre will disinfect the weapon and magazine after each use.		The candidate will complete this task utilizing his or her own weapon and magazine.
Move under direct fire	No specific mitigation measures.		
Perform a tactical combat casualty care patient assessment; triage casualties	Candidate, casualty, and support personnel will wear BSI and mask.		Candidate will perform this task on a mannequin. Support personnel will disinfect the mannequin after each use.
Apply dressing; insert nasopharyngeal airway; treat penetrating chest wound; perform needle decompression; treat abdominal wound; treat eye and head wounds; immobilize fracture; initiate saline lock; complete DD 1380)	Candidate, casualty, and support personnel will wear BSI and mask.	Candidate will utilize new class VIII supplies.	Candidate will perform this task on a mannequin. The mannequin will be disinfected after each use.
Evacuate casualty using carries; evacuate casualties using M997	Candidate, casualty, and support personnel will wear BSI and mask.		Candidate will utilize 200-220 lbs mannequin for task. All touch surfaces will be disinfected after each candidate.

BSI: body substance isolation; COVID-19: Coronavirus; DD: Defense Department (form); HPCON: health protection condition

Appendix 3. Combat testing lane 2 COVID-19 mitigation measures.

Task	HPCON B	HPCON B+	HPCON C
Disassemble, assemble, and Perform a function check on a M-9.	Cadre will disinfect the weapon and magazine after each use.		The candidate will complete this task utilizing his or her own weapon and magazine.
React to indirect fire; React to UXO; Protect from CBRN; Use JSLIST; Protect against CBRN while removing JSLIST; Store protective mask	No additional risk mitigation measures; for many of these tasks, candidates will wear protective JSLIST equipment as part of the performance standards.		
Decontaminate with RSDL; Perform self-aid for nerve agent;	Cadre will disinfect the RSDL and nerve agent antidote training item in between each use.		The candidate will complete this task utilizing his or her own equipment.
Submit explosive hazard report; Submit CBRN report	No additional risk mitigation measures.	Evaluators will wear gloves (tactical or medical).	
Load casualties onto M998; Load casualties onto LMTV	Candidate and support personnel will wear tactical gloves.		Support personnel will wear masks and will disinfect all equipment after each attempt.

CBRN: hemical, biological, radiological, nuclear; COVID-19: Coronavirus; HPCON: health protection condition; JSLST: Joint Services Lightweight Integrated Suite Technology; LMTV: light medium tactical vehicle; RSDL: reactive skin decontamination lotion; UXO: unexploded ordnance

Appendix 4. Combat testing lane 3 COVID-19 mitigation measures.

Task	HPCON B	HPCON B+	HPCON C
Move over, through, or around obstacle; Establish a helicopter landing point	No additional risk mitigation measures.		
Assemble and Operator a SINCGARS; Load FH/COMSEC data and conduct radio check; Prepare and transmit a MEDEVAC request	No additional risk mitigation measures.	Support personnel will disinfect all high touch point after each attempt.	Support personnel will disinfect all surfaces of equipment after each attempt (two sets of equipment per lane for rotation).
Extricate casualties from a vehicle; Evacuate a casualty using a SKED litter; Evacuate casualties using litter carries; Load casualties on a ground evacuation platform (Stryker MEV).	Candidate, casualty and support personnel all wear BSI.	Support personnel will disinfect all high touch point after each attempt.	Support personnel will disinfect all surfaces of equipment after each attempt (two sets of equipment per lane for rotation).

BSI: body substance isolation; COVID-19: Coronavirus; FH: frequency hop; HPCON: health protection condition; MEDEVAC: medical evacuation; MEV: medical evacuation vehicle; SINCGARS: single channel ground and airborne radio system;

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A Citywide Analysis of DWI Events in Association with Bar Reopening and Increased Restaurant Capacity

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Abstract

Background: During the COVID-19 pandemic many bars closed. Simultaneously, many persons experienced stay at home orders linked to an increase in alcohol use. The net impact of these restrictions on the incidence of driving while intoxicated (DWI) events is unclear.

Methods and Material: We conducted a retrospective observational analysis using publicly reported data regarding police traffic encounters. We analyzed changes in DWI encounters in the San Antonio, TX metropolitan area before (1-14 October 2020) versus after (15-28 October 2020) bars reopened during the COVID-19 pandemic. We made these comparisons by comparing medians and through regression modelling to control for potential confounders.

Results: During the study period, 16,609 police traffic encounters met inclusion criteria. Of these, 353 were DWI encounters, 594 were officer traffic stop encounters, 14,565 were traffic related encounters, 113 were wrong way driver encounters, and 984 were other traffic violations. In the before and after analysis, there was no difference in the daily median numbers of DWI encounters (12 versus 10, p=0.461), wrong way driver incidents (3 versus 2, p=0.328), or other traffic violations (34 versus 35, p=0.854). The multivariable regression model similarly identified no change in the daily incidence of DWI encounters (p=0.281).

Conclusions: We detected no change in the incidence of DWI encounters immediately following the reopening of bars in the San Antonio metropolitan area.

Keywords: coronavirus; COVID19; bar; alcohol; restaurant; police

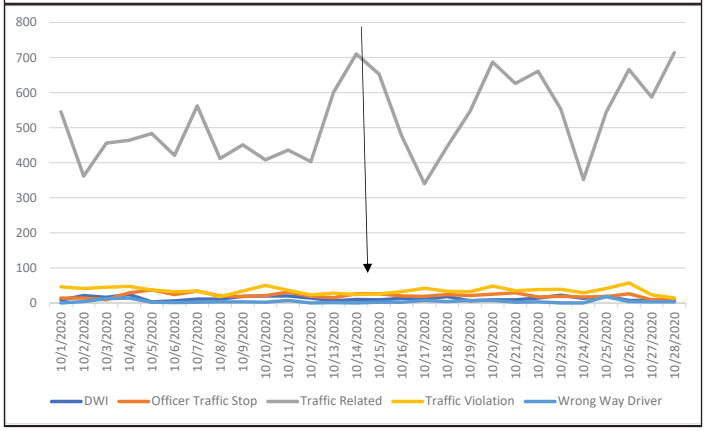
Introduction

Background: One of the most common types of traffic incidents in the US is driving while intoxicated (DWI). These infractions involve drivers operating a motor vehicle under the influence of alcohol or other drugs. In Texas in 2019, there were 24,617 crashes related to a DWI and 886 fatalities, with 2,108 crashes and 54 fatalities in Bexar County alone.[1] Therefore, these crashes demand many hours of police involvement and the victims require the full spectrum of emergency medical services.

In January 2020, the World Health Organization (WHO) declared an international public health emergency, and soon after on March 1st, 2020, the US declared a national emergency as cases rose exponentially.[2,3] Each state varied in lockdown orders, closure restrictions, and social distancing orders. Researchers noted an association between closing restaurants and bars with a significant reduction in the spread of COVID-19.[4,5] Texas Governor Greg Abbott declared a state of emergency on March 13th; on March 23rd, he rendered an executive order closing restaurants and bars except for delivery, carryout, or

curbside pick-up.[6] This prohibition lasted until April 29th, when restaurants re-opened to 25% capacity while bars remained closed.[7] On October 15, 2020, Governor Abbott released an order allowing restaurants to expand to 75% capacity, allowing bars to re-open to 50 percent capacity with all patrons seated.[8]

Figure 1. Volume of daily traffic events during the study period. The vertical axis represents the daily number of traffic events. The horizontal axis represents the day of study. The vertical arrow denotes the start of the after period (15 October) after the executive order re-opening bars and expanded the capacity of restaurants. Each of the lines represents a distinct category of traffic-related event in accordance with the legend.



It remains unclear what effect this final order may have on behavioral changes specifically regarding alcohol use. Closing the bars might logically have reduced the incidence of alcohol use and misuse. However, it is also possible the preponderance of alcohol use occurs outside of these establishment settings. Previous studies reported an increase in alcohol consumption after implementation of the pandemic lockdown orders.[9-11] Patients with mental illnesses such as depression and anxiety frequently experienced exacerbations due to alcohol use.[9,12,13] Poorer overall mental health may lead to increasing dependence on alcohol as a coping mechanism.[13,14]

There are also concerns with the presence of Joint Base San Antonio in the county. The misuse of alcohol and DWI events are prevalent in the military, and increased stress from the pandemic accompanied by the re-openings could exacerbate these problems.[15,16] A previous study indicated decreasing the hours in which alcohol can be sold decreased the number of DWI events, so the opposite may occur when hours for alcohol purchase increase again.[17] This question has significant public health implications insofar as alcohol related incidents may result in increased emergency department (ED) visits and resource consumption, especially with such a large military population in a large city. It remains unclear whether re-opening of bars and expansion of restaurant capacities lead to an increase in intoxicated driving incidents.

Goal of this Investigation: We assess the effects of the statewide order authorizing bars to re-open and restaurants to expand indoor dining capacity on the incidence of DWI events.

Materials & Methods:

Ethics: The Brooke Army Medical Center regulatory office evaluated the study protocol. It determined the protocol was exempt from institutional review board oversight given the utilization of data is publicly available and non-identifiable.

Subjects & Settings: Our study examined the incidence of driving while intoxicated (DWI) encounters within San Antonio, TX, using publicly reported police call data, available at https://www.sanantonio.gov/SAPD/Calls. DWI includes operating a motor vehicle under the influence of alcohol or other drugs. Bexar County has a reported population of 2,003,554 based on the most recent census.gov data.[18] The city accounts for most of the county population at 1,547,253. We extracted all traffic-related data from the public database from 01 October 2020 through 28 October 2020.19 Available publicly reported data includes DWIs, officer traffic stops, traffic violations, wrong way driver, abandoned vehicles, and unspecified traffic stops.

Executive order GA-32 from Governor Abbott authorized bars to reopen at midnight night 14 October 2020. We used a period of 2 weeks before (01 October 2020 through 14 October 2020) versus 2 weeks after opening (15 October 2020 through 28 October 2020) as the after period. We excluded calls for abandoned vehicles and high water calls as these were unlikely to contribute to overall traffic activity, police activity, and commensurate DWI stops.

Table 1. Median (interquartile range) encounters per day before and after the reopening of bars and expansion of restaurant capacity.

Incident	Before	After	p-value*
Driving while intoxicated	12 (7-20)	10 (7-15)	0.461
Officer traffic stop	20 (14-29)	19 (17-25)	0.580
Traffic related	453 (411-549)	570 (468-662)	0.066
Traffic violation	34 (28-41)	35 (27-45)	0.854
Wrong way driver	3 (2-7)	2 (0-2)	0.328

Data Analysis: We performed all statistical analyses using standard statistical commercial software. We reported categorical variables as numbers with percentages; ordinal variables as medians with interquartile ranges; and continuous variables as

means with confidence intervals. We used a least squares regression model to assess difference in differences before and after in unadjusted models and models adjusted for officer traffic stops and traffic violations to account for potential differences in police activity.

Table 2. Monthly volume comparison pre-pandemic and pandemic.

	Median (IQR)/Wilcoxon rank sum			Poisson regression data	
Month	2019	2020	p-value	Goodness of Fit	Effect
January	13 (9-18)	12 (8-18)	0.955	<0.001	0.917
February	12 (10-17)	16 (10-21)	0.321	<0.001	0.066
March	17 (12-21)	10 (6-17)	<0.001	<0.001	<0.001
April	14 (9-21)	6 (4-9)	<0.001	<0.001	<0.001
May	13 (10-18)	9 (6-15)	0.014	<0.001	<0.001
June	14 (10-20)	11 (9-16)	0.070	<0.001	<0.001
July	15 (10-20)	9 (6-12)	<0.001	<0.001	<0.001
August	14 (12-20)	10 (8-15)	0.001	<0.001	<0.001
September	14 (10-19)	10 (7-15)	0.101	<0.001	<0.001
October	13 (10-22)	12 (8-18)	0.119	<0.001	0.002
November	15 (11-20)	13 (9-16)	0.189	<0.001	0.055
December	15 (11-19)	12 (10-18)	0.534	<0.001	0.663

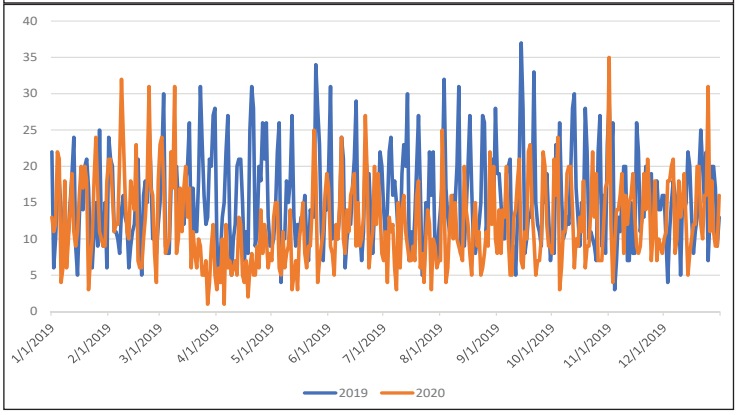
Results

During the study period, 16,609 police traffic encounters met inclusion criteria (Figure 1). Of these, 353 were DWI encounters, 594 were officer traffic stop encounters, 14,565 were traffic related encounters, 113 were wrong way driver encounters, and 984 were other traffic violations (Table 1). In the before and after analysis, there was no difference in the daily median numbers of DWI encounters (12 versus 10, p=0.461), wrong way driver incidents (3 versus 2, p=0.328), or other traffic violations (34 versus 35, p=0.854 (Table 2, Figure 2). The multivariable regression model similarly identified no change in the daily incidence of DWI encounters (p=0.281).

Discussion

In January and February of 2020, there were no significant differences in DWI occurrences compared to the same months in 2019. However, following the state of emergency declaration in March 2020, there was a significant decrease in the rate of DWIs in the months of March, April, May, July, and August when compared to the previous year. Clearly, the early stages of the lockdown in Bexar County helped reduce the DWI incidence rate in 2020. In October 2020, executive order GA-32 re-opened bars and expanded restaurant capacity across the state, including San Antonio. Findings from the publicly reported police traffic data demonstrated no association with DWI volume and the re-opening of bars or expansion of restaurant capacity. There was also no significant differences in the rate of DWIs in the period of October-December 2019 and October-December 2020. Additionally, we found no major increases in reported traffic related stops, traffic violations, or wrong way drivers. Even when adjusting for potential confounders related to overall law enforcement activities— traffic violations and officer traffic stops—we found no significant differences. Our findings suggest the re-opening order was not associated with a material impact on alcohol-related driving incidents.

Figure 2. Volume of incidents per day during the study period. The vertical axis represents the daily number of traffic events. The horizontal axis represents the day of study. Each of the lines represents a different year of police traffic data in accordance with the legend.



A study in India reported an increase in patients with traumatic injuries after easing of lockdown restrictions and subsequent re-opening of liquor stores. This is potentially due to increases in road traffic and people driving under the influence of alcohol.[20] However, in Louisiana, an analysis of crashes before and during a state lockdown order reported a large decrease in total accidents but similar numbers of crashes involving alcohol.[21] Therefore, re-opening may result in a commensurate increase in crashes involving alcohol based on these studies. It is difficult to determine whether fewer people are visiting bars due to the risk of COVID-19 or if they are taking appropriate precautions while driving. More detailed data regarding regional economic activity could shed more light on whether this change in lockdown restrictions had a significant effect on alcohol purchases and consumption. Our data are preliminary as research into the behavioral effects of the lockdown orders.

Limitations of our study include its observational design. As such, we are unable to

infer causality. Furthermore, we relied on publicly reported traffic data without available data on the number of people who went to bars after re-opening. We assumed there were no changes in policing after re-opening and attempted to adjust our model for the published data, but must acknowledge it is an indirect measurement. Also, we could not obtain demographic data such as race, age, gender, socioeconomic status, or zip codes to reach a more detailed conclusion. Based on our results, it is unclear how re-opening bars may contribute to overall pandemic changes and whether they will be a major source of infections. Data specific to pandemic-related outcomes such as overall caseload, hospitalizations, and mortality are necessary. Longitudinal studies are necessary to assess the changes in behavior as more re-openings occur. Additional augmentation with economic data would be helpful.

Conclusion

In conclusion, executive order GA-32 re-opened bars and expanded restaurant dining capacity in Texas during the COVID19 pandemic. We did not detect any significant increase in DWI police encounters in one large metropolitan area following the executive order. Further studies are necessary to assess changes in behavior associated with the reopening actions in Texas.

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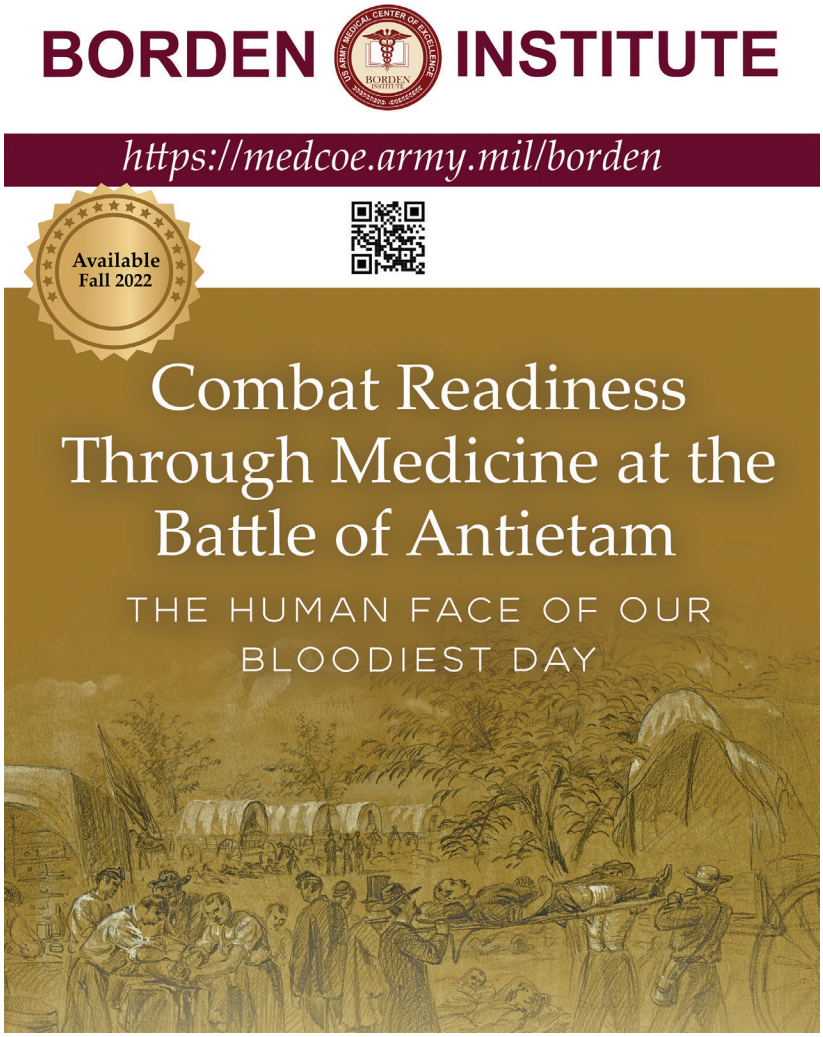

Impact of Mobile COVID-19 Laboratory Testing on Readiness of US Army 1/34th Armored Brigade Combat Team, 34th Infantry Division Deployment to National Training Center, Fort Irwin, CA

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Abstract

The emergence of the novel severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) rapidly evolved into a worldwide pandemic of Coronavirus Disease 2019 (COVID-19). The pandemic had a major operational impact upon the US military, requiring interventions to mitigate transmission risk resulting in DoD-wide disruption of daily operations, restriction of movement, and delays in training. Development of a rapid mobile COVID-19 testing strategy was pursued as a means to allow service members to complete critical missions in select settings. In this report, we describe the first of its kind mobile medical laboratory (MML) that allowed for testing of approximately 4,000 soldiers of the 1/34th Armored Brigade Combat Team (1/34th ABCT), 34th Infantry Division, prior to deployment for validation exercises to the National Training Center, Fort Irwin, CA. We describe the utilizing of the MML, COVID-19 testing workflow, clinical symptom data/cycle threshold (Ct) data from positive patients, and outcomes from this testing mission.

Keywords: SARS-CoV-2; COVID-19; US Army; cycle threshold (Ct); MML

Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic has had global implications since December 2019. The coronavirus causing the severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) emerged from Hubei Province of the People's Republic of China in December 2019.[1] This virus can spread during the presymptomatic, asymptomatic, and symptomatic stages of the infection, making it difficult to control in community settings.[2] SARS-CoV-2 is primarily a respiratory virus infecting and affecting the respiratory system, but with pathogenicity in other body organs.[3]

Extreme measures have been attempted by the World Health Organizations (WHO), national governments, and communities to slow the spread of a disease, which in its most severe form, has overwhelmed intensive care units and respiratory support teams.[4,5] Laboratory testing for SARS-CoV-2 is critical to determining status, isolating the sick, and initiating treatment. The gold standard for SARS-CoV-2 testing is nucleic acid amplification tests (NAATs) to detect the ribonucleic acid (RNA) of viruses numbering close to 1 million copies per ml of transport media during the first days of infection when sampled from a patient's nasopharyngeal passages.[6]

Testing plays an essential role in maintaining force readiness across the world by helping address the concern for rapid and widespread infections of SARS-CoV-2 among trainees and units in operational environments. It has been shown throughout military history, including as recently as Operation Iraqi Freedom (OIF) / Operation New Dawn (OND), disease nonbattle injuries (DNBI) can account for significant degradation in operational unit readiness. Young and healthy patients often present a mild infection when infected with SARS-CoV-2.[7] To minimize DNBI due to SARS-CoV-2, the early establishment of isolation or restriction of movement (ROM) is critical to establish a quarantine for soldiers coming into training or those who have come into close contact with infected individuals.[8] Unit readiness is essential to mission success, and availability of testing is critical to assessing unit readiness during a pandemic such as COVID-19.

Figure 1. COVID-19 mobile molecular laboratory (MML) interior and exterior pictures. Physical establishment of the MML completed 48 hours after arrival at Camp Ripley Training Center, MN. Each laboratory had 2 biosafety cabinets, Cepheid GeneXpert Real-Time-Polymerase Chain Reaction (RT-PCR) instruments, and refrigerators/freezers.

Due to the global impact of COVID-19, US Army mission-essential training was delayed in early 2020 until testing procedures could be developed for screening all soldiers for SARS-CoV-2 before entering the training environment. Availability of sufficient testing capability with rapid turnaround time was critical for time-sensitive decision-making, focused around training and deployment. In June 2020, two mobile medical laboratories (MMLs) were delivered to Camp Ripley, MN, to test all soldiers for COVID-19 before mobilization for capstone validation at the National Training Center (NTC), Fort Irwin, CA. Camp Ripley, MN, is a 53,000-acre regional training center for both civilian and military agencies, located 2 hours northwest of Minneapolis-Saint Paul, MN. The testing for Task Force Viking supported the Bloomington, MN-based 1/34th Armored Brigade Combat Team (1/34th ABCT) of the 34th Infantry Division. This unit was first to complete a National Training Center (NTC) rotation after being halted due to COVID-19 Pandemic. This report presents outcomes and lessons learned from this COVID-19 testing mission at Camp Ripley, MN.

