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9	In re:) Lead Case No.: 2:18-bk-20151-ER)
10	VERITY HEALTH SYSTEM OF CALIFORNIA, INC. <i>et al.</i> ,	 Jointly Administered With: Case No.: 2:18-bk-20162-ER; Case No.: 2:18-bk-20163-ER;
11) Case No.: 2:18-bk-20164-ER;
12	Debtor(s).) Case No.: 2:18-bk-20165-ER;) Case No.: 2:18-bk-20167-ER;
	□ Affects All Debtors) Case No.: 2:18-bk-20168-ER;) Case No.: 2:18-bk-20169-ER;
13	Affects Verity Health System of) Case No.: 2:18-bk-20171-ER;
14	California, Inc. ☑ Affects O'Connor Hospital) Case No.: 2:18-bk-20172-ER;) Case No.: 2:18-bk-20173-ER;
15	☑ Affects Saint Louise Regional Hospital) Case No.: 2:18-bk-20175-ER;
	 ☑ Affects St. Francis Medical Center ☑ Affects St. Vincent Medical Center) Case No.: 2:18-bk-20176-ER;) Case No.: 2:18-bk-20178-ER;
16	Affects Seton Medical Center) Case No.: 2:18-bk-20179-ER;
17	 Affects O'Connor Hospital Foundation Affects Saint Louise Regional Hospital Foundation) Case No.: 2:18-bk-20180-ER;) Case No.: 2:18-bk-20181-ER
18	☐ Affects St. Francis Medical Center of) Chapter 11 Cases
19	Lynwood Foundation ☐ Affects St. Vincent Foundation ⊠ Affects St. Vincent Dialysis Center, Inc.) · · · · · · · · · · · · · · · · · · ·
20 21	☐ Affects Seton Medical Center Foundation	ARTICLES IN SUPPORT OF TENTH REPORT BY PATIENT CARE
22	□ Affects Verity Business Services ⊠ Affects Verity Medical Foundation) OMBUDSMAN, JACOB NATHAN) RUBIN, MD, FACC, PURSUANT TO 11
23	□ Affects Verity Holdings, LLC □ Affects De Paul Ventures, LLC) U.S.C. § 333(b)(2)
23 24	Affects De Paul Ventures – San Jose Dialysis, LLC) NO HEARING REQUIRED
25	Debtors and Debtors In Possession)
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1	Jacob Nathan Rubin, MD, FAAC, the Patient Care Ombudsman ("PCO") appointed under							
2	11 U.S.C. § 333 in the above-referenced chapter 11 bankruptcy cases of the affected debtors and							
3	debtors in possession (collectively, " <u>Debtors</u> "), hereby provides copies of literature and articles in							
4	support of his tenth report (" <u>Report</u> ") to the Court pursuant to 11 U.S.C. § 333(b) regarding the							
5	quality of patient care provided to patients of the affected Debtors.							
6	Submitted by:							
7	LEVENE, NEALE, BENDER, YOO & BRILL L.L.P.							
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9	By: <u>/s/ Ron Bender</u> RON BENDER							
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Exhibit 1

REVIEW

Airborne or Droplet Precautions for Health Workers Treating Coronavirus Disease 2019?

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Infectious Diseases Society of America

Cases of coronavirus disease 2019 (COVID-19) have been reported in more than 200 countries. Thousands of health workers have been infected, and outbreaks have occurred in hospitals, aged care facilities, and prisons. The World Health Organization (WHO) has issued guidelines for contact and droplet precautions for healthcare workers caring for suspected COVID-19 patients, whereas the US Centers for Disease Control and Prevention (CDC) has initially recommended airborne precautions. The 1- to 2-meter (\approx 3–6 feet) rule of spatial separation is central to droplet precautions and assumes that large droplets do not travel further than 2 meters (\approx 6 feet). We aimed to review the evidence for horizontal distance traveled by droplets and the guidelines issued by the WHO, CDC, and European Centre for Disease Prevention and Control on respiratory protection for COVID-19. We found that the evidence base for current guidelines is sparse, and the available data do not support the 1- to 2-meter (\approx 3–6 feet), in some cases up to 8 meters (\approx 26 feet). Several studies of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) support aerosol transmission, and 1 study documented virus at a distance of 4 meters (\approx 13 feet) from the patient. Moreover, evidence suggests that infections cannot neatly be separated into the dichotomy of droplet versus airborne transmission routes. Available studies also show that SARS-CoV-2 can be detected in the air, and remain viable 3 hours after aerosolization. The weight of combined evidence supports airborne precautions for the occupational health and safety of health workers treating patients with COVID-19.