Materials & Methods

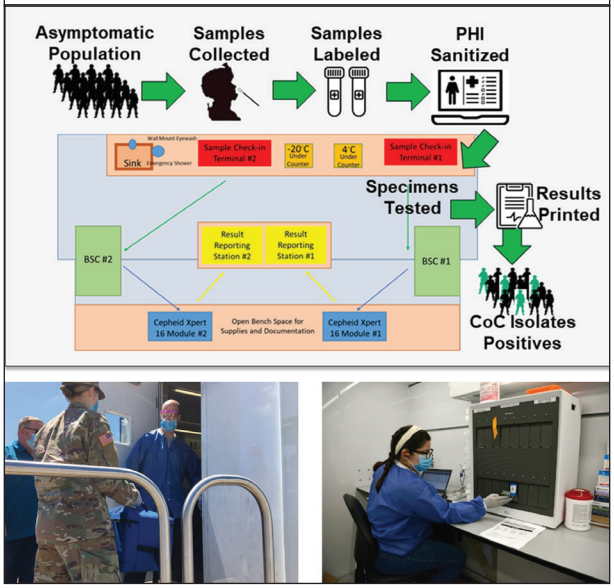
The MML is a first-of-its-kind mobile laboratory with a laboratory sample accessioning area, refrigerated sample storage, bio-safety cabinets, benchtops, and Cepheid GeneXpert testing equipment. Two MML units were contracted and built for Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRN). Labs were designed for rapid deployment and setup at field locations exterior to fixed medical facilities. These laboratory units were built onto a gooseneck trailer for ease of transportation. The lab was set up in a secured empty trailer storage site, which provided external electrical power, water, and access to the storage of laboratory testing supplies. Physical establishment of the MML was complete within 36-48 hours for each laboratory with electricity and water online (Figure 1). Water was not directly onsite but fed via a multi-purpose maintenance building, which served as the operational command site and supply storage while testing was being conducted. Class IIA Biological Safety Hoods and Cepheid GeneXpert (Cepheid, Sunnyville, CA) testing equipment completed verifications within 10 days upon delivery of MML.

Testing personnel consisted of 30 laboratory technicians who conducted testing in 8-hour shifts / 24 hours per day when operations were underway. Technicians completed fire safety training from the Camp Ripley Fire Department and chemical hazard/laboratory hazard training from MML leadership. All technicians were competency accessed on specimen processing, loading, resulting, and certification of final results. Nasopharyngeal swabs and media were sourced by JPEO for this testing mission. Nasopharyngeal swabs were collected from each soldier during each testing day. Informational handouts on COVID-19 testing were available to soldiers who had questions regarding the COVID-19. The MML applied and received Department of Defense (DoD) Clinical Laboratory Improvement Program (CLIP) certification from the DoD Center for Laboratory Medicine Services (CLMS) upon completion of laboratory testing checklist,

inspection, and completed all requirements to serve as a testing facility. This process took 2 weeks to meet all the requirements and regulations for the CLIP approval.

The mission was to complete health checks and COVID-19 testing on all soldiers joining with their respective units. A total of 3,929 soldiers were tested over 8 testing days. As soldiers arrived at Camp Ripley, signs directed all soldiers to the drive-through testing area for initial health screening and to receive patient labels for sample tubes (Figure 2). Soldiers were given a verbal screening questionnaire, which consisted of the current health of the patient and any COVID-19 symptoms (fever >100.4, chills, cough, dyspnea, or sore throat). Additional questions also asked whether soldiers had been in contact with COVID-19 infected family members and any prior COVID-19 confirmed infections. Those with symptoms were sent to a separate screening lane with Camp Ripley medical providers for symptomatic screening. Soldiers arrived 3 days before departure to NTC to allow screening, testing, and identifying close contacts who required removal from the mission and quarantine.

Figure 2. Mobile molecular laboratory (MML) COVID-19 specimen workflow and photos of arrival of first sample and processing.



Symptomatic and asymptomatic areas were established for testing. Medical technicians and nurses performing specimen collection wore sterile gloves and an extended-use plastic gown, N95 respirator, and face shield as personal protective equipment (PPE). Nasopharyngeal collections with nasopharyngeal swabs (NP) were collected into viral transport media (VTM). Before sampling, patient information was confirmed to ensure printed labels matched. Specimen collection occurred in an open bay, a large open-air drive-through, covered garage bay in their vehicles, with swabbing locations separated and mask-wearing to respect social distancing. Collected specimens were then stored in coolers until being transported to the laboratory for testing. After swabbing was completed, soldiers would check in with units, be given directions, and social distancing and mask-wearing reinforced. All soldiers were allowed to take educational information about COVID-19.

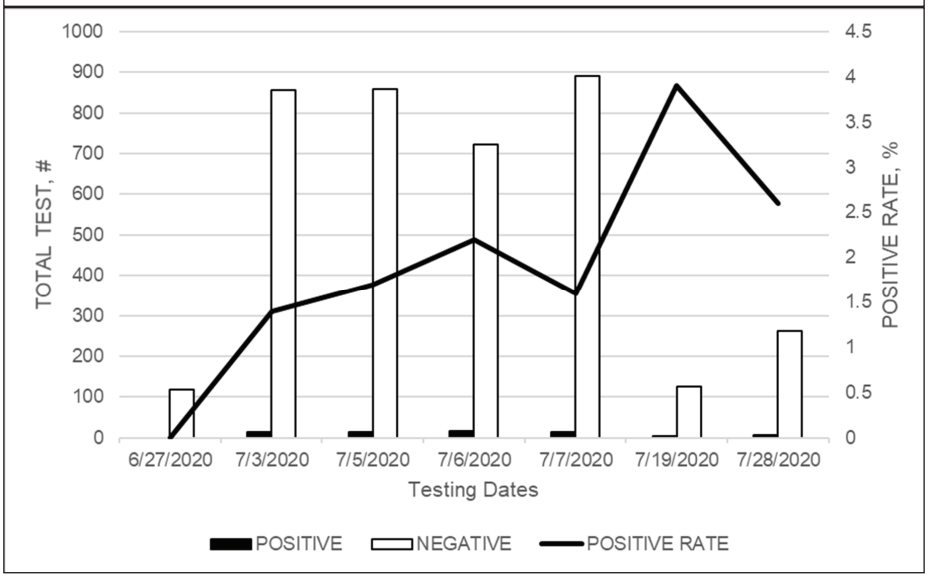
Medical providers screened soldiers for COVID-19 symptoms based on CDC guidance and, if symptomatic, directed soldiers to the Camp Ripley Isolation Support Facility (ISF) for isolation and quarantine. Soldiers would report to the ISF and be given additional medical screening before being placed in a required 10-day quarantine. Close-contacts of COVID-19 positive soldiers were quickly determined and admitted to the ISF for quarantine during the testing period. Close-contact admission occurred when positive COVID-19 results from an individual soldier were reported, and other soldiers reported not adhering to masking/isolation guidelines. Close contact admissions were kept in separate areas of the isolation area away from confirmed positive soldiers. All soldiers had daily health checks by onsite medical providers.

Collected laboratory samples were transported from the collection site to the MML in a cooler with ice packs via government-owned cars. All samples were delivered to the MML located within a half-mile of the collection site. Before specimen arrival at the laboratory, 2 forms of identification (i.e., date of birth, full name) were provided on specimen labels for each soldier; data were confirmed before testing. Sample tracking was of the utmost importance. To conform to Health Insurance Portability and Accountability Act (HIPAA) requirements, specimens were labeled with appropriate personal identifying information. Due to the lack of Laboratory Information System (LIS) access, a unique identifier (first initial of first and last name followed and last four of the DoD identification) was developed for each soldier utilizing the alpha roster provided by 1/34th ABCT leadership and added to the label. The unique identifier was critical for the sample processing, as the Cepheid GeneXpert computer system lacked the personal identifiable information (PII) security requirements. The unique identifier was entered into the GeneXpert computer software for each soldier.

When samples arrived at MML, accessioning of all collected specimens was completed with samples refrigerated until ready for processing. Each sample was run on Cepheid GeneXpert instrument using the company's SARS-CoV-2 Emergency Use Authorization (EUA)

assay. The assay is a Real-Time- Polymerase Chain Reaction (RT-PCR) that tests for the presence of viral COVID-19 RNA. Daily quality control was run at the start of each day before samples arrived. Positive cycle threshold (Ct) cut-off values for the N2/E gene were set at 45 cycles. Ct values represent the number of nucleic acid amplification cycles that occur before a specimen containing the target genetic material generates a signal greater than the predetermined threshold that defines positivity. The resulting Ct value is inversely correlated with the amount of target material in a tested material in a tested specimen and may correlate with outcomes in the patients.[9-11] Criticisms of the use of Ct values for use in patient diagnosis have been documented especially due to challenges of standardization of Ct values generated by different testing platforms, along with preanalytic factors of specimen collection kits and patient collection.[12]

Figure 3. Mobile molecular laboratory (MML) COVID-19 testing totals by date. Data represents first time positive soldiers. Total tested (negative and positive) and positivity rate are displayed.



Sample unique identifiers for each specimen were checked multiple times from the point samples were received, loaded into GeneXpert COVID-19 testing cartridge, and final result prints were generated from the instrument. Hard-copy results were printed off for each patient. The soldier's label was matched to the result. Results were then provided to the medical provider team on duty. Positive results were notified immediately to initiate a rapid response. Camp Ripley medical providers notified unit commanders of positive results and gave information for those commanders to direct COVID-19 positives and close contacts to the appropriate areas at the ISF for assessment and admission. Soldiers with positive results were placed into the ISF isolation wards, as were soldiers with negative test results but symptoms consistent with COVID-19. Contact tracing was conducted for all positive patients. Those deemed to have come into contact with positive patients were evaluated by ISF medical staff to determine the risk of COVID-19 transmission.

Frequency comparisons for categorical variables (age, sex) were analyzed using the Fishers exact test. Differences between medians were compared using the Mann-Whitney U test. Student's T-tests were carried out to determine differences in clinical symptoms, the number of symptoms (pre/post-test), and known prior contacts to positive SARS-CoV-2 patients. Additionally, run data for each specimen was subset by cycle threshold (Ct) value into several groups to compare lower, middle, and higher values. Data was then analyzed by one-way ANOVA using a linear statistical model of Ct group, N2 Primer, E primer, and Ct group x N2/E primer interaction. Two-sided exact P-values are reported. A P-value of <0.05 was considered statistically significant. Frequency analysis of symptoms due to SARS-CoV-2 infection was compared by Ct group, age, and sex. The analyses were performed using standard commercial statistical software.

Results

MML Total Testing Volumes for SARS-CoV-2 Infections: A total of 3,929 nasopharyngeal swabs were run over 8 testing days (27 June 2020 through 28 Jul 2020) (Figure 3). Of the total tested 3,840 (97.7%) negative samples, 69 (1.7%) positive samples, and 6 repeat positive samples were resulted. Only first-time positive data are listed in Figure 3. During the course of the testing period, testing volumes ranged between 117-905 samples per day. The positivity rate ranged between 0-3.8% throughout testing. Overall, the positivity rate was consistent with the community at the time and did not indicate an outbreak. Rapid test results and identification of close contacts allowed for notification to leadership to prevent further spread among the units.

Table 1. Clinical features of soldiers tested positive for COVID-19 based on performance of Real-Time-Polymerase Chain Reaction (RT-PCR). Clinical data were collected at point of reception into Camp Ripley isolation support facility along with daily health checks. Data were analyzed by frequency analysis and One-Way Paired T-Test adjusted for multiple comparisons. Statistical significance set at P<0.05.

Demographics	TOTAL	MALE	FEMALE	*P-value*
Total Tested Positive, N	63	48	13	0.32
N, (Age Range) y	63, (18 - 59)	48, (18-59)	13, (18-39)	0.32
Signs and Symptoms, No. (%)				
Asymptomatic, N (%)	23, (56%)	18, (78%)	5, (22%)	0.33
Fever/ Chills, N	1	1	0	0.50
Myalgia, N	1	1	0	0.50
Cough, N	2	2	0	0.50
Fatigue, N	1	1	0	0.50
Difficulty breathing, N	1	1	0	0.50
Chest Pain, N	1	1	0	0.50
Congestion, N	3	3	0	0.50
Diarrhea, N	2	2	0	0.50
Headache, N	1	1	0	0.50
Sore Throat, N	2	2	0	0.50
Senses, N	5	5	0	0.50
Nausea/Vomiting, N	1	1	0	0.50
Number of Symptoms				
1--3	13	5	0	0.50
3--5	3	3	0	0.50
Known Prior Contact	13	12	1	0.46
Symptoms Pre-Testing				
1-3 d	5	5	0	0.50
3-7 d	2	2	0	0.50
7+	2	2	0	0.50
Symptoms Post-Testing				
1-3 d	1	1	0	0.50
3-7 d	3	2	1	0.20
7+	1	1	0	0.50

Clinical Features SARS-CoV-2 Positive Soldiers: Confirmed SARS-CoV-2 positive soldiers (N=63) were determined within several hours after samples were submitted to the MML. Turn-around time depended on the respective unit's arrival time to Camp Ripley for specimen collection and throughput limitations. Testing averaged 70 samples per hour with four GeneXpert machines running non-stop. Soldiers' clinical histories were taken during processing into the Camp Ripley ISF and tabulated (Table 1). The age range for the positive samples were 18-59. The majority of positives were male soldiers. Asymptomatic positives accounted for a total of 56% of the total positive samples. A small number of positive soldiers had symptoms before testing (9), with the majority reporting development of symptoms with 1-3 days before testing. All symptoms associated with positive infections are shown in Tables 1 and 2.

Interpretation of Ct Values from Confirmed Positive Results: Comparisons of the Ct were subset into three groups (18-30, 31-39, and 40-45), with these all being sorted by the nucleocapsid gene and envelope gene (N2 region of the N-gene and E gene). N2 and E gene analysis was broken into 11, 21, and 7 positive samples for Ct values of 18-30, 31-39, and 40-45, respectively. The E gene Ct value group of 40-45 had nine positive samples. Mean Ct values between all three groups were significantly different (P<0.001) for both N2 and E gene regions (Figure 5a).

Table 2. Clinical features of soldiers with N2/E or N2 only gene detected for COVID-19

N2 Gene Only (Ct) (n=5)	E Gene (Ct), (n=0)	AGE	SEX	Clinical details of patient at time of testing
43.9	0	18-24	M	Senses
39.2	0	18-24	M	Fever, Chills, and Sore Throat
40.2	0	18-24	M	Asymptomatic
41.7	0	18-24	M	Asymptomatic
43.5	0	18-24	M	Fever, Chills, Senses, Cough. and Nausea
N2 Gene (Ct) (n=39)	E Gene (Ct), (n=39)	AGE	SEX	Clinical details of patient at time of testing
18.3	15.8	18-24	F	Asymptomatic
19.3	17.5	25-29	M	Fever, Chills
20.1	18	18-24	M	Asymptomatic
21.6	19.5	18-24	M	Asymptomatic
22.9	20.3	25-29	M	Cough
22.9	20.5	18-24	M	Fever Chills, Difficulty Breathing, Aches, Congestion
24.8	22.6	25-29	M	Asymptomatic
24.8	23.1	18-24	M	Congestion
26.9	24.7	18-24	M	Diarrhea, Congestion, Senses
28.7	26.4	18-24	F	Asymptomatic
31.4	29.1	18-24	F	Asymptomatic
31.6	28.6	18-24	M	Sore throat, Senses, Headache, Fever /Chills, aches
33.9	30.8	18-24	M	Asymptomatic
34.6	31.3	18-24	M	Asymptomatic
35	32.1	25-29	M	Cough
35	32.4	18-24	M	Chest Pain
35.1	32.5	18-24	M	Asymptomatic
35.5	32.1	18-24	F	Difficulty Breathing
35.7	32.1	18-24	M	Asymptomatic
35.9	32.6	18-24	M	Asymptomatic
37	34.7	25-29	M	Asymptomatic
37.4	33.7	18-24	M	Fever/ Chills, Cough, Sore Throat
38.2	36	18-24	M	Asymptomatic
38.4	36.4	18-24	M	Asymptomatic
38.7	40.2	25-29	M	Congestion, Senses
38.8	36.2	18-24	M	Asymptomatic
38.9	38	25-29	F	Asymptomatic
39.4	39.9	18-24	M	Headache
39.9	44.3	18-24	F	Headache
40	39.2	25-29	M	Asymptomatic
40.5	43.4	18-24	F	Headache
40.6	41.3	18-24	M	Asymptomatic
41	41.9	18-24	M	Asymptomatic
41.6	38	30-39	M	Fever/Chills, Cough
42.1	38.9	40-59	M	Headache
43.1	39.4	18-24	M	Asymptomatic
31.6	29	18-24	M	Asymptomatic
n=21, No Clinical Symptoms Available				

Clinical features, demographics, and testing data for those soldiers who had symptoms before testing, those who had symptoms after testing, and those who had known contacts with positive patients can be found in Table 2. Symptoms by N2 grouped regions were plotted on pie charts for each group (Figure 5b-5d). E gene region data was not included in this figure as the data were similar to the N2 gene region results. The groups (18-30 and 31-39) with lower Ct values had more recorded symptoms than the 40-45. The 18-30 Ct value group had multi-symptoms, cough, congestion, fever/chills, but

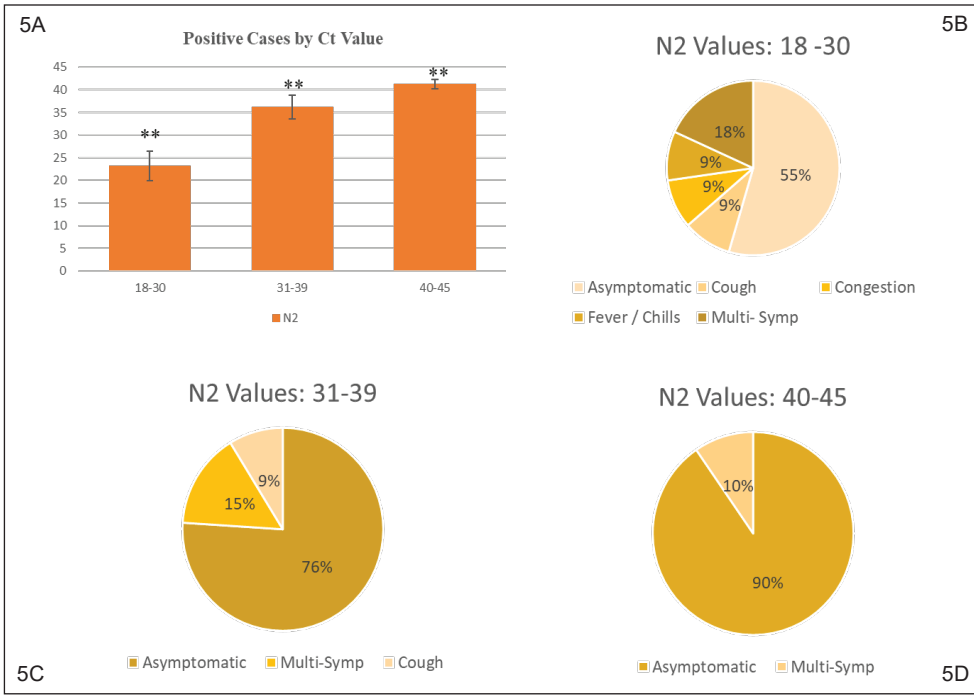


Figure 5A. Cycle threshold (Ct) value analysis of N2 gene values. Positive Cases by Ct value (N2 gene) were determined by mean Ct values broken into three distinct Ct groups: 18-30, 31-39, and 40-45. Statistical significance by Ct value was set at P<0.001. Error bars represent the standard error of mean.

Figures 5B-5D. N2 gene symptoms presented by N2 gene Ct groups of 18-30, 31-39, and 40.45.

asymptomatic symptoms were noted. Among the 18 soldiers who developed symptoms before or after positive test results, N2 Ct values were not significantly different prior-test (P=0.172) and post-test (P=0.118). N2 Ct values of prior-test patients between days 1-3 & 8-10 had mean Ct values of 30.4 versus 39.8, respectively. Though not statistically significant, these data are consistent with a drop in viral/nucleic acid titer over the course of infection and may have lacked the statistical power due to the low numbers of positive patients with incomplete medical screening information. Collectively, the data suggest lower N2 Ct value showed a trend indicating soldiers with more symptoms had higher viral RNA copy load.

Discussion

This study utilized a drive-through methodology, which allowed for a thorough, safe, and efficient procedure for recording soldier data and collecting samples. The study collection site was based out of a multi-purpose maintenance building with 4 drive-through lanes. Soldiers were able to drive through, get samples taken while remaining in their car, and then report to unit leadership. Charter tour buses with soldiers were also used for large groups of soldiers who had traveled farther distances or flown in from other states for testing. Soldiers unloaded from reduced capacity buses while wearing masks, completed health questionnaires, collected specimen labels, and their specimen collected in a socially distanced manner. Use of drive-through screening has been documented as a safe and effective method to test healthcare workers.[13-14] The use of the drive-through mass testing for SARS-CoV-2 was deemed to be a success by leadership.

COVID-19 Ct values have garnered interest within the medical field as a potential benchmark for understanding circulating viral RNA levels. Ct values generated from US Air Force basic trainees tested for COVID-19 in a cohort setting were found to be useful in assessing risk of ongoing transmission among specific cohorts. Trainees with more symptoms and lower Ct values had the greatest risk of starting disease clusters.[8] Our study found greater than 50% of all COVID-19 infections being asymptomatic within N2 Ct subset groups of 18-30, 31-39, and 40-45 with values of 55%, 76%, and 90%, respectively. The remaining infections had a multiple number of symptoms recorded for each soldier during daily rounds. This study found multiple clinical symptoms, including typical upper respiratory infections, gastrointestinal illness, and common cold (head ache, sore throat) in soldiers with lower Ct values. All soldiers were treated on-site at the Camp Ripley ISF, with only 1 being transported to CHI St. Gabriel's Emergency Room, Little Falls, MN, for further evaluation. Overall, our study analyzed both the N2 (spike protein) and E (envelope) regions of the virus. We presented the N2 region Ct values in our analysis. While N2 Ct values are not direct quantitative measures of patient viral loads, the

results presented above may suggest viral RNA levels in the nasopharynx are elevated after symptoms appear.[15]

Use of COVID-19 Ct values as an indicator for disease presence holds potential for training and operational units in the US military. This study has shown the overall positivity rate for our testing mission at 1.7%, with a range of 0-3.8% among cohorts arriving from different locales. This low positivity rate may have been partly due to the isolation protocol disseminated to the units before arrival at Camp Ripley. Social distancing and mask use was ordered for all soldiers upon arrival on base. These experiences are consistent with those noted in Joint Base San Antonio (JBSA) training environment, where disciplined and early non-pharmaceutical interventions (NPI) include quarantine, physical distancing, cloth face coverings, and rapid identification/isolation of potential cases allowed continuous operations during the pandemic.[13] Widespread implementation of NPIs should be considered a critical method for public health prevention from communicable diseases for deploying high intensity validation training units, and the US Army as a whole.

Early and rapid detection of SARS-CoV-2 viral infection is vital to prevent spread of the infection within units. The Minnesota National Guard's 1/34th Armored Brigade Combat Team was the first unit to complete validation training at the National Training Center at Fort Irwin, CA, since the outbreak of the COVID-19 pandemic. This unit, combined with attached force multiplier groups, was composed of members from Minnesota, Iowa, South Dakota, North Dakota, Wisconsin, Michigan, and New Jersey. The movement of these soldiers and integration into their respective units during a pandemic were concerning considering the transmissibility of SARS-CoV-2. Use of the MML for SARS-CoV-2 testing in a remote setting allowed for rapid results within a couple of hours from the point of specimen collection to certified results. COVID-19 test status of each soldiers' test status allowed ABCT leadership to make critical decisions for the upcoming missions at NTC. Additionally, early detection of SARS-CoV-2 positive soldiers allowed those soldiers to join the unit at NTC once they had cleared quarantine. In contrast, lack of rapid test capabilities resulted in degradation of readiness and impacted ongoing operations when a National Guard soldier tested positive for SARS-CoV-2 while completing training at Fort Gordon, GA in 2020.[16]

Lessons Learned: These results indicate the need and effectiveness for rapid testing, isolation, and care of soldiers in military units, especially in training environments (Joint Readiness Training Center or National Training Center) or combat zones. Restriction of movement (ROM) is currently being utilized by the US Air Force and Army for basic trainee/phase 2 training to prevent spread of COVID-19 within units. Until COVID-19 infections are brought under control by NPI, the use of ROM for new service members will be a necessary method for safely determining COVID-19 status of each member.

The support Camp Ripley provided will not be universal from site to site. The setup of the MML's 2 trailers at Camp Ripley was staged on open concrete slabs with adequate security and electrical hookups. Infrastructure requirements of high voltage electrical outlets and electricians needed for hookups, water source for greywater tanks, flammable/chemical storage and lack of hardwire internet/poor cell phone service are all aspects to consider for the MML setup. The MML water source was fed from a 150-foot industrial water hose, which required our team to block a road when the laboratory was operational. Greywater tanks were contracted from a local company and pumped as needed. Greywater tanks were brought in for the laboratories to collect wastewater generated from hand washing and cleaning. Flammable and chemical storage for ethanol was stored in our multi-functional facility, as the MML lacked secure chemical cabinets. Our site lacked hard-wired internet access with our team utilizing wireless hot spots. This area had limited/poor cellular service, due to the location and hot spot wireless carrier. Overall, the MML is reliant on fixed infrastructure for success of the operation. Development of supply and operational push packs that have all the critical components to make it a standalone functional laboratory are needed. We had success with commercial vendors that were able to provide support for Cepheid equipment, biosafety hoods, and other MML equipment, which required servicing. This could be developed for future operations.

Biohazard waste was collected every couple of hours from each laboratory and stored in a locked closet within our operations building. Biohazard waste was collected by the Camp Ripley Troop Medical Clinic (TMC) after each testing day for disposal. Future locations will need a dedicated plan for biological waste, chemical storage, and operations, where soldier results could be verified/compiled prior to release with medical staff. Furthermore, this type of operation required a significant investment of supplies from Army Medical Logistics Departments at the following locations: Camp Ripley, Brooke Army Medical Center, and Fort Leonard Wood. Acquiring supplies during a pandemic was difficult for specific items such as ethanol, PPE (Laboratory Coats, gloves, and mask), and routine laboratory supplies. Going forward, creating MML supply push-packs

with all supplies needed to allow for testing of 500 patients would be beneficial for enabling rapid initiation and implementation.

Lack of a laboratory information system (LIS) made patient specimen accessioning, tracking, and resulting mainly a paper-based process. LIS systems are critical for record management, accessioning, and resulting patient tests while maintaining patient privacy requirements. Patient labels were created with the help of Camp Ripley TMC and 1/34th BCT provided alpha rosters from each unit and label printers. Staff at the Camp Ripley TMC provided a second reviewer for all finalized labels and printed labels for all soldiers. To meet the CLIP/CAP regulatory guidelines for patient labels, unique identifiers were created from the alpha rosters and consisted of aspects of the first/last name and DoD ID. Upon completing the test for each soldier, physical copies of test results were provided to medical providers. These results were then scanned into the National Guard health records database. Soldiers at the ISF were in charge of scanning all records and keeping records for all tests completed. Proper training on how to label, swab, and transport specimens was required to minimize specimen rejection. To ensure compliance in this area, each medic who was sampling soldiers had numbers issued to them and were added to each collected specimen, which could be traced back for re-training in the event trends developed.

This mission was unique because the medical director resided at Brooke Army Medical Center (BAMC) while the Officer in Charge (OIC) was on-ground at Camp Ripley, MN. Ensuring the OIC for the operation has the adequate credentials is essential. The OIC for this mission had a Ph.D and Microbiology certification from the American Society of Clinical Pathology (ASCP), but lacked the American Board of Medical Microbiology (ABMM) certification required to fulfill the medical director role under CLIP rules. In this instance, this relationship worked, as both OIC and the medical director were from BAMC. Phone and email communication were critical and must be considered, even in remote locations. MML COVID-19 testing is only viable with facilities for storage/operations, utilities (requires high voltage), medical logistics able to receive supplies, and staff with laboratory experience to understand molecular infectious disease testing workflow.

The operational cost of this mission is listed below, as an illustration of the expenses associated with this type of effort. Broken out is the cost of the lab, laboratory cleaning/PPE supplies, and personnel cost for the duration of the task. This estimate lacks the following: laboratory contractor personnel contract cost and office supplies. The price per reported test was $158.00 for this mission. This cost per test did not include testing reagent consumed for training, repeat testing/failed runs, or sustainment cost of MML.

- Estimated MML Mission Cost: $619,044
- Cost Per Test: $158
- Mobile Medical Laboratory (MML) One-Time Cost: $300,000
- Cepheid COVID-19 Assays & Collection Kits: $213,000
- Laboratory Cleaning/PPE Supplies: $10,000
- Personnel Total: $96,044

The COVID-19 testing mission with the MML was the first time it was utilized in the field and the first time used for clinical patient testing. Remote clinical testing was successful due to collaboration with multiple DoD commands (US Forces Command (FORSCOM), National Guard Bureau (NGB), MN National Guard (MNNG), Joint Program Executive Office–Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRN), and US Army Medical Command (MEDCOM). Medical logistics from Camp Ripley MEDLOG, Brooke Army Medical Center MEDLOG, and Fort Leonard Wood MEDLOG were critical for this testing mission to get all the necessary supplies needed to complete the mission.

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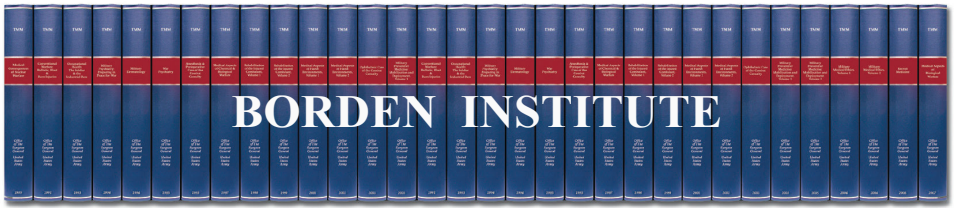

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Battlefield Triage and Resource Allocation during a Pandemic: Learning from the Past and Adapting for the Future

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Introduction

The principle of medical triage, where patients are sorted into categories to guide the order in which they receive treatment, dates back to Baron Dominique Jean Larrey, the surgeon general of Napolean's armies.[1] The concept evolved with military conflicts throughout the 19th century, was subsequently adapted to situations off the battlefield, and is now widely practiced where resources are limited.[2] Military medical providers are taught triage principles early in their careers and its use is routinely integrated into military training scenarios and operational planning.

In the present era of the COVID-19 pandemic, countries across the world have witnessed overwhelmed medical systems, whereby civilian medical leaders have had to rely upon the principles of medical triage to guide their medical response. These critical principles are being used to determine not only who receives limited resources (e.g. ventilators, intensive care unit [ICU] beds), but also in planning for the distribution of newer treatments and anticipated vaccines.

Triage on the battlefield has some noticeable differences from that practiced in civilian settings, but there are some valuable lessons to be learned from the military's long experience and can rightly be applied to the present public health crisis. In this paper, we will consider how battlefield triage may inform triage utilized during public health crises, with a particular emphasis on the underlying ethical principles.

Shifting Ethical Priorities: The similarities and differences between the triage in battlefield medicine and that utilized during public health crises may be best understood by examining their underlying ethical justifications. Most experts in bioethics agree the ethical practice of medicine is guided by 4 principles: beneficence, non-maleficence, justice, and respect for autonomy.[3] When ethical problems arise in clinical medicine, these principles are intended to guide appropriate medical decision making in order to determine the optimal treatment course for the given situation. The principle of autonomy is often given the highest priority in Western medicine.[4] Here, the focus of care is on the wishes of an individual patient. A well-informed patient is granted the latitude to make decisions for his or her medical care, even if the choices require high resource utilization for a small chance at a desired outcome. Aside from the limitations imposed by insurance coverage and other financial constraints, this is the decision-making environment most familiar to those living within the US.

In times of scarce resources, however, the decision must shift to include ethical principles to serve the greatest good. This utilitarian goal of providing the greatest good to the group as a whole, potentially at the expense of individual medical liberties, may be required. The ethical value of maximizing benefit to the community in a just fashion supersedes the more familiar focus on individual patient autonomy.[5] A strict utilitarian approach to care during resource limitations grants no weight to the needs of individual patients, but rather focuses on the aggregate good of the group.[6]

Battlefield Triage: Within the military medical community, this shift in priorities is a familiar one to anyone who has undergone training in battlefield triage. A triage officer must consider not only a patient's physical injuries, but also the availability of personnel, resources, and evacuation capabilities.[7] Each of these factors may

also be influenced by the needs of the ongoing military operation. They have a duty not only to the patient in front of them but to the entire unit, as well as to the broader military mission. When they encounter a patient with devastating injuries not likely to survive despite heroic efforts in the context of an ongoing or even anticipated massive casualty event, they designate them as "expectant" in order to preserve scarce resources for those who are more likely to survive and/or return to duty.[8]

There are situations when triage priorities may even be shifted to give precedence to those friendly combatants with minor injuries who can be quickly returned to the battle. An example would be when a military unit faces likely defeat and loss of further lives without the assistance of injured soldiers who, with quick and timely medical care, can continue to support the mission. This "reverse" or "salvage" triage is guided by the principle of military necessity, whereby the overall number of casualties on the battlefield may be reduced by bringing a swifter end to the battle with a larger fighting force.[9,10] The utilitarian here calculates the greatest good as the greatest number of lives saved above all else, including lives on both sides of the battlefield. It is important to note while this practice has been justified from an ethical perspective, it violates the Geneva Convention, which specifies "Only urgent medical reasons will authorize priority in the order of treatment to be administered."[11] As a result, this type of triage is not routinely practiced on the modern battlefield.

When individuals join the military, they choose to join an organization that achieves its goals both implicitly and explicitly through individual sacrifice for the greater good. By virtue of donning a uniform, a service member has agreed to suspend some individual liberties in favor of working towards a common goal. The need to shift to community-focused medical ethics in the context of a military mass casualty event is congruent with this community-focused mindset of military service. While implementation of triage on the battlefield will never be a smooth or straightforward process given the circumstances necessitating its use, the principles are well-understood and accepted by those who will fall under its practice. This allows for a degree of trust in the military triage officer to apply fair and equitable standards when making these difficult decisions in order to maximize the benefit of scarce resources.

Triage in a Public Health Crisis: During a public health crisis, much like on the battlefield, the prognostication of survival is of utmost importance. Public health officials have an obligation to safeguard resources in such a manner they are utilized to maximize benefits for the most patients.[5,12] In theory, this would obligate life-saving resources be prioritized for patients with the greatest likelihood of survival. While logical and straightforward in theory, the practical application of this principle is fraught with difficulty. There is an inherent challenge in attempting to predict a patient's likelihood of recovery based on objective factors at the time of presentation to the medical system.[13-15] This is further complicated by the fact patients will vary in age and arrive with a host of comorbidities. Additionally, it is almost impossible to predict how long a patient would require a particular scarce resource, such as a ventilator. This becomes especially problematic when a patient is already using a resource, no longer has the highest likelihood of benefit from its use, but its discontinuation would result in the patient's death.

Whether long-term or short-term, how survival should be prioritized remains controversial.[16,17] This need to differentiate between types of survival is an additional requirement, which is less important in battlefield triage. Most combatants are relatively young and healthy without long-term serious health conditions, which may affect long-term survival.

In addition to safeguarding resources in a manner to maximize the medical benefit for the greatest number of patients, triage during a public health crisis ought to make efforts to overcome existing and emerging health disparities.[18] This stems from an egalitarian view of triage, where the assumption is there is equal value to all human life and everyone has an equal right to healthcare.[3] Based on this view, those determining the allocation of scarce resources during a public health crisis have a more complex responsibility to ensure they are connected with the local community, addressing barriers which may prevent some from access to those resources.

Unlike military service members who join a community that has previously accepted the principles of battlefield triage, community members in a public health crisis have likely never experienced such rationing and, therefore, may not be as accepting. Public health leaders developing triage algorithms have the difficult task of creating standards which will be acceptable to their local communities; otherwise, there is risk of considerable resistance from those within them. In order to develop public trust, a transparent process to engage and include the community in developing such guidelines for resource allocation is necessary.

Public health experts in Maryland performed this type of community engagement in the development of their statewide guidelines for allocation of scarce mechanical ventilators prior to the COVID-19 pandemic.[19,20] The

project identified the likelihood of short-term survival and likelihood of long-term survival (based on presence of comorbid conditions) as the 2 ethical considerations of greatest importance to those within their community. They additionally determined, in the case of a tie (where two individuals had equal chance for both short- and long-term survival), the life stage of the patient could be considered as a secondary criterion. While Maryland public health officials plan to use this process for resource allocation if needed during the current pandemic, their medical systems have not yet had to use it at the time of this writing. It is unclear whether those within the Maryland community will truly be more accepting of such allocation strategies as compared to those within other states, if ventilators become scarce since patients within the United States are not accustomed to having such access be restricted. Still, the Maryland example demonstrates how public health experts should strive to include the voice of the community in developing guidelines for the allocation of scarce life-saving resources in an effort to increase transparency and build trust for their final decision.

Table 1. Application of battlefield triage to public health triage.

Principle	Battlefield triage standard	Public health triage consideration
Primary goal	Saving the most lives to accomplish a military mission	Saving the most lives while ensuring an equitable distribution of resources
Triage agent	Triage officer is not part of treating medical team	Triage decisions should not be made by those actively caring for patients
Triage decision-making	Accepted upon joining military	Consider seeking input for the process of triage decision-making from community
Process of triage	Accepted upon joining military	Consider widely sharing accepted triage processes in place for ensuring just resource allocation
Moral distress	Experience attending to battlefield medical workers	Prioritization of the potential suffering of those who experience excessive death in public health settings

Learning from Battlefield Triage: Communities across the world have faced extreme resource challenges throughout the COVID-19 pandemic. Many countries have been forced to impose strict criteria for the use of certain life-saving resources (e.g. ventilators, intensive care unit beds) due to an overwhelming number of patients. Some have left rationing decisions to individual hospital systems or communities, often with guidance from large medical organizations.[21-23] Healthcare workers have struggled to implement bedside rationing, as it is in direct conflict with the basic tenet of providing care for the sick and dying.[24] As a result, frontline healthcare workers are vulnerable to moral injury and distress in the midst of such a pandemic, much like medical workers on the battlefield who experience mass casualty events.[25] While the military is far from perfect in addressing such distress, civilian medical systems would do well to examine the lessons the military has learned over the years in the importance of attending to such suffering.

Beyond the distress of caring for sick patients during a pandemic, healthcare workers can experience heightened feelings of anguish when they are responsible for triage decisions. While those caring for individual patients will have the most insight into their clinical course and most likely outcome, they have an inherent obligation to the individual patient. On the battlefield, triage officers assign the order in which patients are treated based on the accepted triage principles of the military, taking into account the available resources and needs of the patients. This assigned individual, who must have some medical knowledge, is not typically part of the primary treating team and may not even be a nurse or physician.[8,26] This allows the medical treatment teams to focus on their primary responsibilities to the individual patients they see before them, removing them from the distress of making the decision about who to treat and in what order. While the mass casualty situation on the battlefield is not perfectly analogous to the resource limitations during this pandemic, hospitals should assign triage officers (or even teams) who are responsible for making the difficult decisions of resource allocation, based on accepted guidelines. This critical step is important in allowing healthcare workers to focus their attention on the primary responsibility of caring for individual patients. It may also help alleviate the burden of distress they experience throughout the pandemic.

While most ethical guidance recommends transparency with the development of any rationing or triage principles, individual hospitals and hospital systems have struggled with the process of making their guidelines known to their community of potential patients. Even regional systems with well established guidelines easily available to the public (e.g. through public websites) can expect some degree of surprise and frustration from patients and families who may not have access to usual life-saving resources under such rationing decisions. As has been discussed, there is inherent difficulty in getting a community to accept such a major change to their expectations of healthcare. While it is important for community members to serve as representative voices in the development of any triage and rationing guidelines, that simply begins the process of trust-building between the

local community and the medical system. For it to mature, the process of how triage decisions are made must be well-publicized throughout a community. As such, a community may be able to see value in the consistency of medical decision making, even if they are not satisfied with an individual decision.

On the battlefield, this is accomplished in part through standard military trainings, where all service members learn such principles long before they encounter such situations. While there is no perfect parallel within the civilian sector, medical systems can ensure their employees are well-versed in protocolized decision-making processes during crisis situations. Additionally, they should make guidelines regarding the process of triage decision-making as publicized within their community as possible. Hospital leadership may feel apprehensive about publishing their guidance given the controversial nature of the topic, but they must resist the urge to keep them hidden in order to start the process of developing trust with their employees and the community they service. It is only through this establishment of trust they will be able to move to a more accepted community-minded approach to resource allocation (Table 1).

Conclusion

Differences exist between triage practiced on the battlefield versus triage during public health crises. Some arise from the basic underlying ethical principles and others are due to the differing nature of the overarching goals in the two settings. Importantly, the distinct nature of the populations within each scenario necessitate different strategies for the planning, implementation, and practice of triage medicine. Those within the military recognize the suspension of personal liberties for the sake of a larger group may be necessary and therefore may be more accepting of utilitarian minded triage strategies. Civilian populations during a public health crisis, however, will be much less accustomed to such limitations. They may have difficulty placing their trust in a larger medical system to determine which patients receive and which do not receive life-saving medical resources. Yet, many lessons from battlefield triage can be applied to the current pandemic.

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The Experiences of Clinical Engineering when Responding to the COVID-19 Pandemic

CW4 Kevin O'Reilly

Introduction

The scope of this article is limited to the actions and experiences of the Landstuhl Regional Medical Center (LRMC) Clinical Engineering Branch (CEB) when planning and executing the COVID-19 response at the only US military Role 4 medical treatment facility (MTF) in Europe between 1 February and 1 May 2020. Aspects of the COVID-19 response extended throughout the Regional Health Command; therefore, the full breadth and scope of the total response is far too great to expound within this account alone. The entire medical staff, along with an innumerable number of partners, were immensely engaged in the response and performed remarkably well given the rapidly developing pandemic. It is a testament to the agility of Army Medicine and the robustness of the American and European health systems to develop such a complicated medical response in such a short amount of time.

Lead up to the Event: Well before the onset of the pandemic, continuous analysis of medical technologies used within the facility was a routine practice for the purpose of determining readiness to respond to a multitude of real world contingencies including military conflict, natural disasters, and pandemic emergencies. As recently as January 2020, an analysis was performed by the CEB and the Department of Inpatient Services on the status and applicability of the current mechanical ventilator inventory to support a bed expansion in the event of a pandemic emergency.

Beginning in late February 2020, the Regional Health Command Europe (RHCE) G4 issued a set of e-mail requests soliciting information on life support and laboratory testing capabilities such as the current maintenance status of mechanical ventilators and nucleic acid processors due to open sourced media reports describing an emerging global pandemic. They also provided standing procedural guidance on pandemic response and the wartime bed expansion plan.[1,2] Thereafter, phone conversations between the clinical engineering elements of the G4, the United States Army Medical Material Center–Europe (USAMMC-E), the 30th Medical Brigade, and the LRMC CEB became more frequent events where limited informal capability assessments were conducted and general conversations pertaining to the uptime, availability, surge capability, and readiness of the hospital's organic medical technology were discussed. In addition, preliminary lessons learned were beginning to stream in from US Army units within the Republic of Korea (ROK), which experienced their first wave of the pandemic the month prior,[3] along with information from LRMC's Italian Clinical Engineering operation and civilian partners in Vicenza, Italy.[4] These conversations proved to be immensely valuable as the situation evolved and allowed the team to quickly identify the distinct material resourcing objectives of supporting inpatient bed expansion and SARS-CoV-2 laboratory testing.

Bed Expansion: The overall COVID-19 bed expansion response started with the existing wartime contingency expansion plan. Overall, the facility generally possessed the appropriate amount of medical equipment to execute its wartime mission; however, the threat posed by COVID-19 created a critical gap in the capacity to support mechanical ventilation. At the time of the analysis, the facility possessed transport and intensive care ventilators, however, fewer than required estimated to respond to the pandemic. To complicate the situation, a few transport ventilators were pending warranty repair. The ensuing global demand for ventilator equipment, and their servicing, was rapidly gripping the market, and LRMC would undoubtedly be affected by this reality.[5,6] To increase the probability of success, 3 procurement sources were simultaneously exercised to meet the demand. The first procurement was rendered through the Defense Medical Logistics Standard Support (DMLSS) system directly through the Defense Logistics Agency (DLA) utilizing an existing Indefinite Delivery Indefinite Quantity contract via a system called the Electronic

Catalogue (E-CAT).[7] The second sourcing method utilized the Army's Prepositioned Stock (APS) program which contains sets of equipment, such as tanks, wheeled vehicles, and medical technology of an armored brigade combat team and are strategically prepositioned in climate-controlled facilities worldwide. APS reduces deployment response times by allowing soldiers to fly to a theater and fall in directly on all the equipment they need to fight, sustain, and win.[8] The third source was USAMMC-E's Operational Readiness Float (ORF) program which serves as a safety stock to provide a fully mission capable piece of equipment in exchange for a non-mission capable piece of equipment. All 3 methods were successful after the initial orders. The DLA provided M731 transport ventilators directly from industry, the Army Prepositioned Stock (APS-2) out of Duelmen, Germany provided T1 ventilators, and the USAMMC-E provided a few older M731 units, comfortably fulfilling the primary gap of the response.

Like all life support technologies, ventilators do not operate on their own. Thus, a set of complementary equipment was identified to provide advanced treatment to COVID-19 patients with severe lung infection. In-line humidifiers were procured utilizing the methodology of E-CAT. These devices provide moisture in the inhaled air during mechanical ventilation to prevent airway obstruction from thick mucinous secretions common in the acute phase of severe COVID-19. In addition, patient feeding pump systems were procured through a local vendor to ensure critically ill patients would be properly nourished during hospitalization. Finally, the exhaled air from infected COVID-19 patients can permeate into the facility and further spread infection. To overcome this obstacle, a filtering or scavenging system is required to block the spread of the infection. The respiratory therapy staff, along with the CEB, met to determine the best solution. After an analysis exploring various options offered by industry, an inline filtration system was chosen to mitigate the problem.[9,10]

Beyond the most pressing issue of procuring mechanical ventilators and adjunct care devices, additional equipment was needed to ensure an effective, safe, and efficient response to the pandemic: APS-2 provided additional beds and vital signs monitors; a set of point-of-care whole blood analyzers, along with aspirators were provided through E-CAT. As mentioned earlier, the facility possessed the appropriate types and quantities of medical technology to execute its wartime contingency plan; however, the technology was dispersed throughout the facility. In particular, a large fleet of intravenous infusion pump systems and portable vital signs and acute monitoring systems, consisting of various types and manufacturers, were dispersed throughout the hospital. A coordinated analysis was conducted in conjunction with the Department of Inpatient Services to identify the requirements and match them to the hospital's infusion and monitoring capabilities to develop a consolidation plan.