Keywords. airborne transmission; COVID-19; droplet precautions; mask; respiratory protection.

The epidemic of coronavirus disease 2019 (COVID-19) was reported to the World Health Organization (WHO) on December 31, 2019 [1], with the number of confirmed cases remaining approximately 40–60 until January 20, 2020, when a surge of cases occurred, possibly associated with increased domestic and international travel in China for the Lunar New Year celebration. On January 30, 2020, the number of cases surged to surpass the severe acute respiratory syndrome (SARS) epidemic, with cases spreading to over 28 other countries, mostly through travel from China [2]. On March 11, 2020, with more than 118 000 cases spread across 114 countries and 4291 deaths, it was recognized as a pandemic by the WHO [1].

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Coronaviruses (CoVs) are respiratory pathogens, and the SARS-CoV-2 has been identified in both upper and lower respiratory tract samples from patients [3]. Fever, dry cough, malaise, lethargy, shortness of breath, and myalgia are the most common symptoms [2]. Less common symptoms are headache, productive cough, and diarrhea. Mild cases may present with a common cold-like syndrome, whereas severe cases may develop severe acute respiratory distress syndrome and pneumonia. According to the WHO, 21% of cases in China have a severe illness [2]. Early estimates of the reproduction number, R_o, give values of approximately 2.2 with a mean incubation period of 5.2 days [4] and a range of up to 24 days. In a recent review, researchers found the average R_o value for COVID-19 to be up to 3.28 and a median value to be approximately 2.79 [5]. In a more recent study, researchers estimated the maximum-likelihood value of R_0 to be 2.28 for the Diamond Princess cruise ship [6]. All of these estimates are similar to R_0 estimates for SARS [7].

In the past epidemics of SARS and Middle East respiratory syndrome (MERS) coronavirus, healthcare workers (HCWs) have paid a heavy toll. During SARS, HCWs comprised 21% of all cases and in some countries, such as Hong Kong, Singapore, and Canada, more than half of the cases were HCWs, with deaths reported among them [8]. Healthcare worker deaths have already been reported with COVID-19.

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The WHO has issued guidelines for protection of HCWs that recommend contact and droplet precautions for HCWs caring for suspected COVID-19 patients [9]. Specifically, a medical mask is recommended for routine care, whereas a respirator (airborne precautions) is recommended if HCWs are conducting an aerosol-generating procedure such as endotracheal intubation, bronchoscopy or airway suctioning, along with droplet precautions [9]. Droplet precautions include the recommendation to maintain spatial separation of 1 meter (≈3 feet) with an infected patient, in the belief that large droplets can only spread horizontally to a maximum of 1 meter (≈3 feet) [10]. The initial guidelines released by the US Centers for Disease Control and Prevention (CDC) recommended a more precautionary approach, which includes the use of a mask by the patient (source control [11]) and airborne precautions for HCWs [12].

We aimed to review the evidence supporting the rule of 1-meter (\approx 3 feet) spatial separation for droplet precautions in the context of guidelines issued by the WHO, CDC, and European Centre for Disease Prevention and Control (ECDC) for HCWs on respiratory protection for COVID-19.

METHODS

A systematic review was conducted for evidence of horizontal distance traveled by respiratory droplets, using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria [13]. We used an open date strategy up to March 2020 for searching the literature. The search was made on PubMed and Scopus database, and the search terms used for literature search are as follows: (cough OR sneeze AND droplet AND spread) OR (cough OR sneeze AND droplet AND distance).

There are few studies on horizontal spread of droplets in medical journals, so we included original research studies from various science and engineering disciplines, including mathematical, numerical, and experimental studies, published in English language journals. We searched the Scopus database with the same keywords and date strategy for studies published in nonmedical journals. Editorials and reviews were excluded from the review.