There were two parts to the analysis. The first was to review published COVID-19 infusion therapy lessons learned,[11,12] and align the facility's infusion pumps along with its various vital signs and acute monitoring devices to the contingency bed expansion plan. The second part was to develop an adequate distribution plan to be executed on short notice. For example, monitoring and infusion devices exist throughout the facility and support a host of functions such as emergency care, intensive care, ambulatory care, radiology services, and training. The analysis studied which hospital sections would not be needed for COVID-19 patient care during the pandemic and reallocate their technology to the expansion plan while existing critical functions remained intact. The analysis identified the facility did not hold the correct quantity, in the correct locations, of acute bedside monitoring equipment that possessed the capability of end-tidal CO2 (EtCO2) necessary to monitor a ventilated patient. To overcome this gap, an emergency Medical Care Support Equipment (MEDCASE), which provides major medical capital equipment over a $250,000 threshold to support Army MTFs worldwide,[13] was issued to the DLA for a 19-room centralized patient monitoring system including a nursing station with the critical capability of (EtCO2).[14]

Beyond the material requirements to enable mechanical ventilation, valuable lessons learned from experiences in Milan, Italy and New York City informed the team of the hefty consumption of oxygen needed when treating COVID-19 patients. Further consultation with the respiratory therapy section revealed a flow rate of 10 liters per minute, per patient, of oxygen was required to treat a COVID-19 patient. An analysis was then conducted to better understand the facility's oxygen delivery capabilities and whether the capacity was adequate to sustain the bed expansion plan consisting of mechanical ventilation for an extended period. The facility possesses a liquid oxygen cryogenic system along with an in-line backup system containing gaseous oxygen cylinders. This analysis was utilized to estimate the amount of oxygen available within the system and was used as the Class-VIII planning factor to estimate oxygen consumption in the event of an increased number of patients being treated for COVID-19.[14,15]

Testing: Command outlined a clear numerical goal of

SARS-CoV-2 tests within a designated time period.[17] To achieve this goal, both centralized and de-centralized acquisition strategies were adopted. The centralized acquisition strategy was designed to procure a large number of laboratory testing instrumentation for the entire enterprise where technology scoping decisions were managed by the United States Army Medical Command (USAMEDCOM) staff. Consequently, the de-centralized procurement strategy delegated technology scoping and procurement functions to local commanders where specific pieces of technology would be procured to augment or enhance a facility's current capabilities similarly to the methodology performed to augment the wartime contingency bed expansion plan.

During normal operations prior to the implementation of the COVID-19 expansion plan, LRMC possessed a robust laboratory with molecular diagnostic testing capacity consisting of various types of Reverse Transcription Polymerase Chain Reaction (RT-PCR) instruments. The further addition of new laboratory instrumentation served only to increase capacity and enhance testing efficiency. Specifically, the delivery of instrumentation where extraction and RT-PCR are performed in a completely automated manner to achieve an effective throughput[18] served as the most consequential addition to the testing regiment. Additionally, to develop redundancy within the system, the command authorized the procurement of stand-alone RT-PCR systems and extractors through the E-CAT program.

While LRMC was expanding and consolidating testing capabilities, the USAMEDCOM, understanding the global reach of this pandemic and circulation of US personnel worldwide, started a large-scale fielding of laboratory testing technology to rapidly expand capacity throughout the entire enterprise. One of the technologies chosen by the USAMEDCOM to accomplish this task was a stand-alone RT-PCR system. At the time of the initial COVID-19 breakout, the LRMC virology section possessed a single device. To create the conditions to facilitate a rapid procurement of this technology, the USAMEDCOM staff reached out to the CEB to coordinate an information technology security scan of the existing technology. To support this request, the LRMC information management division (IMD) prepared the device to be network capable and meet all security requirements for placement on the network. Following this preparation, the LRMC IMD along with the virology section placed the unit onto the network and facilitated a successful scan of the device to demonstrate it would meet all information technology (IT) security requirements. This action accelerated the issuance of an authority to operate (ATO) and facilitated a more rapid procurement producing systems for the worldwide COVID-19 response.[19]

Sustainment: During the first week of April 2020, the CEB began assessing strategies and methodologies to not only sustain a long-term COVID-19 response, but also to sustain other critical healthcare obligations. With the rapid increase in the number of mechanical ventilators and adjunct support devices, along with the reallocation of existing medical equipment to combat the pandemic, 2 strategies were adopted to ensure mission success. The first was preliminary technician training on new equipment brought into the footprint along with enhanced training for existing equipment reallocated to the pandemic response. The second strategy was staggering the service schedule so maintenance could be evenly spread amongst the fleet to prevent technician fatigue and ensure schedule part replacement (SPR) availability.

Training is the cornerstone of sustaining any technology. The CEB was fortunate to have staff subject matter experts on all the devices introduced during the execution of the COVID-19 expansion plan. Impromptu classes were developed and made available to not only LRMC technicians, but also to technicians assigned to the 30th Medical Brigade and USAMMC-E. Additionally, a healthy bench stock of SPRs were ordered with the understanding any sustainment item requests would be on backorder due to the global demand for medical technology. Due to these two factors, staggering the service schedule evenly over a 6-month period in accordance with the Emergency Care Research Institute (ECRI) standards[16] allowed the maintenance operation to be more efficient for the response to the pandemic as well as the hospital's standing mission.

At this point, a large number of medical devices were dedicated to support the COVID-19 response, but the process for reporting critical equipment status to the command required clarification. To achieve this task, the CEB turned to a business intelligence tool named Business Objects (BO). To enable effective use of this tool, the property book was aligned to ECRI to achieve nomenclature consistency. Specifically, the Equipment Readiness Code (ERC) within DMLSS was set to 'A' for each item slated to the pandemic response. All like items such as ventilators, laboratory instrumentation, and infusion pump nomenclatures were individually applied an established device code, effectively standardizing the electronic record to the enterprise. Once complete, a query within BO was used to generate a list of uniquely identified material. Conditions could then be applied (such as repair work orders, failed

services, and pending replacements) making it a powerful and accurate tool for equipment management. The report was then exported to a standard spreadsheet to facilitate communication with the command and other sections of the organization.

An additional point in sustainment was securing the facility itself. The CEB was not the proponent of entry point screening; however, it was consulted to scope the necessary technology for rapid patient screening before entering the facility. The screening methodologies were not intended for diagnosis but to identify individuals at risk for COVID-19 (and thus requiring assessment by the appropriate medical professional for further diagnoses and treatment). To achieve this task, a local vendor was leveraged to procure handheld infrared temperature devices to facilitate patient screening before entry to the facility.

When operating within any environment, technician safety, security, and well-being are of the upmost importance. Mission success depends on the workforce maintaining the ability to sustain medical operations. Replacing or repairing equipment, improving facilities, and scoping medical technology procurements are challenging and resource intensive tasks impossible without an adequate pool of highly competent and dedicated technicians. Two sources of risk were identified during the COVID-19 response: illness from the infection itself and fatigue from overwork. To reduce the risk of infection, the team once again consulted ECRI and the LRMC's infection control team to guide necessary prevention measures such as hand washing, social distancing, personal protective equipment, staff testing, and isolation recommendations (when indicated). Beyond these measures, increased sanitation measures for medical devices were strictly enforced before maintenance was performed[17] and the CEB staff was fit-tested with N95 masks as most maintenance and servicing of medical technology are performed within patient care areas of the facility.

Conclusion

The COVID-19 response has been a success thus far. The CEB provided the command the best available equipment, at optimized locations, and in adequate quantities to sustain the COVID-19 response while ensuring normal hospital operations. Additionally, the CEB created a process to account for the status, the reallocation of medical equipment, and procurement strategies to support command decisions. The command's guidance was to execute the wartime contingency expansion plan with the identified capability requirements to sustain a large quantity and prolonged duration of life support using mechanical ventilation, and to expand and enhance COVID-19 testing capacity. The CEB was able to procure new resources and reallocate existing resources to meet these requirements. More importantly, the CEB was able to rapidly identify evolving resource gaps to inform the command and quickly adapt medical support operational plans.

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National Guard Response to COVID-19: A Snapshot in Time during the Pandemic

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Abstract

Background: Since March of 2020, thousands of National Guard service members have played a key role in the domestic response to COVID-19, ranging from medical support, health screening, decontamination, personal protective equipment (PPE) training, and more. As a result of these missions, there was a hypothesized potential increase in COVID-19 exposure risk.

Objectives: Assess COVID-19 transmission rates and mortality rates in the US population compared to the National Guard.

Methods: Six months of retrospective data were assessed with analysis of a snapshot in time for pandemic data on 29 July 2020. Potential relationships between National Guard COVID-19 response personnel, cumulative US COVID-19 cases, National Guard COVID-19 cases, and National Guard COVID-19 fatalities were assessed.

Results: No evidence of correlations exist between the number of National Guard personnel supporting the COVID-19 response and the number of deaths in the National Guard due to COVID-19 ($p=0.547$), and the number of National Guard COVID-19 cases and the number of deaths in the National Guard due to COVID-19 ($p=0.214$). The number of COVID-19 cases in the US was positively correlated to the number of deaths in the US due to COVID-19 ($rs=0.947$, $p<.001$).

Conclusions: Though much of the data could not be reported due to operational security (OPSEC) and capabilities, activities, limitations, and intentions (CALI) concerns, the data herein demonstrate National Guard service members are significantly less likely to suffer COVID-19 related mortality compared to US civilians. Since the National Guard adheres the same medical and physical fitness standards as set by their parent service (Army and Air Force), it follows overall levels of medical readiness and fitness should start with a higher baseline. Age, medical screening, PPE, and physical fitness requirements have likely contributed to this phenomenon. These results should empower National Guard service members to feel more confident in their roles as they continue to support the COVID-19 response efforts.

Keywords: national guard; COVID-19; coronavirus; DSCA; domestic response

Introduction

COVID-19, the disease caused by the SARS-COV-2 virus, colloquially known as Coronavirus, has resulted in significant global impacts, hardships, and fatalities. At the time of this article, over 500,000 Americans have died due to COVID-19.[1] On March 13, 2020, President Donald J. Trump declared a national state of emergency, authorizing full federal support for COVID-19 response. On March 22, 2020, President Trump signed the memorandum "Providing Federal Support for Governors' Use of the National Guard to Respond to COVID-19," which authorized 100% federal cost share and support of operations or missions to prevent and respond to the spread of COVID-19.[2] On August 3, 2020, this memorandum was resigned in order to extend federal resources for states responding to COVID-19. The COVID-19 pandemic has impacted states at different rates, with ebbs and flows in COVID-19 case rates. The result has been a dynamic situation leading to frequent shifts

in policy, unique to each state, in an effort to address a moving target. As each state deals with the hardships and impact brought on by COVID-19, one thing remains consistent among each state: the support of the National Guard. The National Guard has lived up to the call and has been a key player in the domestic response to civil authorities for COVID-19. Missions have varied across the nation based on the needs of the state and at the discretion of each state's governor or adjutant general. Throughout this discussion, specific numbers and statistics were not reported in order to preserve operational security (OPSEC) and avoid providing potential capabilities, activities, limitations, and intentions (CALI) to US adversaries.

As of October 9, 2020, thousands of National Guard soldiers and airmen have been deployed in support of COVID-19 relief.[3] National Guard domestic operations have involved both direct and indirect patient contact, care, and support. Currently, the National Guard has been requested to, and remains involved with, standing up and augmenting COVID-19 test sites; establishing expedient medical field clinics and hospitals; augmenting medical staff to civilian hospital systems; transporting patients to offload stressed healthcare systems; providing instruction of new sterilization/disinfection systems, reinforcing current practices in efforts to execute better environmental cleaning and disinfecting of common areas thus reducing overall communicability; providing first responders training and education in proper use of personal protective equipment (PPE) and decontamination techniques to mitigate transmission risk; and providing both kitchen and scullery support in overburdened senior care and veterans centers, which have been overwhelmingly affected by the impact of COVID-19. Additionally, the National Guard has provided indirect support by staffing state emergency operations centers (EOC), using air mobility for ensuring logistical support and expedient transportation both in the continental US and its territories, and finally, packaging and distributing food and other supplies locally.[3]

The National Guard felt the effects of the COVID-19 pandemic when one of its own traditional guardsmen lost his battle with the disease. This inactive duty training (IDT) soldier was not mobilized with the National Guard for the COVID-19 effort, but was in fact a medical provider. As of the writing of this manuscript, he was neither the only National Guard service member to have been diagnosed with COVID-19, nor was he the only National Guard service member to have lost his life due to COVID-19; however, he was at the time of the data collection. The unfortunate loss of this soldier's life and the significant resources allocated by the National Guard in serving the public, prompted the following research questions:

1) Have the National Guard personnel activated to the COVID-19 response mission seen an increased rate of COVID-19 transmission in their respective states?

2) Are there significant differences in the rates of mortality in the US compared to the National Guard?

Materials & Methods

From January 30, 2020 to July 29, 2020 (6 months), preexisting data were reviewed. Data were retrieved from sources not disclosed for purposes of preserving OPSEC and CALI. The COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University & Medicine was utilized for presented data regarding state/US COVID-19 cases and mortality. No individual patient identifiers were in any of the data sources listed. Hawaii National Guard publica affairs officer (PAO), judge advocate general (JAG), and OPSEC approval was granted on March 30, 2021. Descriptive statistics were computed, analyzed, and reported in a CALI compliant manner.

Secondary datasets were analyzed using standard statistical software. Data were analyzed from a fixed point in time as the pandemic data continues to change by the day. July 29, 2020 was selected to review the data as a snapshot in time. All variables were stratified by state or territory. The data underwent statistical analysis to uncover potential relationships between independent variables (predictors), which included the number of National Guard personnel activated to the COVID-19 response (continuous) and the number of cumulative COVID-19 cases in the US (continuous). The primary dependent variables (outcome) assessed included the number of National Guard COVID-19 cases (continuous), the number of National Guard COVID-19 fatalities (continuous), and the number of cumulative COVID-19 fatalities in the US (continuous), the number of cumulative COVID-19 fatalities in the National Guard (continuous).

Power analysis was conducted. Alpha was set at .05, Power set at .80, and Cohen effect size of Medium set at .30. Sample size requirements were determined to be n=89 to achieve adequate significance. Kurtosis and skewness were assessed to determine normality of distribution. Descriptive statistics were computed, analyzed, and reported. Bivariate correlations were conducted for continuous data. P values <0.05 were considered significant with confidence intervals (CIs) set at 95%.

Results

Power analysis requirements of 89 were not obtained, as there were only 54 states and territories with data for interpretation. Data were still analyzed and interpreted, understanding the increased risk of a Type I error.

All data was analyzed as a snapshot in time of the cumulative numbers tabulated thru July 29, 2020. Sample size was 54 as the data were separated by 54 states and territories. The mean number of National Guard personnel assigned to the COVID-19 response in each state was described. The mean number of National Guard personnel diagnosed with COVID-19 in each state was described. The mean number of National Guard personnel who died due to COVID-19 in each state was described, as only one National Guard fatality was present in one state at the time of the analysis (publically reported), this number was exceedingly low. The mean number of COVID-19 cases in each state was described along with the mean number of COVID-19 fatalities in each state in the civilian population.

Non-Federalized National Guard COVID-19 response personnel were reported based on duty status. Active duty operational support (ADOS), traditional inactive duty training (IDT), and state active duty (SAD) soldiers/airmen percentages were calculated based on the National Guard COVID-19 response force on July 29, 2020.

Non-Federalized National Guard COVID-19 response personnel were reported by state and split by Army National Guard and Air National Guard. Total cumulative active and recovered cases of COVID-19 in the National Guard were split by hospitalization versus non-hospitalization as of July 29, 2020. The largest percentage of COVID-19 hospitalizations in the National Guard were analyzed, but not documented here in order to remain compliant with CALI preservation.

A one-day snapshot on July 29, 2020 assessed the number of COVID-19 cases and number of deaths due to COVID-19 in both the US and the National Guard. A logarithmic scale was used to improve visualization. The cumulative number of COVID-19 cases in the US was compared to the National Guard. The relative mortality rate based on this data and snapshot in time indicates a mortality rate 133 times higher in the civilian population when compared to the National Guard. The US mortality rate documented here is only a rough estimate based on the snapshot in time, and should not be used as an indicator of the actual mortality rate seen in the US.

Kurtosis and skewness results indicated data was skewed to the right and with a heavy right-sided tail, therefore failing to follow normal assumptions of linearity. Due to a lack of normality, Spearman's Rho correlations were performed. No evidence of correlations exist between the number of National Guard personnel supporting the COVID-19 response and the number of deaths in the National Guard due to COVID-19 ($p=0.547$). No evidence of correlations exist between the number of National Guard COVID-19 cases and the number of deaths in the National Guard due to COVID-19 ($p=0.214$). The number of COVID-19 cases in the US was positively correlated to the number of deaths in the US due to COVID-19 ($r_s=0.947$, $p<0.001$).

Discussion

Specified results were not published to preserve OPSEC and concerns adversaries would have the potential to gain advantages based on violations in CALI. Despite this, conclusions were drawn and discussion is still feasible. Results will be discussed here in an effort to answer the two primary research questions posed. First, "have the National Guard personnel activated to the COVID-19 response mission seen an increased rate of COVID-19 transmission in their respective states?" Based on the data available, we cannot confidently answer this question. Unfortunately, the number of National Guard personnel activated for COVID-19 response was not separated from National Guard personnel not activated. It is reasonable to discern in states with higher COVID-19 transmission rates, a larger number of National Guard personnel were responding. Based on the significant training and protocols provided to the National Guard personnel responding or participating in COVID-19 response efforts, the rate of transmission based on mission response alone should be lower than the rate of transmission in the normal population. One significant limitation in all data when assessing disease transmission rates is the time at which the disease was transmitted. For example, does disease transmission occur while on duty supporting COVID-19 response or instead while grocery shopping during off-duty hours. These questions remain unanswered.

Second, "are there significant differences in the rates of mortality in the US compared to the National Guard?" Based on the data analyzed, there was a significant difference between rates of mortality reported in the US compared to the National Guard. As of July 29, 2020, one National Guard fatality was reported in social media. Although this manuscript does not intend to demonstrate the actual mortality rate of the US, nor should these results be used as a means to document the rate of mortality due to COVID-19 in the US, our data does

suggest the National Guard are 133 times less likely to parish following COVID-19. This is intuitive, but requires some additional exploration.

Generally, the National Guard and the military as a whole have medical screening processes, which eliminate the vast majority of comorbid conditions. As a result, the National Guard force can reasonably be expected to be in a better state of health. Additionally, the CDC has demonstrated when compared to those individuals 18-29 years old, risk of mortality is 30 times higher in 50-64 year olds, 90 times higher in 65-74 year olds, 220 times higher in 75-84 year olds, and 630 times higher in >85 year olds.[4] Since the maximum age of military retirement is set at 62 years old, this also reduces the number of service members who would be most at risk.

In addition to age differences, there are engineering controls built into the National Guard response efforts further mitigating risk to soldiers and airmen. All National Guard units and/or individuals called up in support of COVID-19 operations regardless of tasking, are fit-tested and educated by a subject matter expert, who usually is one the following; an occupational nurse guardsmen, a physician assistant assigned to the civil support teams or medical detachments, or the state's National Guard occupational health department. By utilizing these subject matter experts to directly conduct and monitor testing, the following risks are minimized: 1) Improper mask sizing; 2) False-Negative fit-test results due to lack of sensitivity solution reaction; 3) Proper masking procedures and fitting requirements; 4) Prolonged mask use and reuse education; 5) Personnel decontamination of assigned N-95 and surgical masks. The National Guard conducts PPE education such as proper wearing and removing of overgarments to reduce spreading the disease as well as controlled zones for garment removal and gross contamination decontamination at sites. Emphasis on CDC personal protective measures are reinforced and enforced from the lowest level to the highest level. Accountability of personnel is paramount in these settings. Additionally, documentation of all training, to include fit-testing and PPE education is captured, and in compliance with NIOSH, OSHA, CDC and Army Medical Department (AMEDD) guidance and protocols, all in effort to support the responding force.

Limitations: Some important limitations include the fact this analysis did not reach the sample size required to achieve adequate power. Therefore, the possibility of documenting a difference when in fact there is none is possible, so results must be used with caution. Based on the data available, we were unable to calculate relative risk of being diagnosed with COVID-19 as a result of responding to a mission in direct support of the National Guard. Tables/graphs for visualization were removed along with the reporting of quantifiable data in order to maintain OPSEC, limiting the ability to scrutinize the statistical analysis and results. Lastly, mortality rates provided in this manuscript are crude assessments based on a moment in time. We recommend the CDC be used as the authoritative source for COVID-19 mortality in the US.

Conclusion

As this nation engages with COVID-19, the responding medical community has been dealt a disproportionately high toll of both morbidity and mortality, where, according to Nguyen et al, it was identified there was an overall increased risk of a positive COVID-19 test in healthcare workers.[5] The study rationalized healthcare systems should provide "adequate PPE, and develop strategies to protect healthcare workers from an increased risk of infection."

Medical providers within the National Guard, who have been activated to respond to COVID-19, have yet to suffer the same mortality rates as their civilian counterparts. The National Guard has served this nation in previous times of need and again now, heeding the call for COVID-19 support. As of October 9, 2020, the National Guard (Army and Air Force) has activated thousands of soldiers and airmen responding in one capacity or another to support an overwhelmed public health sector and the medical response community. There are currently no data sets collected indicating how many National Guard soliders and airmen have been directly infected as a result of COVID-19 support operations. As of October 9, 2020, 99.7% of active COVID-19 cases within the National Guard had recovered. There have been 2 publically documented cases of mortality related to COVID-19 complications regarding National Guard soldiers. Both guardsmen at the time of their deaths, were not on state active duty orders in support of COVID-19 operations. Based on public knowledge, the first National Guardsmen from the New Jersey Guard, a 57-year-old male physician assistant contracted the virus while performing regular medical duties and COVID-19 outreach, which was not related to direct support of National Guard COVID-19 operations. The second National Guardsmen to pass away was a 36-year-old male from the California National Guard; due to privacy requests from the family no further information could be attained regarding the circumstances of exposure.

From the onset of activation to perform COVID-19 relief, the National Guard has followed the CDC's recommendations for COVID-19 prevention to reduce unnecessary exposures.[6] Further, states have utilized their subject

matter experts to implement strategies to include a robust respiratory protection program, established in each state by both the Occupational Health Division and the Civil Support Team's Respiratory Protection Officers. These respiratory protection officers enforce regulation, proper training, testing, and consulting with various task force planning teams to implement new changes and alternate methods of respiratory protection and decontamination. It is possible these force health protection mitigation efforts aide in the reduction of COVID-19 transmission among these personnel, as was identified in a World Health Organization (WHO) funded study by Chou et al, where it was concluded that adequate PPE, and infectious disease prevention training reduced overall exposure and risks to healthcare workers.[7]

Rates of COVID-19 are exceedingly low in the National Guard population with mortality approaching zero at the time of this article, though these data could not be reported due to OPSEC and CALI concerns. The National Guard follows the same medical and physical fitness standards as set by their parent service, i.e, Army and Air Force. The standards to enter the military are rigid. Even though the average National Guard service member's median age is much older compared to their active duty counterparts, the medical entry requirements are the same. Likelihood is low for anyone with pre-existing comorbidities that can be exacerbated or compromised by COVID-19 has been allowed entry into the military.

In 2018, the median age of service members was 30.0 years of age in the Army National Guard and 34.5 in the Air National Guard. In the Army National Guard about 11.8% of enlisted service members were at or over the age of 41 and 34.7% of officers over the age of 41. The percentage goes up in the Air National Guard with 22.9% of enlisted and 44.6% of officers at or over the age of 41.[8] By contrast in 2019, the general population of the US had a median age of 38.3 with 47.8% being at or over the age of 40.[9] The National Guard has few if any service members over the age of 65, but persons 65 or older make up 16.3% of the US population. Being 65 years old or older seems to be one of the greatest risk factors in severe disease, as the generally younger population likely offers a protective benefit compared to the US population as a whole. Although we are unable to determine the direct mortality rate of National Guard personnel assigned to COVID-19 response missions, the low mortality rate documented in this population makes the risk significantly low. This research highlights the low risk of mortality to National Guard soldiers and airmen from COVID-19, and therefore should promote continued use of this military population as a means to help combat the pandemic across the US.

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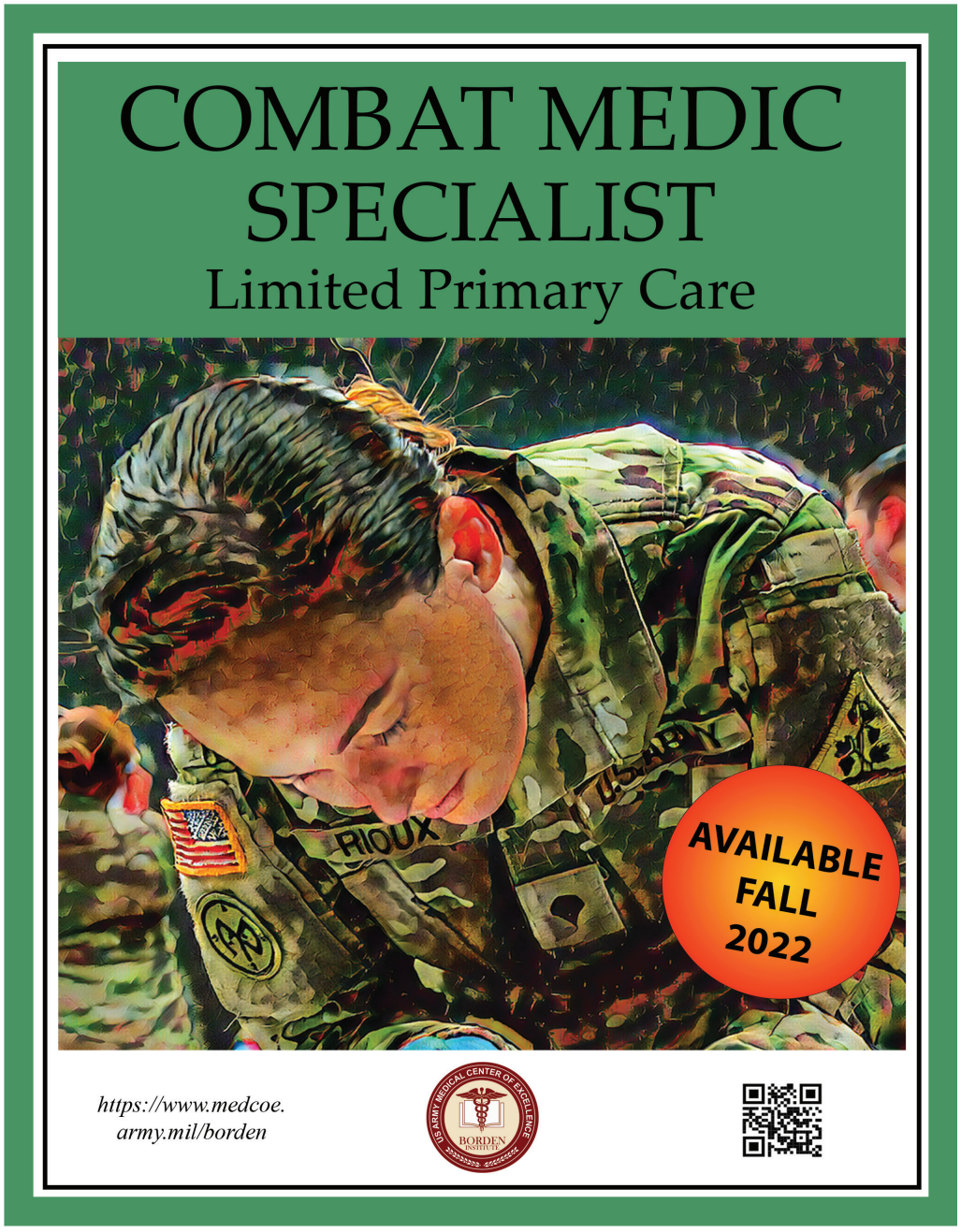

The Relationship of Serum 25-Hydroxyvitamin D at Admission and Severity of Illness in COVID-19 Patients

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Abstract

Background: COVID-19 is a rapidly propagating respiratory virus causing a global pandemic. At the time of development of this study, not much was known about susceptibility to severe illness, especially without other known risk factors. Retrospective research suggested vitamin D level may correlate with severity of illness. This prospective, observational study seeks to determine if vitamin D level at admission is correlated with severity of illness as determined by needing intensive care unit (ICU)-level care within this first 28 days after admission. This study also looked at the relationship of vitamin D level at admission and mortality, need for ventilator, and number of hospital-free, ICU-free, and ventilator-free days in the 28 days after initial admission.

Methods: This study is a prospective, observational study of patients admitted to Brooke Army Medical Center (BAMC), San Antonio, TX, for a diagnosis or complication of COVID-19 illness. A vitamin D level was drawn at admission and chart review was used at the end of 28 days after admission to identify outcome measures. Fisher's Exact test was used for categorical variables, and Kruskal-Wallis test was used for all continuous variables.

Results: Deficient vitamin D level at admission (<20ng/mL) was associated with an increased risk of requiring ICU-level care during the 28-day period after initial admission (p=0.028). Secondary outcomes measurements also favored the hypothesis, but none were statistically significant.

Conclusions: This prospective, observational study further strengthens the hypothesis vitamin D level at admission is correlated with severity of illness in COVID-19 illness; however, this small study was limited in its ability to control for confounders. It does not prove causation, nor does it imply vitamin D supplementation will prevent COVID-19 or improve outcomes in COVID-19. Further research should aim to include a larger cohort to better understand the relationship of vitamin D level and severity of illness in COVID-19 disease.

Introduction

SARS-COV-2, which causes the clinical illness of COVID-19, continues to propagate, affecting the US as well as most areas of the world. While conditions such as chronic kidney disease, chronic obstructive pulmonary disease, congestive heart failure and coronary artery disease are known to increase the risk of severe illness,[1] during development of this protocol, little research existed about possible risk factors in otherwise healthy individuals. Additionally, there were not many—if any—known prognostic indicators or scoring systems for identifying those at higher risk of needing intensive care unit (ICU)-level care or mechanical ventilation other than hypoxia. Identifying risk factors in all comers to include healthy individuals could potentially aid in the triage of patients in high volume settings and in the allocation of resources in overwhelmed facilities.

Limited research existed relating to vitamin D and COVID-19 at the time of protocol development; however, a large amount of research exists from the past 10 years with regard to the role of vitamin D in both the innate and adaptive immune response.[2-9] The active metabolites of

vitamin D act as steroid hormones in multiple tissues in the body, assisting in its ability to modulate the response to infection by upregulating antimicrobial peptides, increasing the presence of anti-inflammatory cytokines, and downregulating inflammatory cytokines.[2-9] Cytokine storm plays a significant role in severe COVID-19 disease, including high levels of pro-inflammatory interleukin six (IL-6) and tumor necrosis factor-alpha (TNF-alpha).[6] Prior to the development of this protocol, many authors postulated vitamin D's potential role in curbing cytokine storm, but no prospective research was published to further corroborate this theory.[9-14]

Previous research found a possible correlation between vitamin D level and COVID test positivity.[14,15] One study between 1 March to 14 April 2020, evaluated 107 Swiss patients undergoing COVID-19 polymerase chain reaction (PCR) testing; vitamin D levels were drawn during the same time frame.[14] Investigators retrospectively compared the vitamin D levels of those with positive COVID-19 PCR with the levels of those patients who had negative tests. The positive test group was observed to have statistically significant lower serum 25-hydroxyvitamin D levels (11.1ng/mL) compared to the negative group (24.6ng/mL, p=0.004).14 This study was limited since vitamin D levels were not drawn at the same time as COVID test. Additionally, investigators did not identify any clinical outcomes, limiting its practical application. A study out of the United Kingdom also found a possible correlation between vitamin D level and positive COVID test, but this correlation did not remain when controlling for covariates.[15] This study was similarly limited in its lack of clinical outcome information. This study also evaluated vitamin D levels drawn up to 14 years prior to COVID test, limiting overall utility.

Further research attempted to compare population-level statistics of multiple countries to evaluate the relationship of vitamin D level and clinical outcomes in COVID-19. Daneshkhah et al compared adjusted case mortality ratios (A-CMR) of COVID patients in 10 different countries with the average serum 25-hydroxyvitamin D levels of the elderly populations in those same countries.[9] Investigators found the A-CMR to be lower in those countries with higher average vitamin D. This correlation proved stronger than the elderly ratio of the population, the prevalence of diabetes, or the prevalence of heart disease.[9] While one of the only studies to attempt to evaluate clinical outcomes of COVID-19 as they relate to vitamin D levels, these findings are limited as this was a metadata look at population level statistics.

Finally, a pre-publication release of a retrospective study in the Philippines by Alipio[16,17] identified what seemed to be a strong correlation between vitamin D and clinical outcomes in COVID-19. Investigators demonstrated for every standard deviation increase in 25-hydroxyvitamin D, the likelihood of having a mild outcome rather than a critical outcome increased by 19.61 times. The incidence of severe and critical outcomes was significantly higher in vitamin D insufficient and deficient patients compared to those patients with sufficient vitamin D levels.[16,17] This study had limitations in both reporting of its methodology and its lack of an attempt to control for confounders. Despite these limitations, it was the only study directly comparing individual vitamin D level to clinical outcomes at the time of the of protocol development and was therefore used to calculate sample size. The publishing journal later retracted the Alipio study for unknown reasons.[17]

Methods

This study was a prospective, observational study aimed at evaluating vitamin D level as a prognostic indicator of disease severity in admitted COVID-19 patients. The independent variable in this study was vitamin D level at admission, defined as sufficient (≥30ng/ml [75nmol/L]), insufficient (21-29ng/mL [51-74nmol/L]), and deficient (≤20ng/mL[50nmol/L]) based on commonly used cut-offs and values utilized in previous related research.[16,18,19] The primary independent variable was ever needing ICU-level care within 28 days post-admission. This was used as the defining factor of "severe illness" for the primary hypothesis. Secondary independent variables were number of ICU-free days, number of ventilator-free days, number of hospital-free days, ever needing a ventilator, and mortality all within the 28 days after admission.

Investigators initially determined a goal sample size of 42 subjects based on a conservative, three-fold increase in complications for those with low vitamin D levels compared to normal. This was less than what was observed in Alipio, in which 65% of those with insufficient or deficient vitamin D experienced severe or critical outcomes compared to 6% of those with normal vitamin D levels. Investigators then determined a need to include an r-squared value of 60% to attempt to allow for the influence of other covariates, ultimately leading to the required sample size of 220 subjects as sufficient to establish significance under these conditions with power set to 80% and an alpha of 0.05.

The target population for this study included adult patients admitted to Brooke Army Medical Center (BAMC), San Antonio, TX, for COVID-19-related illness. This included anyone over 18 admitted to BAMC

for COVID-19 or its known sequelae (such as pneumonia, pulmonary embolism, and hypoxia) with a positive COVID-19 test. This did not include any patients with an incidental finding of positive COVID-19 test admitted for unrelated reason (i.e. surgical or trauma patient screened for COVID-19 at admission). Investigators defined exclusion criteria as pregnancy, previous admission and discharge for COVID-19, ventilator use at baseline, and terminal illness diagnosed prior to COVID-19 infection.

Table 1. Baseline vitamin D level by sample characteristics.

Principle	Battlefield triage standard	Public health triage consideration
Primary goal	Saving the most lives to accomplish a military mission	Saving the most lives while ensuring an equitable distribution of resources
Triage agent	Triage officer is not part of treating medical team	Triage decisions should not be made by those actively caring for patients
Triage decision-making	Accepted upon joining military	Consider seeking input for the process of triage decision-making from community
Process of triage	Accepted upon joining military	Consider widely sharing accepted triage processes in place for ensuring just resource allocation
Moral distress	Experience attending to battlefield medical workers	Prioritization of the potential suffering of those who experience excessive death in public health settings

Investigators identified potential subjects through the inpatient and emergency room electronic medical records (EMR). Any admitted patients with a positive COVID-19 test or pending COVID-19 test were further reviewed for reason for admission. Any patient with COVID-19 as the reason for admission within the history and physical was included as a potential subject. All patients admitted to BAMC at this time were required to have a COVID-19 test in the facility and this test was used to confirm infection. Investigators further screened the chart for the previously-described exclusion criteria.

Once potential participants were identified, investigators donned proper personal protective equipment (PPE) and entered the patient's room. Investigators brought copies of the informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization forms with them into the room for the patient's records if he/she decided to participate. The investigator then introduced herself, discussed her role in the study, and thoroughly reviewed the informed consent and HIPAA authorization forms with the patient.

If the patient gave verbal consent to participate, the investigator confirmed lack of the previously discussed exclusion criteria. The investigator informed the patient their signature was not necessary on informed consent (as approved by Internal Review Board), but they were given the copy of informed consent and HIPAA authorization for their own records. The investigator also asked for the patient's race/ethnicity, and previous daily use of vitamin D supplements prior to COVID-19 infection. All other demographic information (military service status, rank [if applicable], other comorbidities) was obtained from the patient's medical record.

Outcome data was obtained from the patient's EMR at least 28 days after admission to BAMC. At this point, the principal investigator reviewed participant charts to find vitamin D level at admission, the number of days the patient was in the hospital (to calculate number of hospital-free days in 28 days), whether or not the patient needed ICU-level care and for how long (to calculate number of ICU-free days in 28 day period and ever needing ICU level care), and number of days requiring mechanical ventilation (to calculate number of vent-free days and ever needing mechanical ventilation). The principal investigator also screened for any additional admissions within the 28 days following initial admission to BAMC.

Time and resource constraints affected certain factors of the study design. Investigators defined vitamin D level at admission as within 48 hours of admission to allow time for identification of subjects by investigators, consent of subjects by investigators, and convenient collection of blood draw by nursing staff. Additionally, data collection occurred on a short timeline as the primary investigator was conducting this study as part of a graduation requirement for a doctoral program.

Results

Enrollment occurred from 25 March 2021–18 June 2021, and data collection continued through 15 July 2021, exactly 28 days after the last subject was enrolled. Investigators enrolled 24 subjects in the study, which was less than initially anticipated or desired. Of these 24 subjects, 3 subjects' vitamin D labs were either never drawn or never resulted (for unknown reasons), leaving 21 subjects available for analysis.

The sample spanned a wide group of ages from 20 to 72 years old, with at least 3 subjects from each decade in-between. The sample population was 71.4% male, compared to 88.5% of all Texas veterans who are male, according to data obtained from the Veteran's Affairs Administration.[20] The sample group was also

Table 2. Primary outcome as "outcome (percent)."

	Deficient	Not Deficient	*p* value
Total	5	16	
ICU	3 (60%)	1 (6.25%)	P= 0.028

Table 3. Categorical variable results as "outcome (percent)."

	Deficient	Not Deficient	*p* value
Total	5	16	
Intubated	2 (40%)	1 (6.25%)	P= 0.13
Mortality	1 (20%)	1 (6.25%)	P= 0.43

predominantly white, with a notable number of subjects identifying as Hispanic ethnicity. In this study, 47.5% of participants identified as white/non-Hispanic, compared to 63.8% of total veterans in the state of Texas who identify as white/non-Hispanic. Only 2 participants in this study were Black, compared to 14% of all Texas veterans.[20] This comparison group only looks at veterans, however, and this study included 6 participants who were not current or former service members. No public data on relevant demographic statistics of Tricare beneficiaries could be identified for comparison to the study group.

The most common comorbidity among the sample was hypertension. Twelve out of 21 subjects had previously been diagnosed with hypertension prior to the start of the study. This equates to 57.1% of the sample, which is slightly higher than the 45% of the general American population with this illness.[21] The second most-prevalent comorbidity was type two diabetes. Six out of 21 participants (28.6%) held a diagnosis of type two diabetes, again slightly higher than the national 13% of US adults with diabetes.[22] Three participants enrolled with autoimmune diseases, 2 with coronary artery disease, 1 with chronic kidney disease, and 1 with a recent, non-terminal malignancy. No participants in the study had a history of chronic obstructive pulmonary disease, congestive heart failure, or type one diabetes. Further detail of vitamin D levels by sample characteristics are shown in Table 1.

As previously mentioned, significantly fewer patients enrolled in this study than initially planned. Investigators were unable to compare all 3 vitamin D levels (deficient, insufficient, and sufficient) separately as planned due to the low number of participants. For the primary outcome, investigators ultimately compared patients with deficient vitamin D levels (≤20ng/ml) with those who had higher levels of vitamin D ("not deficient" >20ng/ml). This change in data analysis still supported the primary hypothesis of the study as it did not specify stratification levels of vitamin D, but rather an inverse relationship between vitamin D level and severity of illness. The study's secondary hypotheses, however, were worded in a way that required specific comparison of deficient and insufficient vitamin D levels (≤29ng/ml) with sufficient levels of vitamin D (≥30ng/ml). This stratification did not yield any statistically significant results and therefore post-hoc analysis was performed utilizing the more clinically-relevant stratification of vitamin D levels (deficient vs not deficient) as was used for the primary hypothesis.

Five patients were found to have deficient vitamin D levels (≤20ng/ml) compared to 16 participants with not deficient vitamin D levels (>20ng/ml) (Table 1). Investigators planned to use either Chi Squared of Fisher's Exact test to analyze categorical data; however, all cases required use of Fisher's Exact test as the sample size did not produce a large enough count in each arm to conduct a Chi Square test. Due to low numbers, Kruskal-Wallis test was used for all continuous variables. The initial plan to combine factors significantly associated with each dependent variable in a multiple logistic regression analysis was not possible due to small sample size.

For the primary outcome, a deficient vitamin D level (≤20ng/ml) was significantly associated with ever needing ICU level care with a prevalence of 60% (3/5) in the deficient group compared to a prevalence of 6.25% (1/16) in the non-vitamin D deficient subjects (2-Tailed Fisher's Exact test, p=0.028) (Table 2). The odds of ever needing ICU level care were 22.5 times higher for those in the vitamin D deficient group than in the non-vitamin D deficient group (OR 22.5, 95% CI: 1.51-335.34).

Additional categorical variables were also analyzed using Fisher's Exact test (Table 3). While the prevalence of ever needing a ventilator was higher in the vitamin D deficient group (40% [2/5]) compared to the non-deficient group (6% [1/16]), the results were not statistically significant (2-Tailed Fisher's Exact Test, p=0.13). Prevalence of mortality was also higher in the vitamin D deficient group (20% [1/5]) than the non-deficient group (6.25% [1/16]) but not statistically significant (2-Tailed Fisher's Exact test, p=0.43).

Continuous variables were assessed as well (Table 4). The mean number of hospital-free days was higher for the non-deficient vitamin D group than the deficient group (20.94 (CI:17.48-24.39), 12.8 (CI:1.98-27.58), respectively. The mean

Table 4. Continuous variable results as "average days (confidence interval)."

	Deficient	Not Deficient	*p* value
Hospital-Free Days	12.8 (95% CI -1.98 – 27.58)	20.94 (95% CI 17.48 – 24.40)	P= 0.097
ICU-Free Days	16.4 (95% CI -2.22 – 35.02)	26.56 (95% CI 23.5 – 29.63)	P= 0.008
Vent-Free Days	18.6 (95% CI 2.14 – 35.06)	26.75 (95% CI 24.4 – 29.41)	P= 0.067

number of vent-free days was also higher in the non-deficient group (26.75 [CI:24.09-29.41] vs 18.6 [CI:2.14-35.06]). The mean number of ICU-free days was higher for the non-deficient group as well (26.56 [CI:23.5-29.63] vs 16.4 [CI:-2.22-35.017]). Investigators used Kruskal-Wallis test to analyze these continuous variables. The difference in ICU-free days between comparison groups was found to be statistically significant based on p-value; however the confidence interval for these results was notably wide. None of the other continuous variables yielded significant results.

Discussion

This study serves as a small steppingstone in the vast pool of COVID-19 research. Despite some limitations to the study, the primary outcome measurement was determined to be significant. Those patients with deficient vitamin D levels were more likely to require ICU level care during the 28 days after admission than those patients with higher levels of vitamin D (p=0.028).

There were multiple notable findings for the participants who required ICU-level care on a more individual and observational level. It is interesting to note. Of the 4 patients in the study who required ICU level care, 2 of them had no known underlying medical conditions or risk factors. Both of these men were healthy, active duty service members in their 40s-50s without any previous significant diagnoses, hospital admissions, or daily medications. Neither patient took vitamin D supplements prior to hospital admission. The only notable finding identified by investigators for these men was their vitamin D level, which was in the deficient range for both participants (≤20ng/ml). One of these patients had a brief, 2-day stay in the ICU; the other remained in the ICU for the entire 28 day follow up period.

The other 2 participants who required ICU level care had few risk factors—one with only hypertension and the other with hypertension and a recent, non-terminal malignancy. Only 1 patient who required ICU level care had a sufficient vitamin D level; this participant reported taking vitamin D supplements prior to admission. The patient with the lowest vitamin D level in the entire study (8ng/ml) was 1 of the 4 to require ICU level care and passed away 5 days after admission to the hospital. While this information is not statistically relevant, investigators found it pertinent to the discussion and important to note for any future researchers.

Investigators failed to reject the null hypothesis for almost all the secondary hypotheses in this study. The only statistically significant secondary outcome measure, ICU-free days, still consisted of a significantly wide confidence interval, limiting its utility. All other data obtained from this study, although not statistically significant, still favored the directions of the hypotheses. In every single outcome measure, deficient vitamin D levels were associated with more severe illness when compared to higher vitamin D levels. These findings, while not statistically significant, are encouraging to researchers. This aligns with previous research on vitamin D with relation to both COVID-19 illness as well as other respiratory illnesses.

Limitations of the Study: The biggest limitation to this study was the sample size, which prohibited a multivariate analysis and possibly limited the study's validity. Investigators did not come close to meeting the initial goal of 220 subjects; in fact, just over 10% of that goal enrolled and data resulted for just less than 10% of the goal. Multiple reasons exist for this small sample size. Protocol development initially occurred in June of 2020. Unfortunately, due to unforeseen circumstances this study was not approved for execution until late March of 2021. By this time during the pandemic, vaccinations were widely available and numbers of positive cases as well as hospital admissions were significantly lower than at any other point during the pandemic so far.[23] Additionally, this study is part of a graduation requirement for a Doctor of Science degree program and therefore concluded on a timeline, ultimately requiring cessation of data collection just prior to an additional surge of hospitalizations attributable to the Delta variant.[23]

Researchers also noticed a subtle change in attitude of potential subjects as time progressed through data collection. In the beginning, most potential subjects seemed eager to participate. As time went on, it became more common for subjects to turn down participation, despite no change in the investigators counseling and consent process. While one cannot know the true motivations behind this shift in desire to participate in research, it is possible this was influenced by societal fatigue with COVID-19, vaccination regret, and possibly distrust of the medical system—all of which are understandable barriers for those diagnosed with COVID-19 in March through June of 2021. These shifting attitudes possibly affected validity both through contribution to small sample size as well as a selection bias—those who agreed to participate may have a higher level of trust of the medical system at baseline and be more likely to want to know their vitamin D level or take vitamin D supplements than those who did not participate.

History served as another threat to validity. Some patients took vitamin D supplements prior to COVID-19 illness while others did not. All those patients taking

vitamin D supplementation had vitamin D levels in the sufficient range. One of these patients did require ICU level care and eventually passed away during the 28-day follow up period. It is also possible teams providing care for these patients initiated vitamin D supplementation after noting a deficiency in their admission labs; there is no way to know if this occurred or the extent to which it may have affected outcomes. This may have adversely affected the validity of the study if some patients were supplemented, and some patients were not.

Conclusion

This study established a possible association between deficient levels of vitamin D and an increased risk for severe outcomes in COVID-19 illness through a prospective, observational study, something not previously accomplished prior to the development of this protocol. Further research is recommended to allow controlling for confounders and improving upon both the internal validity and external generalizability of this study. It is recommended future research track a more comprehensive list of comorbidities and confounders, based off knowledge gained over the past 2 years, to include other lung diseases, obesity, HIV/immunosuppression, smoking, substance use, stroke history, and dementia.[24]

Future research should also seek to evaluate vitamin D levels of all-comers with possible COVID-19, designing a study to assess vitamin D level for everyone as they are tested for COVID-19. This would allow comparison of those without COVID-19 as well as those with mild illness, rather than only patients admitted to the hospital. If the observed correlation continues after controlling for confounders, additional studies could evaluate the efficacy of preventing severe COVID-19 or other respiratory illnesses with vitamin D supplementation either prior to contracting COVID-19 or during the early days of illness.

This small prospective, observational study concluded there is indeed an association between deficient vitamin D and severity of illness in COVID-19 patients as measured by needing ICU level care. While the sample analyzed was small, the primary outcome remained statistically significant, prompting this conclusion. Those with deficient vitamin D also had statistically fewer ICU-free days than those patients with higher level of vitamin D. Significant limitations existed, as previously discussed, which may have affected outcomes. Further research is needed to delineate the relationship between vitamin D level and severity of illness in COVID-19 patients and control for confounders.

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Surgical Tracheostomy in a COVID-19 Positive Patient: A Case Study

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Abstract

COVID-19 has caused a worldwide epidemic, essentially forcing healthcare workers to adapt and innovate in an effort to provide quality patient care while also protecting themselves from potential infection. Current clinical guidelines do not recommend the routine placement of tracheostomies in COVID-19 positive patients. Inevitably, patients who require intubation secondary to COVID-19 related pulmonary infections may require prolonged ventilation, placing the patients at risk for tracheal and laryngeal stenosis, vocal cord paralysis, and ventilation-associated pneumonias among other complications. This case study demonstrates the successful performance of a surgical tracheostomy in a COVID-19 positive patient while additionally discussing the personal protective equipment used by the anesthesia and surgical teams and reviewing recommendations for anesthetic care during tracheostomy in a COVID-19 positive patient.

Background

Officials in Wuhan, China discovered a cluster of patients with pneumonia of unknown cause on December 8, 2019.[1] This pneumonia presented early with severe respiratory symptoms and rapidly progressed to acute respiratory distress syndrome, multiple organ failure, and death in some patients.[1] On December 31, 2019, the World Health Organization (WHO) received notification of this pneumonia cluster.[2] On January 7, 2020, a pharyngeal swab from an affected patient identified a novel coronavirus.[1] Three weeks later, the WHO announced this pneumonia outbreak as a Public Health Emergency of International Concern and, subsequently, provided an official name for the new disease on February 11, 2020, now widely known as coronavirus disease 19 (COVID-19).[2]

As of December 1, 2020, COVID-19 was present in 218 countries worldwide, has caused more than 21.75 million infections, and contributed to 771,635 deaths.[3] In the US alone, COVID-19 caused upwards of 13.29 million infections and is associated with 266,051 deaths.[4] COVID-19 infection was linked to 154,811 deaths within the US between February 1 and August 15, 2020, representing 9% of all deaths during that time; the mortality rate of pneumonia with COVID-19 during the same time period was 3.9%.[5]

Coronaviruses are primarily responsible for respiratory infections in humans, including past outbreaks such as the severe acute respiratory syndrome (SARS) pandemic of 2002 and 2003, and Middle East respiratory syndrome, which dates back to June 2012.[6] COVID-19 contains approximately a 70% match of the genetic profile of the coronavirus that caused SARS.[6] Secondary to the lack of data from the evolving COVID-19 pandemic, the SARS pandemic of 2002 and 2003 is likely the closest event to mirror recommendations for anesthetic care during tracheostomy.[7]

Aerosol generating medical procedures (AGMPs) may result in the formation of aerosol or droplet particles.[8] Small aerosols (<10 micrometers [μm]) can spread over distances of 2 meters or greater and present the possibility of airborne spread; whereas, droplet particles contain larger particulate and do not transmit beyond a 2-meter area.[8] Typical AGMPs encountered in anesthesia practice include but are not limited to the following: endotracheal intubation, tracheotomy or tracheostomy, open airway procedures, positive pressure ventilation, endotracheal suctioning, and electrocautery.[8,9] Electrocautery is a droplet-generating procedure and is known to result in aerosol particles, including blood, smaller than one μm in size, with a direct correlation between the electrical current used and the number of particles

generated; the clinical importance of this is unknown.[8] Airborne transmission of COVID-19 is possible for up to 3 hours, and COVID-19 may live on surfaces for extended durations of time.[9]

Throughout the SARS epidemic, surgical tracheostomy was the most frequently performed surgical procedure on SARS patients.[10-12] One systematic review found a 4.2-fold increased risk of SARS transmission to healthcare providers (HCPs) exposed to aerosols during tracheostomy.[13] Despite the prevalence of tracheostomy in SARS patients and predicted risk to HCPs, no HCPs who were present during performance of a tracheostomy in the operating room (OR) during SARS-positive tracheostomies were infected.[10-12] In addition to standard barrier method personal protective equipment (PPE) with droplet precautions, improved PPE was utilized by OR personnel across multiple sites while performing 15 SARS tracheostomies in the form of powered air-purifying respirators (PAPRs), and 7 SARS tracheostomies were performed by OR staff outfitted with face shields in addition to standard PPE.[10-12] The purpose of this case study is to present the method chosen to proceed with surgical tracheostomy, describe PPE procedures, and review available literature recommendations to prevent COVID-19 transmission during performance of a tracheostomy on a COVID-19 positive patient.

Table 1. Patient findings on evaluation.

Scoring System	Criteria Met	Specific Criteria	Concerns, Management, and other criteria met (or borderline)	Additional Information
qSOFA[14] (Sepsis)	2/3	+1 AMS, +1 tachycardia	3-14 fold increase in hospital mortality	Lactate WNL (0.8)
SIRS[15] Sepsis	3/4	+1 each: tachycardia, tachypnea, febrile	Borderline leukopenia (0.46)	COVID Cause of infection
NEWS[16] (COVID specific)	11	+3 tachypnea > 25, AVPU (not fully alert) +2 on supplemental O2 +1 each: O2 Sat 94%, HR low 100s, Temp > 100.5 (38^{0}C)	Requires immediate assessment and transfer to high level of care	
Risk Factors[17] (COVID specific)		Age > 55, HTN, Obesity, CV Disease (CAD on CT)	Elevated fasting blood glucose Questionable history of pulmonary disease (OSA)	
Lab Risk[17] Factors (COVID specific)		CK 2x ULN (14185) Increased Trop (0.04) Increased D-Dimer > 1 (1.16 with peak post trach 18.9)	Increased LDH > 245 (671) Ferritin > 300 (313) Increased AST (257)/ALT (104)/CRP (7/79)	Lymphopenia: % Lymph in blood 7.3; in Diff 5 ALC- 0.46 -0.66 (WBC 9.1)
ARDS Net[18]	3/3	Bilateral heterogeneous patchy infiltrates	No evidence of cardiac failure	P/F between 100-200

qSOFA: quick sepsis related organ failure assessment; AMS: altered mental status; WNL: within normal limits; SIRS: systemic inflammatory response syndrome; NEWS: national early warning score; AVPU: alert, verbal, pain, unresponsive; HR: heart rate; HTN: hypertension; CV: cardiovascular; CAD: coronary artery disease, CT: computed tomography; OSA: obstructive sleep apnea; CK: creatinine kinase; ULN: upper limit of normal; LDH: lactate dehydrogenase; AST: aspartate aminotransferase; ALT: alanine aminotransferase; CRP: C-reactive protein; ALC: absolute lymphocyte count; ARDS: acute respiratory distress syndrome; P/F: PaO2/FiO2 (arterial oxygen partial pressure/fractional inspired oxygen) ratio

Case Report

Patient Demographics, Admission, & Hospital Course: A 64-year-old male presented to the emergency department (ED) by emergency medical services with altered mental status after a ground level fall the day prior. It is unknown if the patient lost consciousness. His past medical history was significant for Parkinson's disease with autonomic instability, obstructive sleep apnea, and hypertension. He denied any recent travel or known sick contacts, although he admitted having been at a local store without facemask covering. His review of symptoms was positive for dyspnea, fever, productive cough, and generalized malaise. Table 1 contains a detailed list of findings from the patient's extensive work up.

The patient was admitted from the ED to an isolation room in the inpatient medical/surgical unit. On hospital day 2, he was transferred to an isolation room in the intensive care unit (ICU) secondary to increasing dyspnea. There the patient failed a brief trial of self-prone positioning and high flow nasal cannula. On hospital day 2, the patient was intubated following the facility's standard operating procedure (SOP) for intubation of COVID-19 positive patients.[19]

Two experienced anesthesia providers, 1 respiratory technician, and 1 ICU nurse were outfitted with PPE including OR coveralls, high top shoe covers, double gloves, an isolation gown, eye protection, a facemask, and PAPRs. The patient was pre-oxygenated by the anesthesia team with a bag valve mask at 100% fraction of inspired oxygen (FiO_2) for 5 minutes. The patient had several risk factors for being a difficult intubation including a body mass index of 40, short and thick neck with a beard, and no assessment of Mallampati score due to COVID-19 infection. Intubation occurred via a rapid sequence intubation with the use of video laryngoscopy, where a grade 1 Cormack-Lehane view was appreciated and a size 8.0 millimeter (mm) endotracheal tube with rigid stylet passed atraumatically through the glottic opening and secured at 24 centimeters (cm) depth relative to the incisors. The attending ICU physician placed the patient on the following ventilator settings: volume-control assist-control with a tidal volume (TV) of 400 milliliters (mL), rate of 28 breaths per minute, 10 centimeters of water (cm H_2O) positive end expiratory pressure (PEEP), and FiO_2 at 55%. The patient remained otherwise stable for the remainder of his hospital stay, only requiring sedative medications and never needing vasoactive medication infusions. The patient received an endotracheal tube exchange on hospital day 7 secondary to a cuff leak. This procedure was accomplished using standard protocol and PPE via an

airway exchange catheter to allow for continued ventilation during the procedure.

Figure 1. Sentinel XL PAPR illustration.

On hospital day 17, the intensivist consulted anesthesia and otolaryngology to discuss placement of a tracheostomy as prolonged weaning from mechanical ventilation was likely due to the patient's comorbidities. On hospital day 18, a tracheostomy was completed. The patient's ventilator settings on day of surgery were volume control-mandatory minute ventilation, tidal volume (TV) of 420 mL, respiratory rate of 20 breaths per minute, positive end expiratory pressure (PEEP) of 5 cm H_2O, FiO_2 of 40%, and pressure support of 14 cm H_2O.

The facility designated 2 ORs for COVID-19 positive or suspected patients. The ORs and antechambers both allowed negative pressure with high efficiency particulate air (HEPA) filtration. All parties involved participated in and completed a walkthrough of the procedure on the day prior to surgery. Two anesthesia providers, 2 surgeons, and 1 surgical technician were outfitted with PPE and PAPRs as outlined by the SOP. One surgical nurse was also present in the OR with PPE, which included a N-95 respirator mask, but no PAPR, since the nurse was able to maintain a distance greater than 6 feet from the patient. Two additional anesthesia providers, 2 OR nurses, and 1 surgical technician remained staged in the antechamber to aid with donning and doffing of PPE. All other surgical cases were held until the completion of the case and transport of the patient back to ICU.

The patient was transported to the OR using his ICU ventilator with the settings as above. The sedative infusion was turned off and anesthesia assumed responsibility of the patient. Throughout the patient's care in the OR, the ICU ventilator was used in order to prevent contamination of the anesthesia machine. As such, the patient received a total intravenous anesthetic. Anesthetic induction proceeded with 2 milligrams (mg) midazolam, 100 mg ketamine, 50 mg propofol, and 10 mg vecuronium. A propofol infusion was titrated to optimize the patient's hemodynamics. A non-depolarizing muscle blocker was used to prevent any bucking or coughing during the procedure. The patient also received intermittent boluses of ketamine for analgesia. The patient required no narcotic medication during the case.

Surgery proceeded without complication. Nineteen minutes in to the procedure, the FiO_2 was reduced to 30% per surgeon request. Twenty-one minutes into the procedure, the endotracheal tube was retracted 4 cm and clamped per surgeon request and the ventilator was stopped. Two minutes and 30 seconds later, an 8.0 mm tracheostomy tube was placed through the newly created tracheostomy. The patient experienced a transient decrease in pulse oximetry to 83% that quickly resolved with resumption of mechanical ventilation. Due to de-recruitment within the distal airways, the patient required changes in ventilation to include an increase in FiO_2 to 100% and was titrated down as tolerated, an increase in PEEP to 10 cm H_2O, and an increase in respiratory rate to 25 breaths per minute to correct hypercapnia. At the completion of surgery, the patient's sedation was restarted, and he was transported to the ICU in stable condition.

The remainder of the patient's stay in the hospital was uneventful. Following 1 confirmed negative COVID-19 test and improved ventilator settings, the patient was transferred to a long term acute care facility on hospital day 27. Ventilator settings on transfer were volume control-mandatory minute ventilation, tidal volume (TV) of 420 mL, respiratory rate of 20 breaths per minute, positive end expiratory pressure (PEEP) of 5 cm H_2O, FiO_2 of 40%, and pressure support of 11 cm H_2O.

All staff involved in the direct and indirect care of this patient remained asymptomatic for the requisite 14 days after the procedure. No staff members required isolation or testing following the procedure. On follow up with the patient's daughter, he is doing well but remains at the long term acute care facility due to a non-healing decubitus ulcer. His respiratory status improved significantly with plans to remove his tracheostomy once his decubitus ulcer is resolved.

The PPE utilized by the anesthesia providers during the delivery of anesthesia care included the Sentinel XL PAPR system (Figure 1), extra protection coverall, level 2 isolation gown (yellow gown), hi guard ultra full coverage boot, and nitrile gloves.

PAPR Information: The Sentinel XL PAPR system

(model number S-5000) is a chemical, biological, radiological, nuclear (CBRN) system, which includes a one-size-fits-all butyl hood (part number [P/N] S-2001), blower (P/N S-2002), rechargeable NiMH battery pack (P/N-2003), 3 NIOSH approved CBRN cartridge (P/N S-2016), adjustable waist belt (P/N S-2007), quick release belt clip (P/N S-4011), fast battery charger (P/N S-2009), a flow meter assembly utilized to check sufficient blower air flow (P/N S-2010), and an alkaline battery adaptor (P/N S-4013). [20]

The PAPR system is capable of protecting against inhalation of certain biological, gas and chemical, radiologic, and nuclear dust particulates.[20] The system functions by pulling air through the NIOSH approved CBRN filter cartridges where filtering of particulate takes place. The filtered air is then pushed into the butyl hood via a hose connected to the motor. The hood covers the user's head and neck, and extends out approximately to the shoulders. This full hood cover system carries a protection factor rating of 10,000, which provides 1,000 times the protection of an N95 mask.[21]

The PAPR system was available to staff at our facility who were at the highest risk of exposure to COVID-19 during aerosolizing procedures. Staff members who were authorized use of the PAPRs completed a respiratory evaluation through Occupational Health and received Occupational Safety and Health Administration compliant PAPR training in accordance with facility safety.[22,23]

PPE Donning Procedure: The PPE donning procedure adhered to the facility SOP for usage of the PAPR system. This ensued, under the assumptions proper cleaning occurred after each use, the system had passed the daily inspection and function check with the flow meter assembly, and it was properly stored. The butyl hood was disconnected from the blower, caps positioned on the CBRN filter cartridge inlets, and the blower NiMH battery pack connected to the fast battery charger during system storage.[24]

Donning began by ensuring hair was secure, and jewelry and watches were removed. After performing proper hand hygiene, the provider donned gloves. After donning the coverall and full coverage boots the components of the PAPR system were again inspected for integrity. Upon verification of integrity (no holes, cracks, complete components, etc.), the blower was disconnected from the charger. Following removal of the inlet filter covers from all 3 filters, a repeat PAPR flow test was performed.[24]

Upon a successful pass of the system check and inspection, the provider donned the adjustable waist belt with the quick release belt clip and blower with all the 3 filters attached. With the blower running and assistance from the designated donning and doffing provider (assistant), the hood was donned and the hose attached to the blower. A yellow gown was then donned over top of the PAPR and coverall with assistance. The assistant inspected the provider with the PAPR system in place and assisted with necessary adjustments for comfort in addition to ensuring the inlet holes on the filters were free of obstruction. The provider then carried out hand hygiene and donned a second pair of nitrile gloves as preferred by the provider. The provider then entered the patient care area and assumed provider responsibilities upon patient arrival. The assistant again performed hand hygiene with an alcohol-based solution and maintained his or her position to assist with activities outside the room (e.g. handing in supplies, preparing for doffing procedures, etc.).[24]

PPE Doffing Procedure: The PPE doffing procedure also followed the facility SOP for usage of the PAPR system. PAPR system cleaning occurred in 2 stages after use, with the help of the assistant in order to maximize safety and minimize potential end user exposure. PPE for the assistant consisted of head cover, eye protection, face shield, N95 mask, yellow gown, and nitrile gloves. In an effort to conserve N95 masks due to logistic shortages, the assistant also wore a surgical mask over the N95 mask. A primary and secondary cleaning of the PAPR system was completed with the use of disinfecting wipes with bleach in accordance with the facility's SOP for cleaning and disinfecting PAPRs.[24]

Prior to exiting the patient care area, the provider performed hand hygiene with gloves on. Using a disinfecting wipe, the provider cleaned the door handle and removed the outermost pair of gloves. The provider then removed the yellow gown and full coverage boots, performed hand hygiene, exited the patient care area into the anteroom, removed the other pair of gloves, performed hand hygiene, and donned a new pair of gloves. The assistant wiped down the PAPR system starting with the blower. The hose on the butyl hood was cleaned from top to bottom, and the butyl hood was subsequently cleaned from top to bottom as well. The provider then removed the belt with the blower attached with help from the assistant, and the assistant wiped down the belt. The provider then bent at the waist, and the assistant folded up the back of the hood flaps. With the blower still running, the provider doffed the hood into a red biohazard bag with help from the assistant. The blower was then turned off and caps placed on the inlet ports on the filters and placed in the same bag. The provider performed hand

hygiene, the coveralls were doffed, gloves removed, and repeated hand hygiene. The assistant also doffed their protective equipment and performed hand hygiene.[24]

Both the provider and assistant donned a new pair of gloves and transported the equipment to the decontamination room to perform the secondary cleaning. Both donned an N95 mask with surgical mask over top, eye protection, yellow gown, and gloves prior to the secondary cleaning. The PAPR system was then removed from the biohazard bag, the butyl hood hose was disconnected from the blower, and both were hung from a prepositioned IV pole to facilitate ease of cleaning. The equipment was wiped down a second time, the hood was wiped down both inside and out, and the equipment was left to dry. Once dry, all equipment was returned to the staging area and positioned for use.[24]

Recommendations for Tracheostomy: A literature search and review was performed using the PubMed and EbscoHost databases from inception to May 11, 2020. The literature search utilized the following search terms and combinations: COVID-19 or Coronavirus or "Novel Coronavirus" or SARS-CoV-2 and tracheostomy, surgical airway, or anesthesia. In total, one author evaluated 370 titles and abstracts for inclusion criteria including adult subjects, COVID-19 or SARS, invasive/advanced airway, and English language; 45 articles met inclusion criteria after eliminating duplicates. Primary references of the literature search articles were obtained as able.

Numerous professional societies and medical centers have published recommendations for performance of tracheostomy in COVID-19 positive patients. While minor variances exist among the recommendations, the overall themes are consistent with goals of infection prevention, maintaining patient and staff safety, and reducing aerosol generation.

Patient Selection: Patients who are confirmed to have active COVID-19 infection should not undergo tracheostomy unless an endotracheal tube (ETT) fails or is insufficient; prolonged intubation is not an indication for tracheostomy placement in a COVID-19 patient.[25,26] If feasible, delay performing a tracheostomy until approximately 21 days have elapsed after development of COVID-19 symptoms to reduce viral shedding and viral load.[26-29] One hospital in Wuhan, China found median viral shedding occurs for 20 days following onset of symptoms, ranging from 8 to 37 days.[30] Alternately, delay tracheostomy until COVID-19 test results are negative, if possible.[7,25,26,29,31] Avoid tracheostomy for any patient who is deemed to have an extremely high mortality risk.[27] Ventilator requirements associated with safe performance of a tracheostomy include positive end expiratory pressure (PEEP) less than 12 cm H_2O and FiO_2 less than 60%.[28]

Location: The ideal location to perform tracheostomy is either an OR or in a negative pressure room within the ICU.[7,25-28,32,33] If a negative pressure room is not available, no entry should occur to the affected room for at least 3 hours after the procedure due to the possibility of viral aerosols remaining.[26] Alternately, a portable HEPA filtration system may be employed in the ICU setting.[7,27] Within the OR, specific rooms should be allocated to care for COVID-19 patients to minimize risks of cross-contamination.[27] Ultimately, the decision on location must include consideration of the inherent risks and benefits of patient transportation and of open surgical versus percutaneous tracheostomy technique.[25] Regardless of the location performed, only essential supplies and equipment should be present in the room to minimize the risks of contamination. Backup supplies should remain outside of the room but immediately available.[26]

PPE: Recommended PPE to prevent airborne and droplet disease transmission is required.[27] Minimal PPE during a COVID-19 tracheostomy procedure mandates barrier protection including an impermeable surgical gown, gloves, a fit-tested N95 mask, goggles, cap, and face shield over the goggles and N95 mask.[7,25,27] Consider the addition of a PAPR to standard PPE as PAPRs confer 2.5 to 1,000-times increased protection when compared to the N95 mask of standard PPE alone.[7,26,27,32] Use of a N95 mask under the PAPR is recommended as a failsafe to provide continued protection if the PAPR fails.[26] Double gloving reduces the risks of contamination while doffing PPE.[7,26] Double gowning may provide a similar benefit.[26] Doffing PPE is a moment of high risk for self-contamination, thus, a PPE observer should monitor for adherence to doffing protocol.[28,33] An anteroom immediately adjacent to the procedure room should be used for donning and doffing of PPE.[31]

Staff: The most skilled, experienced surgeon and anesthesia provider available should perform the tracheostomy, and minimize all staff in the procedural area to the lowest number possible to safely perform the procedure.[7,25-29,32] A resource person should remain immediately available outside of the room to assist with communication and equipment or supply needs.[26] A designated COVID-19 airway team is recommended; all designated staff should participate in simulation opportunities and dry runs of the procedure.[31]

Preparation for Procedure: All members of the operating team should participate in a pre-procedural briefing utilizing open communication.[31,33] Transport the patient to the procedural area utilizing the ICU ventilator, if the

patient is already intubated.[32] A viral filter attached to the expiratory limb of the ventilator or anesthesia machine will protect the machinery from contamination.[33] A viral filter may also be attached to the inspiratory limb to protect the machinery from cross-contamination between uses.[33]

Procedure: A HEPA viral filter must be present on all ventilators, anesthesia machines, and suction apparatuses prior to use in order to filter viral particles and prevent aerosolization.[26,28] Establish neuromuscular paralysis,[7,25-29,31-33] analgesia,[26] and sedation[26,31] prior to the procedure and maintain throughout the procedure to reduce the likelihood of aerosol generation via cough. Consider glycopyrrolate administration if an antisialagogue effect is desired.[27] Utilize an appropriately sized non-fenestrated, cuffed tracheostomy tube with a balloon to secure the tracheostomy.[25,26,29,32] Completely drape the patient and bed to prevent contamination of surroundings.[26]

Open Surgical Tracheostomy: Prior to surgical entry of the trachea, advance the ETT so the ETT cuff is distal to the site of tracheal incision to prevent air escape from the tracheal incision.[25,29,31] Ideally, avoid employment of electrical instruments such as cautery or ultrasonic shears due to potential for viral particulate presence in smoke. Instead, "cold instrumentation" is favored for tracheal entry.[7,26,27,29,32] If cautery is employed, high flow suction is mandatory.[33]

Percutaneous/Dilational Tracheostomy: Performance of a percutaneous dilational tracheostomy (PDT) traditionally requires flexible fiberoptic bronchoscopy, where bronchoscopy is an AGMP.[25,26] If bronchoscopy is necessary, a video bronchoscope with all connectors securely attached will reduce aerosol generation.[25] A disposable bronchoscope is also preferable, if available.[26] Minimize bronchoscopy time to the extent possible.[7] Avoid performing bronchoscopy in the presence of a deflated cuff or with concurrent ventilation.[27] If a PDT is performed without bronchoscopy, consider palpating the trachea during ETT withdrawal, verifying airflow via doppler during ETT withdrawal, or blindly placing a needle and aspirating air to confirm tracheal placement.[26] Avoid electrocautery as it may increase potential for aerosol generation and possibly viral particulate presence in smoke.[7,26]

Either Approach to Tracheostomy: Preoxygenate the patient prior to any pause of ventilation.[27] PEEP should also be employed during preoxygenation.[31] Pause ventilation any time there is an open airway with potential for aerosol generation, including any time the ETT cuff is deflated, during tracheal entry, prior to insertion of the tracheostomy tube, and any time the tracheostomy tube cuff is deflated.[7,25,26,28,29,32,33] Additionally, when the airway is open, cease gas flow to the ETT and consider clamping the ETT.[31,33] Suction may be applied to the surgical site to generate a negative pressure environment on the surgical field while exchanging the ETT for the tracheostomy tube.[28] However, the practice of suctioning after tracheal incision is controversial and may increase risk of aerosolizing secretions contaminated by a high viral load.[7,29] Prior to any resumption of ventilation, verify cuff inflation and a closed circuit.[26,27] Following insertion of the tracheostomy tube, remove the ETT from the patient's mouth and immediately place the ETT into a plastic bag for secure disposal.[26] Attach a new heat and moisture exchanger (HME) with a viral filter directly to the tracheostomy tube to prevent aerosol generation if the integrity of the anesthetic circuit is compromised.[12,31,33] The HME should remain attached to the tracheostomy tube and all tubing disconnects should occur distal to the HME.[25,29] Confirm positioning of the tracheostomy tube in the trachea using end-tidal carbon dioxide only; abstain from use of a stethoscope for auscultation to decrease contamination.[31] Perform all airway suctioning using in-line suction into a closed circuit with an inflated cuff and a viral filter to reduce aerosol generation.[7,25,28,29,31,32] After insertion of the tracheostomy tube and removal of the ETT, no personnel should enter or exit the room until the interval of known air exchange times has passed.[32]

Non-Standard Barrier Approaches: Since the onset of the COVID-19 outbreak, 1 non-experimental study and multiple case reports have described utilization of surgical field barriers to potentially reduce transmission of COVID-19 during open surgical tracheostomy performance. The non-experimental study demonstrated successful employment of 2 horizontal bars mounted to the patient's bed, covered with a clear surgical drape, and securely sealed at the caudal end and left side, with a sealed modification to incorporate suction under the barrier.[34] After performing 5 tracheostomies under this apparatus, all 5 drapes were contaminated with droplets between 0.2 and 2.8 mm in size. Greater than 90% of the contamination occurred within the central portion of the drape, 5% contamination on the sealed side of the drape, and 3% contamination on the non-sealed side of the drape.[34] Notably, no observable droplet presence existed on the face shields of the surgeon or scrub nurse in any of the 5 cases.[34] Case studies described utilization of an Omni-Tract retractor covered with a clear surgical drape and alternate options of Bookwalter or Thompson retractors;[35] a metal frame made from external fixator equipment and covered with a sterile C-arm drape;[36] and a laryngoscope suspension device covered with x-ray cassette drapes and a modified sterile C-arm drape

covering the suspension device and the patient with holes made for the surgeon's and assistant's hands, and a hole for instrument passage, complete with a flap over the instrument passage hole.[37]

One case report described performance of PDT with measures to reduce the risk of aerosolization. The PDT was performed with the ETT cuff inflated in the distal trachea to allow continued ventilation during tracheal access, and subsequent guidewire placement, skin incision, and dilation without increasing the risk of aerosol generation.[38] After completing the aforementioned steps, ventilation ceased, the ETT was removed with direct visualization, the tracheostomy tube inserted and cuff inflated, bronchoscopy completed to confirm location of the tracheostomy tube within the trachea, and once the ventilator was connected and circuit closed, ventilation resumed.[38] In total, 96 out of 98 patients successfully underwent this procedure, and none of the 8 staff members involved in any case demonstrated symptoms of COVID-19; 4 of the staff members submitted to COVID-19 testing and all were negative.[38]

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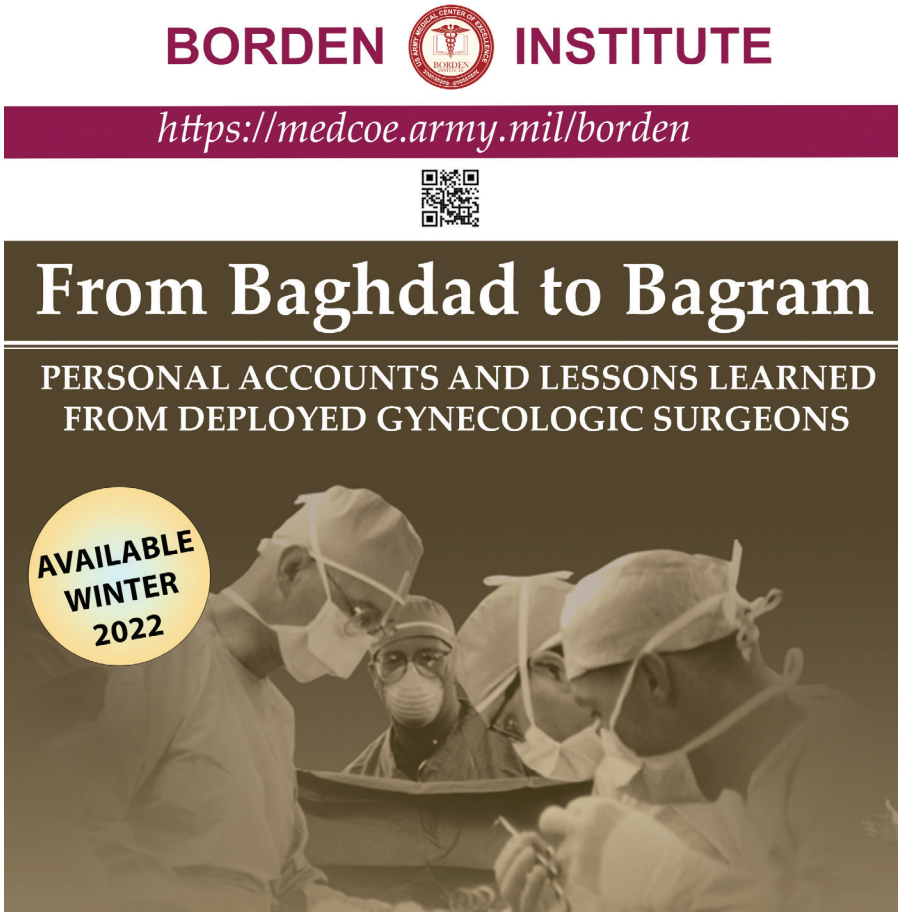

Quarantine in a COVID-19 Pandemic: Lessons from a Deployed Role I

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Abstract

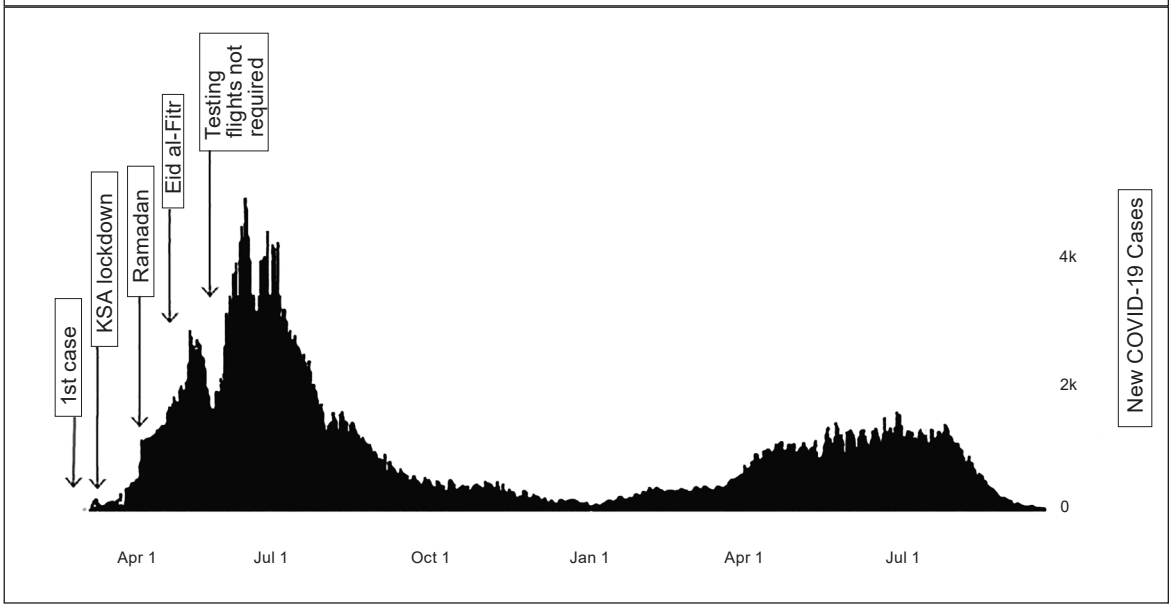
The coronavirus (COVID-19) pandemic has changed the world; and the US military changed with it. Although this virus presents with a wide spectrum of disease progression (no symptoms to acute respiratory distress syndrome leading to death), its impact extends beyond health outcomes. At the time of this study, numerous research and development projects were underway to develop a COVID-19 vaccine or other treatment modalities; however, there were no Federal Drug Administration (FDA) approved vaccines or medical therapeutics that definitively provided a cure. Instead, public health officials relied on non-pharmaceutical interventions (NPI) as a main strategy to contain and mitigate the disease. The US military in partnership with host nation countries, such as the Kingdom of Saudi Arabia, exemplified unity of effort through a coordinated response: mass testing, prompt contact tracing, quarantine, and isolation. One main non-pharmaceutical intervention (NPI) strategy includes social distancing which has been shown to significantly impact pandemic influenza transmission translating to COVID-19 mitigation measures. In the military, strict adherence to quarantine, restriction of movement, and isolation orders can be a challenge since appropriate facilities and resources are limited in deployed and training environments. Further, asymptomatic carriage and transmission of COVID-19 disease (mean incubation time 6.2 days and range of 2-14 days) can complicate quarantine and testing methodologies. Moreover, deployment of the NPI mitigation strategies such as quarantine and isolation in an effective and timely manner is essential to prevent further spread. In essence, quarantine is the prevention, and isolation is the cure. This paper aims to describe how a deployed US Army Role I can effectively utilize NPI and containment strategies during a global pandemic in an austere environment.

Introduction

The coronavirus (COVID-19) pandemic has changed the world; and the US military changed with it. The World Health Organization (WHO) declared COVID-19 a public health emergency of international concern on January 30, 2020, as total global deaths escalated beyond 4.485 million with more than 215,397,147 confirmed cases as of 28 August 2021.[1] In the US, the Centers for Disease and Control and Prevention (CDC) COVID-19 tracker estimated total of 38,527, 411 confirmed COVID-19 cases and 632,786 deaths.[2]

Although this virus presents with a wide spectrum of disease progression (no symptoms to acute respiratory distress syndrome leading to death),[3] its impact extends beyond health outcomes. The pandemic also infected the global economy with unprecedented closures in businesses and schools along with travel restrictions and stay-at-home orders based on quarantine and isolation recommendations. Globally, governments imposed strict screening and restriction of movement at key entry points regarding persons and shipping lines costing an estimated $1.1 trillion in lost income.[4]

Figure 1. Number of COVID-19 cases for spring-summer 2020 in the Kingdom of Saudi Arabia (KSA).[18]



At the time of this study, numerous research and development projects were underway to develop a COVID-19 vaccine or other treatment modalities; however, there were no Federal Drug Administration (FDA) approved vaccines or medical therapeutics that definitively provided a cure. Instead, public health officials relied on non-pharmaceutical interventions (NPI) as a main strategy to contain and mitigate the disease. In response to the containment strategies designed to prevent sustained community disease transmission, the US military in partnership with host nation countries such as South Korea exemplified unity of effort through a coordinated response: mass testing, prompt contact tracing, quarantine, and isolation.[5]

One main non-pharmaceutical intervention (NPI) strategy includes social distancing, which has been shown to significantly impact pandemic influenza transmission translating to COVID-19 mitigation measures.[5-7] However, these mitigation strategies also rely on other NPI measures such as hand hygiene, disinfection, travel restrictions, school closures, quarantine, restriction of movement, and isolation procedures.

In one study examining 10,579 basic trainees at Joint Base San Antonio-Lackland, implementation of NPI (screening, testing, administrative measures, quarantine, isolation, and source control) has proven to limit transmission of symptomatic COVID-19 cases to ensure mission readiness.[6] Several studies also concluded timely and quick implementation of these control measures could significantly reduce the peak of an epidemic.[7-12]

In the military, strict adherence to quarantine, restriction of movement, and isolation orders can be a challenge since appropriate facilities and resources are limited in deployed and training environments.[10,13] Further, asymptomatic carriage and transmission of COVID-19 disease (mean incubation time 6.2 days and range of 2-14 days) can complicate quarantine and testing methodologies.[10,14] Moreover, deployment of the NPI mitigation strategies such as quarantine and isolation in an effective and timely manner is essential to prevent further spread.[15] In essence, quarantine is the prevention, and isolation is the cure. This paper aims to describe how a deployed US Army Role I can effectively utilize NPI and containment strategies during a global pandemic in an austere environment.

Background

On about March 2, 2020, the Kingdom of Saudi Arabia (KSA) identified its first confirmed case of COVID-19 (Figure 1). All social events were banned and international flights were suspended on March 14, 2020. On or about March 16, the Public Health Emergency Working Group (PHEWG) in a Role I Military Treatment Facility (MTF) located on Eskan Village (EV) was activated by a joint command decision, with regular meetings approximately 5 days each week.

As per the first recorded PHEWG meeting, EV was in

Table 1. Health protection condition (HPCON) levels in Eskan Village (EV).

A	WHO or CDC declares an infectious disease a public health emergency AND Low range quarantine levels	1. Review guidance from WHO, CDC, and CENTCOM daily. 2. Provide periodic updates to all mission partners at town halls. 3. Educate community on good hygiene practices. Provide public outreach on preventative measures. 4. Inventory and order medical supplies, PPE, and disinfectants. 5. Review mission essential personnel lists. 6. Update HPCON measures. 7. Initiate public health emergency working group with representatives from all mission partners. 8. Coordinate with local resources to align public health response protocols.
B	Reports of multiple disease cases imported to KSA OR Single case of human-to-human transmission in KSA AND Low range quarantine levels	1. EVCC implements screening at clinic entrance: query travel history, symptoms, and provide appropriate PPE. Screen patients requesting appointments for flu-like symptoms via telephone. 2. Establish strict personal and interpersonal hygiene measures (no handshakes, hugging, or kissing). 3. Designate medical personnel, medical equipment, triage areas, and transportation for suspect cases. 4. Highly encouraged sick leave for symptomatic individuals. Medics provide treatment. 5. Dispense over-the counter medication packs to symptomatic individuals. 6. Consider prohibition of unofficial guest access to Eskan Village. Limit official guest visits. 7. Screen every person entering Eskan Village for contact, travel history, and COVID-19 symptoms. 8. Implement quarantine protocol for positively screened cases after consultation with PHEO/APHEO.
C	Eskan Village resident or employee is suspected/confirmed to have disease, in absence of Eskan-wide outbreak OR Sustained human-to-human community transmission OR Mid-range 1 quarantine levels OR Mid-range 2 (medically augmented) quarantine levels	1. Recommend declaration of public health emergency on Eskan Village. 2. Consider stop movement order. 3. Initiate social distancing via command order. Minimize in-person meetings and large gatherings. 4. Limit access to mission essential personnel and residents only. 5. Stop non-acute clinic operations. 6. Implement isolation protocol for suspected/confirmed cases after consultation with PHEO/APHEO. 7. Consider return of dependents and non-essential personnel. 8. Supplement EVCC clinic staff/SMC contractors with organic medical assets (OPM-SANG, TF Spartan). 9. Consider 24/7 COVID-19 medical response capabilities: day and night working shifts. 10. Stop buffet style meals and salad bars at ECC, commissary, and DFAC. Encourage takeout meals. Implement self-bagging only at commissary and BX. 11. Consider time-partition of gyms, dining facilities, and public spaces by unit to reduce crowding.
D	Evidence that local health care response is insufficient OR Significant outbreak on Eskan OR High range quarantine levels	1. Consider Eskan Village lock-down with allowances for critical mission needs. 2. Return dependents and non-essential personnel. Cease all inbound travel. 3. Consider mass evacuation in accordance with guidance from CENTCOM, CDC, and DOS. 4. Focus medical support to quarantined individuals and mission essential personnel only.

HPCON: health protection condition; WHO: World Health Organization; CDC: Centers for Disease Control; CENTCOM: central command; PPE: personal protective equipment; EVCC: Eskan Village community clinic; PHEO: public health emergency officer; APHEO: asistant public health emergency officer; SMC: specialized medical center; OPM-SANG: office of the program manager/ Saudi Arabian National Guard; TF: task force; ECC: Eskan community center; DFAC: dining facilityes administration center; BX: base exchange; DOS: department of state.

health protection condition (HPCON) Bravo (Table 1). At that time, Security Forces (SECFOR) Command published COVID-19 mitigation measures, defined HPCON triggers, and implemented additional guidance in coordination with other EV program partners.

The KSA government also instituted a 21-day curfew from 1900-0600 hours. The following day, the Eskan Village Community Clinic (EVCC) was able to perform rapid, point-of-care Influenza A + B testing, but was unable to perform specific COVID-19 testing. The following day, KSA also reported their first COVID-19 associated death.

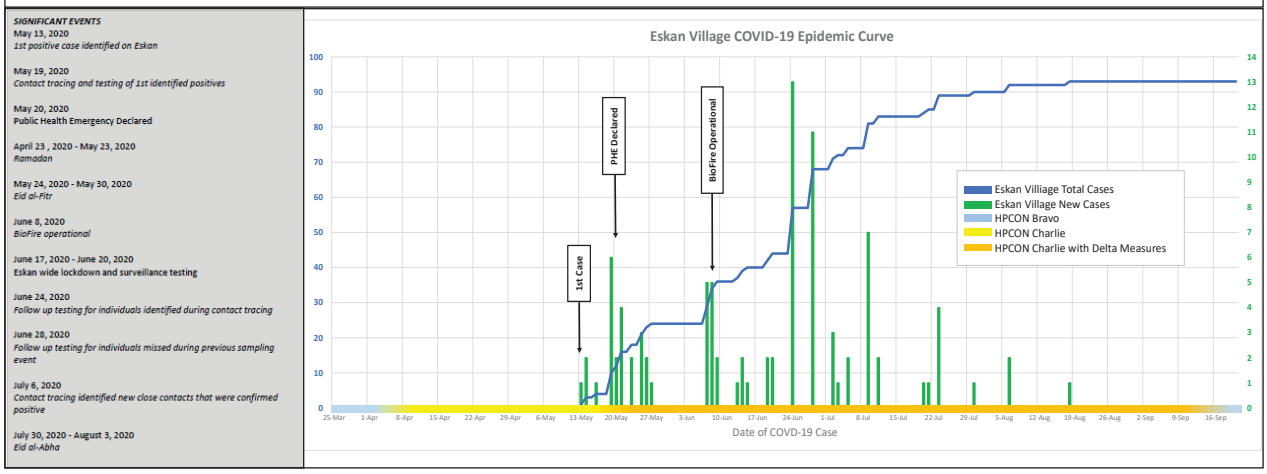
On April 2, EV then raised the HPCON level to Charlie (Figure 2). On April 6, 2020, the KSA government expanded the curfew in Riyadh to 24 hours. On April 20, the PHEWG reviewed the US military Central Command (CENTCOM) guidance for the COVID-19 pandemic response and determined to evacuate symptomatic patients, lab confirmed positive for COVID-19, out of theater (e.g. Landstuhl Regional Medical Center [LRMC]). Ramadan began on April 23, and by April 26, the KSA government partially lifted the curfew allowing travel between 0900-1700 hours. By May 7, the first nasal pharyngeal (NP) specimen was submitted to the KSA Ministry of Defense Medical Services Directorate for COVID-19 real-time polymerase chain reaction (RT-PCR) testing.

On May 13, 2020, the first positive individual on EV was identified. By May 16, the fourth COVID-19 positive case was identified on EV, and the HPCON level was increased to Charlie with Delta measures at some facilities. The first evacuation mission to LRMC was completed on May 18. By May 19, the tenth positive case was confirmed, and the medical control center (MCC) was established.

Primary medical team operations subsequently shifted the posture towards COVID-19 surveillance with strict quarantine and isolation measures. By May 20, 2020, EV declared a public health emergency (PHE), and the EVCC prioritized sick call appointments based on risk. Eid, the nationally recognized religious event, started on May 25, and by May 27, there were a total of 24 COVID-19 cases identified on EV. By June 1, KSA began publishing plans to reopen the country based on risk mitigation postures. On June 8, the KSA government no longer required testing for travelers, and the EVCC offered real-time PCR testing.

By June 17, 2020, EV had a total of 40 positive cases; and the military leadership enacted a strict lockdown of non-mission essential operations in order to conduct an installation wide COVID-19 surveillance activity on its at-risk population. On the same day, Riyadh reported the highest number of daily cases at 2,371. By June 20, the EV installation completed the COVID-19 surveillance

Figure 2. Epidemic curve of cumulative COVID-19 cases in Eskan Village (EV).



testing event for over 950 Department of Defense (DoD) service members, foreign affiliates, contractors, civilians, and third country nationals.

These lab samples were also forwarded to a DoD reference laboratory at LRMC for follow on testing. As a result, only 4 new positives were identified during this time period. By July 5, 2020, the MCC refined the COVID-19 emergency response plan, creating processes to effectively manage the quarantined and isolated individuals.

This plan was based on Force Health Protection Guidance (Supplement 10)—Department of Defense Guidance for Coronavirus Disease 2019 Clinical Laboratory Diagnostic Testing Services and Supplement 10—Attachment 1 Clinical Testing and Management—COVID-19 (11 JUN 20). Additional sentinel surveillance testing was completed on July 11, 2020, for approximately 150 service members. At this time, EV reported a total of 83 COVID-19 cases. On July 27, a trial run sending 20 samples via commercial shipping increased the total number of cases to 89.

The Joint Public Health Emergency Working Group (JPHEWG) reconvened on August 13, 2020, to re-establish a path forward with respect to COVID-19 disease surveillance and response amongst the different program partners residing on EV. By August 29, EV reported a total of 98 COVID-19 cases, flattening the epidemiologic curve. The local Role I MTF collected all lab confirmed COVID-19 data as part of the disease surveillance and reportable disease program. With the assistance of leader engagement and the re-establishment of JPHEWG, EV was able to reduce the HPCON level safely as a dial down approach. As of September 17, EV moved into HPCON Bravo.

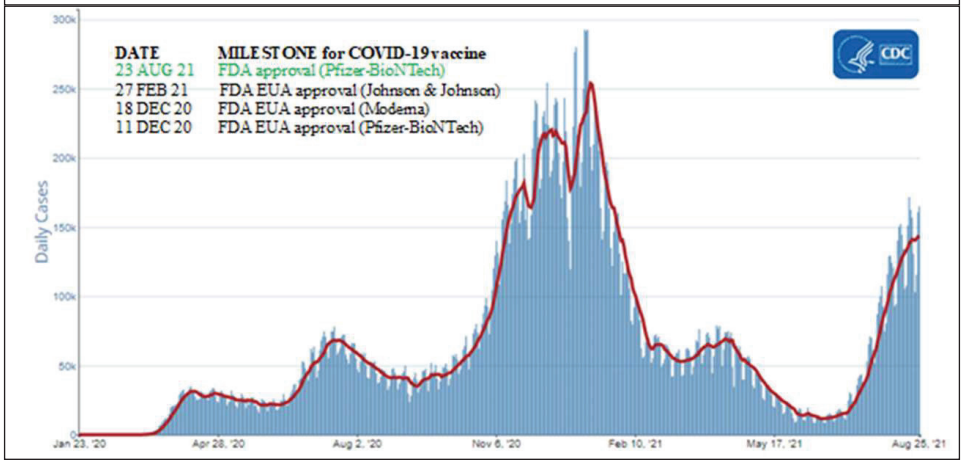
Discussion

This data from EV on a US Army Role I MTF represents a unique confluence of the timely implementation of quarantine/isolation and NPI procedures, strong senior military leadership support, and host nation medical partnerships. The ultimate outcome was the rapid control and subsequent mitigation of a major outbreak during the COVID-19 pandemic in the US Central Command (CENTCOM) area of responsibility (AOR). In early 2020, as the COVID-19 virus continued to spread unabated throughout the globe, it became clear to the medical leadership action was needed to prevent a large-scale COVID-19 outbreak at the EV compound.

The unusual nature of the mission made the likelihood of an outbreak far more likely than in other deployed locations. The setting of the EV mission, a mix between Title 10 & Title 22 assets, involved significant interaction with host nation partners often requiring daily in-person interactions. Thus, the exposure of the residents of the compound closely reflected the surrounding host nation disease landscape. As early as March 2020, entry point controls such as mandatory temperature checks and symptom screening questionnaires were implemented for all persons entering the site.

The COVID-19 outbreak in EV began as early as May 2020, with a cohort of individuals who had extensive contacts with both host nation US military partners and others. This initial outbreak prompted the public health authorities at EV to implement a rigorously controlled system of isolation, quarantine, and contact tracing. Despite these initial measures, there continued to be several subsequent pockets of coronavirus infection, many linked to the initial outbreak group.

Figure 3. Number of COVID-19 cases in the US.[19]



Over the subsequent 3-4 weeks, it became clear clinically asymptomatic carriers were likely spreading the virus to other populations on EV. In response, a policy of testing all close contacts of confirmed COVID-19 positive individuals was enacted along with a 14-day post-exposure quarantine. This testing strategy focused on testing close contacts on day 5 and day 12 post-exposure/close contact. By identifying and further segregating asymptomatic carriers of the COVID-19 virus as well as resetting the quarantine timelines of the individuals subsequently exposed, this contained the spread of the initial outbreak.

Support from the senior military leaders on the installation, including a public health emergency (PHE) declaration on or around May 20, provided a key element in this success. Without significant buy-in from the command structure, such measures could not have been implemented in a uniform and effective manner. The mutual cooperation between agencies and inter-service partnerships was essential in ensuring all public health measures were fully enacted and enforced.

The use of small, cohort-based quarantine groups constituted another element in the success of coronavirus mitigation on EV. Individuals in both travel as well as medical quarantine were limited to standard cohorts of no more than 5-6 individuals. These persons were placed in individual sleeping areas and had access to dedicated restroom facilities. All of the above measures served to minimize both respiratory as well as fomite-based disease transmission. The use of limited sized patient cohorts allowed for truly effective use of the quarantining modality. From a strictly public health standpoint, limiting any disease outbreaks through effective quarantine measures would be preferable over a restriction of movement type of quarantine as practiced elsewhere in the AOR.

The significant host-nation/mission partnership requirements, which were difficult to fully curtail, remained one of the main challenges in epidemiological terms. These requirements ensured a continued threat of multiple independent outbreaks on EV. Indeed, this eventuality transitioned to a reality on multiple occasions. While the testing of asymptomatic close contacts of COVID-19 positive individuals was prudent from a public health standpoint and served to curtail community-based viral spread, it was resource intensive.

As a result, command under the guidance of medical leadership strove to leverage host nation partnerships and mutual cooperation towards disease containment and mitigation strategies. Subsequently, a host nation military (Ministry of Defense) partnership was quickly pioneered. This agreement allowed US military medical personnel to submit samples for COVID-19 PCR testing to host nation laboratories. This auxiliary laboratory testing capacity added an additional capability during a time when such testing platforms were simply unavailable elsewhere in the AOR. The ability to perform large scale PCR testing at a host nation facility liberated rapid testing resources which were repurposed for use solely on symptomatic patients. This partnership ultimately allowed for mass testing of nearly all close contacts and thereby facilitated the rapid control of an emerging, community-based outbreak on the compound.

The command teams for both Title 10 and Title 22 personnel successfully synchronized with the medical team to execute appropriate HPCON levels as the pandemic in the KSA grew worse. The challenge facing both

commanders was the need to continue mission-essential operations during the pandemic. The commanders emplaced risk mitigation measures based on the input provided by the medical team, but the commanders jointly decided to implement health protection measures. For example, after the first outbreak occurred on base, both commanders jointly initiated a PHE for the base. This PHE provided the leadership with certain authorities over the population on the base to stem the outbreak. The PHE enabled the leadership to significantly restrict movement of personnel on and off base along with certain activities (e.g. dining facility, gym, post exchange, morale welfare and recreation, etc.). Despite this restriction on movement, command and control of current operations continued.

Overall, the successful implementation of NPI measures required both host nation and installation coordination. Although Role I assets are quite limited, this paper demonstrates the ingenuity and team-based approach as a unity of effort to combat an unforeseen adversary.

Several practices contributed to the successful stemming of the pandemic outbreak on the compound. The first was the direct interaction of the medical leadership with the command team. Throughout the viral outbreak, the medical leadership held daily communication touch points with the chain of command on the base. The second was the availability of very competent medical personnel who were capable of providing lifesaving treatment. Lastly, the pandemic unified all units together to fight against further spread of the virus. All military, civilian personnel, and leadership were focused on the same mission to defeat the virus. All personnel living on the base remained in full compliance with quarantine, isolation, and health protection measures. This joint effort of the command and medical leadership stopped the viral outbreak and has become the uniting force against an invisible enemy.

In the most current events regarding COVID-19 risk mitigation strategies, several FDA and FDA emergency use authorization (EUA) products were developed to include highly effective vaccines.[16] As the immunization campaign evolved, continued COVID-19 outbreaks plagued even the most developed countries such as the US (Figure 3) while re-opening strategies remained a high priority. One comprehensive ecological study with 190 countries concluded combinations of more types of NPIs (especially distancing) was significantly associated with a decrease in the effective reproduction number (Rt) of COVID-19 transmissibility.[17] Upon reflection, current and future pandemic response planning may include a two-pronged approach: an offense (vaccines) and a defense (NPIs).

Conclusion

The COVID-19 pandemic directly manifested into a paradigm shift within Force Health Protection as the unforeseen enemy became a military and medical objective for both strategic and operational leaders alike. Synchronization of command priorities was essential in the operations process. During the initial phase of the deployment, the main effort was on combat operations in the deployed theater.

As the global COVID-19 outbreak crossed over into the operational realm, the main effort shifted to defeating the virus in order to protect the force. Very rapidly, COVID-19 became the unforeseen enemy and the decisive operation was to prevent and/or mitigate an outbreak. Quick implementation of NPI and risk mitigation strategies are key to a successful pandemic response.

To that end, the command allocated the weight of its resources substantively in favor of the medical team and medical mission priorities. The impact of command support was substantial, in that the resources and capabilities of a division headquarters were brought to bear on this effort. Shaping operations to defeat the outbreak included the implementation of aggressive quarantine measures to support the main effort of outbreak mitigation and control. Decisive operations took on a combat footing becoming heavily focused on suppressing viral spread among the fighting force. Creating a common operating picture developed by medical and operational experts with common lines of effort and objectives supported a successful campaign against the virus here in a Role I MTF on Eskan Village. This coordinated effort represented an enduring example for the future war against a faceless adversary such as COVID-19.

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Nursing Opportunities and Challenges Related to COVID-19 UAMTF Deployments

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Introduction

Military medicine is immersed in an operational tempo (OPTEMPO), which is unprecedented in modern times. The emergence of the novel corona virus disease 2019 (COVID-19) quickly spread into a global pandemic and has stressed healthcare's infantryman—the frontline healthcare workers—to a potential breaking point. Registered nurses (RNs), doctors, respiratory therapists, medics, and others are experiencing multiple, open ended, short notice deployments, which have not only stressed their clinical skillset, but also their support systems. Understanding the background on OPTEMPO as well as the opportunities and challenges of the COVID-19 response will help leaders plan for future operations.

Background

While the first case of COVID-19 was confirmed in Wuhan, China in December 2019, the first US case wasn't reported until nearly a month later.[1] This rapidly spreading respiratory illness challenged healthcare providers and systems because of its wide range or lack of symptom presentation. Despite the implementation of a variety of evidence-based control measures such as facemasks, physical distancing of at least 6 feet, and handwashing, the virus continued to spread throughout the country and the world.

Healthcare analysts turned to different models, such as University of Pennsylvania's COVID Hospital Impact Model for Epidemics (CHIME), to help anticipate patient surges, bed utilization, and personal protective equipment needs during the pandemic. Despite the public availability of these models and the witnessing of the overcrowding of European hospitals, the US struggled to respond as seriously ill COVID-19 patients overwhelmed US hospitals, beginning in March 2020 in New York. The first wave of US COVID-19 cases peaked in April 2020, with a 7-day case rate of 66 per 100,000.[2] The second wave's peak was more than double the previous case rate with July 2020 showing a 7-day case rate of nearly 142 per 100,00.[2] The most recent and drastic wave occurred between October 2020 and February 2021, with a peak case rate of 525 per 100,000 in early January 2021. In mid-February 2021, the US began seeing a downward trend in the third wave of COVID-19 cases, but at the time hospitals continued to feel the impact as the rates of new hospital admissions of COVID-19 patients remained high.[3] Department of Defense (DoD) assets have been critical to providing support to those areas most affected.

The use of federal troops on domestic soil is a hotly contested issue. However, DoD troops and active duty personnel have been used for law enforcement functions as far back as the early 1800s to put down border incursions with Mexico. Most recently, President George H. W. Bush used marines and soldiers to help restore order in the wake of the 1989 Los Angeles, CA, riots.[4] Far less contentious is the use of DoD personnel to save lives and provide humanitarian assistance. For example, in the aftermath of Hurricane Katrina in 2005, the 14th Combat Support Hospital (CSH) deployed to New Orleans, LA, setting up a hospital at the airport.[5] They were relieved by the 21st CSH a month later, after they had moved to a convention center. One of the lessons learned from Hurricane Katrina was the need to work through state and federal agencies to allow medical professionals reciprocity for state licenses, which has vastly improved over the past 17 years.

During the current COVID-19 crisis, the need for clinical support to civilian facilities has waxed and waned with geographically dispersed surges in patients and has varied in the type of support needed. Initially, one

of the high visibility missions during the COVID-19 response involved the deployment of the 531st Hospital Center (HC), 9th HC, and other units to New York City. These units established the high profile New York Javits Medical Station (NYJMS), setting a high bar by working with local, state, and federal agencies in converting a convention center to a hospital with more than a 1,000 beds.[6] Simultaneously, the units deployed liaison officers (LNOs) to local hospitals in New York City and in Federal Emergency Management Agency (FEMA) Area 1, from Philadelphia to Boston, to facilitate patient transfers and provide oversight for military healthcare workers from all branches of service assigned to those healthcare facilities. In the end, NYJMS treated 1,094 patients.[7]

More recently, a deployment to North Dakota in late 2020, utilized primarily US Air Force (USAF) medical staff to supplement a healthcare facility. Similarly, a deployment in December 2020, sent a combined US Forces Command (FORSCOM) and US Medical Command (MEDCOM) team of over 3 dozen RNs and respiratory therapists to Wisconsin to staff several COVID-19 medical and intensive care units, including units at a level 2 trauma center. Clearly, while the core of each mission is to alleviate suffering and support a whole-of-America approach to stemming the COVID-19 virus, each mission has varied in composition and duration. However, lessons learned from each have provided foundational building blocks to improve the next rotation.

Opportunities: Significant opportunities exist when mobilized for Urban Augmentee Medical Task Force (UAMTF) support. Only 67% of 66S (Army critical care RNs) are stationed at Army medical centers (MEDCENs) (email communication with US Army Human Resources Command, Army Nurse Corps branch, March 1, 2021). The remaining third are working in clinical facilities or positions and may have difficulty meeting designated Individual Critical Task Lists (ICTLs). While Madigan, Landstuhl, and Eisenhower are technically medical centers, they may not have the volume of critical care patients to effectively keep RNs current on their skills, similar to the challenges of 66S stationed at Army community hospitals (ACH).

Blanchfield ACH at Fort Campbell, KY, is home to the 101st Airborne Division (Air Assault), 5th Special Forces Group, and the 160th Special Operations Air Regiment. The generally young and healthy population stationed here does not afford the assigned 66S the opportunity to stay current on critical care skills. Deployment of 66Ss from Blanchfield—whether Modified Table of Organization and Equipment (MTOE) Assigned Personnel (MAP) assigned to the 531st HC with duty at Blanchfield or MEDCOM organic assets assigned to Blanchfield—introduced the potential to remain current on low-volume critical ICTLs when opportunities are lacking at their current facility.

For example, in calendar year 2020 during the height of the COVID pandemic, the Blanchfield Intensive Care Unit (ICU) had a total of 2 ventilator occurrences. By comparison, during the 531st HC's deployment to a 500-bed medical center in Wisconsin, caring for ventilated patients was a common occurrence. An ad hoc survey of the 10 military ICU RNs, deployed to the aforementioned level 2 trauma center, indicated they cared for ventilated patients 11 times and titrated vasoactive medications approximately 360 times over the course of 4 weeks. While a rigorous scientific study was not conducted, the feedback from these RNs clearly indicated the acuity faced by nurses on UAMTFs outpaced what is available in most Army community hospitals.

The UAMTF model also allows the Army's medical-surgical RNs (66H) opportunities to maintain currency in their ICTLs. Of the 6 MEDCOM RNs placed in a small Wisconsin 40-bed hospital, 2 junior officers served clinical nurse officers-in-charge of ambulatory care or surgical clinics, 1 served as chief of hospital education, and another worked on a postpartum floor as part of their current military assignments. The remaining 2 worked on the medical surgical floor at their home station. The patients' conditions at the Wisconsin community hospital were often complex. Some of the RNs required refresher training on tasks such as bi-level positive airway pressure (BiPAP) usage, heparin intravenous therapy, and nursing time management skills. The RNs who more recently spent time at the bedside were more familiar with the ICTLs and the tasks required to care for the COVID-19 patients.

One benefit for caring for the COVID-19 patients in the civilian community hospital was the nurses' ability to care for patients with a longer length of stay. As the Army pivots from counterinsurgency operations to large scale combat operations (LSCO) against a near peer adversary, the need to provide extended care will become far more critical. The medical-surgical nurse will have to manage patients with chest tubes, watch for signs of deep vein thrombosis and stroke, maintain nasogastric tubes and feedings, and monitor the patient's skin integrity for signs of breakdown. The experience in Wisconsin allowed the nurses and respiratory therapists to obtain "sets and reps" in those low volume, but highly essential tasks to support LSCO medical care.

Another benefit of the Wisconsin experience is it assembled MAP personnel from a variety of facilities

and backgrounds. Nurses who joined the UAMTF from Brooke Army Medical Center, the military's only level 1 trauma center, worked side-by-side with ICU nurses from Walter Reed, the flagship of military medicine. At many of the augmented facilities in Wisconsin, several of the nurses staffing the units were transient travel nurses, traveling between civilian facilities in support of COVID-19 care. Military RNs, who worked at less critical readiness platforms such as the ACHs, had access to those military RNs working in the most acute settings for reference and mentorship. This provided a safety net and bonded military nurses to each other, despite limited exposure to each other prior to the deployment.

The UAMTF also presented opportunities for the Baylor Masters in Healthcare Administration (MHA) trained nurses, often used in the role of a nurse methods analyst (NMA) in military treatment facilities (MTFs). The Baylor MHA affords medical professionals the opportunity to obtain their graduate degree over 2 years, with 1 year of didactic classroom and a year internship. Nurses matriculating from the program are often used in clinical analysis and leadership roles, with many obtaining board certification as a nurse executive or, in subsequent years, as a Fellow in the American College of Healthcare Executives (FACHE).

While the Army Medical Department has long struggled to codify the benefit of the "Baylor Nurse", it was abundantly clear what value they brought to the table in Wisconsin. Serving as LNOs, Baylor nurses seamlessly integrated into a variety of daily clinical and administrative leadership meetings with their civilian C-Suite partners. Possessing the skillset and credentials that go along with a board certified nurse executive or FACHE helped establish instant credibility with our civilian peers.

The LNOs also helped to identify patient safety issues and engaged with their civilian counterparts, sharing military healthcare systems (MHS) best practices and solution sets to better protect patients. Further, as articulation of nursing workload became a driving factor for termination of support, LNOs identified faulty processes, which led to the reporting of inflated nursing workload. Identification of this gap allowed a more transparent conversation with other governmental agencies, providing clear data that a 2- or 4-week extension was not warranted. This freed critical healthcare providers to return to their home duty stations and prepare for the next COVID-19 support mission location or the next mission of COVID-19 vaccination, if called.

As eluded to earlier, cross collaboration with civilian partners allowed military staff exposure to other practices they would not experience in their MTFs. Civilian healthcare facilities that survive on profit margin experience a variety of challenges from which military facilities are insulated. Practices military RNs may be inexperienced or uncomfortable with, such as mixing pressor medications or insulin drips due to a lack of a pharmacist in the civilian facility after hours, may be common for civilian nursing staff. This was an opportunity for military RNs to partner with and learn from organic civilian staff, as well as move to work at the top of their scope of practice.

Challenges: One prominent challenge identified was how nursing workload in a civilian hospital was measured. The Army uses 2 separate systems to measure workload. These systems currently require double entry with charting in the electronic health record (EHR) and the online workload management system, but the outcome provides leadership with workload and expected staffing requirements. The emerging MHS EHR and the associated inpatient module provide a patient acuity module that measures nursing hours per patient. However, this acuity module is propriety in nature, and the MHS has yet to be able to objectively validate its accuracy. The hospital system the military RNs supplemented in Wisconsin did not measure patient acuity. While they had a similar EHR, they had not purchased the supplemental acuity model to measure safe patient workload. Many times, workload was measured by reporting the number of patients assigned to the military RNs, and this led to second and third order effects.

The military augmentees of 531st HC arrived in Wisconsin just as the COVID-19 peak began to abate. Less than a week after arrival, the COVID-19 patient census at the large tertiary hospital was in the low 40s. Four weeks later, it was less than half with only 3 patients remaining in the COVID-19 ICU. Just short of midway through deployment, concerns about reporting were identified. While military RNs continued to work 48 hours per week, the organic civilian staff were being reassigned from the COVID-19 unit to other areas of the hospital for shifts or being called off. When this briefly occurred upon arrival, it was viewed with benevolence and seen as military personnel giving organic civilian nursing personnel respite to alleviate the long hours they had been working. However, as this practice continued, it resulted in artificially inflating the military RN to patient ratio, and whether or not actual, took the appearance of cost savings measure to help the civilian facility with their profit margin. Anecdotally, a similar occurrence was reported from a Texas UAMTF mission.

For example, if there were 12 COVID-19 patients on a unit with 3 military RNs and 3 organic civilian nurses

assigned, the ratio would be 1 nurse to 2 patients or 1:2. If all 3 organic civilian nurses were down staffed (with or without pay) or floated, the military RN to patient ratio was raised to 1:4, making the military RNs appear needed based off of reporting metrics. The reporting tool allowed for free text in an executive summary area, but did not incorporate hard metrics to show the decreased workload. This area is ripe for a nurse methods analyst to assist and facilitate improvement.

Interviews revealed military clinical integration for the Wisconsin mission went well, with minor opportunities for improvement. Many of those who had participated in the NYJMS experience expressed the Wisconsin experience was better, especially the pre-arrival portion. Military personnel sent forward a mini-credentialing packet, including professional licenses, basic life support card, other credentials and certificates, as well as driver's license photos. The latter allowed the civilian medical facility to expedite staff identification cards. Further, a lesson learned included the establishment of an electronic online meeting platform between the host facility and supplemental military personnel in order to preposition these packets and facilitate information exchange. This process is currently being utilized in the Vaccine Augmentation Medical Task Force operations as well.

Of the 65 UAMTF personnel deployed in support of missions to Wisconsin, Texas, and California, 75% of these personnel were nurses (M. Hart, 531st HC operations officer, email communication, March 17, 2021). However, nurses were underrepresented in clinical oversight and leadership positions in these operations. The intricacies of measuring nursing workload and efficiencies are critical to understanding how to make best use of limited military assets. The workload management provided by nursing experts on a daily basis across MTFs is not incorporated in the UAMTF structure or hierarchy which can lead to decisions based on inaccurate information.

Conclusion

The Wisconsin experience highlights opportunities for nurses serving primarily in administrative roles to refresh their skills and demonstrate ICTLs in earnest. Further, it allows nurses at smaller MTFs the opportunity to increase their comfort level with higher acuity patients. The UAMTF missions will continue to provide a mutually beneficial relationship for both military and civilian healthcare partners. It provides a venue for exposure to a greater range of critical patients, all while helping support a whole-of-nation approach to curtailing the devastating effects of COVID-19. Including a nurse methods analyst (NMA) will ensure the correct metrics are captured and provide better fidelity to US government partners. This will ensure supported agencies, such as FEMA, have accurate, timely, quantifiable, and reliable information when considering extensions of critically limited assets. Lessons learned from these and other experiences will help military leadership anticipate issues and improve the experiences for all involved.

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- **Potential Topics of Interest:** Manuscripts within the scope of this special topic include those addressing a range of subjects associated with veterinary medicine including but not limited to original research, analysis, treatment, organization, response, preparation, education, clinical/medical research, readiness, dentistry, historical reviews, etc. Papers may address virtually any important aspect related to veterinary medicine, to include discovery, prevention, ethics, policy, training, etc. Submissions should be original, unpublished, fully developed, focused, scholarly, and clearly presented.

- **Submission & Peer-Review Process:** Submissions must be vetted and peer-reviewed by authors' own organizations prior to submitting. Authors' internal vetting and peer-review should focus on content, merit, and accuracy. Authors must also have OPSEC/PAO approval for publication. Manuscripts within scope and quality standards will be considered for publication. Manuscripts out of scope for this special topic, but within the general scope for the journal, may be considered for general topic publication at another time. Submissions should adhere to manuscript guidelines, to include American Medical Association (AMA) style format. For more about the journal, submission requirements, and archives please visit https://medcoe.army.mil/the-medical-journal.

- **Point of Contact:** Please direct any questions regarding the special call for papers or regular submissions to usarmy.jbsa.medical-coe.list.amedd-journal@army.mil

- **Submission Deadline**: August 31, 2022.

The Medical Journal, *a quarterly, peer-reviewed, professional periodical with worldwide distribution, provides a forum for the presentation and exchange of current, high level healthcare, clinical, and medical research information, as well as medically related combat experiences and military doctrine development ideas and proposals. The journal encourages dialogue on important healthcare initiatives, seeks to expand knowledge of domestic and international military medical issues and technological advances, conveys clinical and health service support information, enhances the working relationships among the various medical corps and specialties, and promotes collaborative partnerships among the armed services.*

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