Initial screening of articles was done by 1 reviewer (P.B.). For initial screening, the title and abstract of all the articles were reviewed. Articles were excluded if there is no information on droplet spread. All the articles that were potentially relevant after initial screening were procured in full text. Articles were included for the final review only if it specifically measured the horizontal distance of droplet spread. References of the papers were also included for screening if they fit the inclusion criteria. Four reviewers with expertise in fluid dynamics (P.B., C.D., C.d.S., and L.B.) reviewed the selected articles.

For the review, we focused on the following 4 variables among the studies included: (1) type of study, ie, experimental or modeling; (2) methodology used for modeling; (3) use of human subjects for data; and (4) data on extent of horizontal spread. Separate to review of original research evidence for horizontal spread of droplets, the guidelines for respiratory protection issued by the WHO, CDC, and ECDC for SARS, MERS, and COVID-19 coronaviruses were reviewed.

RESULTS

We found 393 papers in the initial search. After reviewing the titles and abstracts, 28 papers were selected for full text review. Finally, 10 papers were included in the review (Figure 1).

Eight of the 10 studies discussed a horizontal trajectory greater than 2 meters (≈ 6 feet) for a range of droplet sizes of less than 60 µm [14-21]. Seven of 10 studies are based on modeling, and among them the extent of horizontal spread of droplets vary between 2 and 8 meters (\approx 6–26 feet) [14–20], highlighting the different findings between them, which can be partially attributed to the methodologies used. Specifically, 4 of these studies rely on computational fluid dynamics approaches that do not accurately account for the multiphase particle-flow interaction physics [14, 15, 18, 20], and 3 of them model cough as a turbulent jet (continuous ejection with conservation of momentum flux) instead of a turbulent puff (short sudden ejection with conservation of momentum) [15, 18, 20]. The fourth study used Lagrangian modeling for the droplet dispersion, and it was acknowledged that this approach assigns a larger momentum to air hence, making it difficult to translate the results into relevant settings for hospital infection control [14].

Two studies used analogous water tank experiments to validate the mathematical modeling developed and reported distances up to 1.4 meters (\approx 4.5 feet) and 2.5 meters (\approx 8.2 feet) [17, 22]. One of these 2 studies modeled coughs as turbulent jets

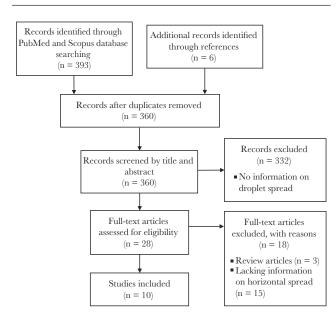


Figure 1. Flow diagram of literature search.

(continuous emission) [22] despite published contrary evidence showing that the physics of violent exhalations is captured by puffs, sudden high momentum emission of moist and hot air [17].

In 5 studies, experiments were performed on human subjects [14, 17, 19, 21, 23], 4 of them generated undisturbed/natural sneezes and coughs, without injestion of fluid or powders by the human subjects [17, 19, 21, 23]. Of 5 studies, 2 used the human subject measurements to develop and validate the mathematical modeling of the droplet dispersal and showed the importance of the exhaled gas cloud of hot and moist air in trapping and extending the range of all droplets [17, 19]. One involved injection of powder in the mouth of the human subject potentially shifting the natural droplet sizes ejected [14]. The other

Summary of Studies on Horizontal Spread of Dronlets

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2 used still photographs [23] and particle counters [21], and the distance reported among these 2 vary from 1 to 3 meters (\approx 3–10 feet). Table 1 summarizes all the findings, and Figure 2 shows the horizontal distance of droplet spread reported by all the studies.

Table 2 summarizes the respiratory protection guidelines by the WHO, CDC, and ECDC for SARS, MERS CoV, and COVID-19. Guidelines differentiate between high-risk and lowrisk situations. High-risk is categorized as situations involving an aerosol-generating procedure, ie, endotracheal intubation, bronchoscopy, open suctioning, administration of nebulized treatment, manual ventilation before intubation, turning the patient to the prone position, disconnecting the patient from the ventilator, noninvasive positive-pressure ventilation,

Author (Year)	Type of Study	Type of Experiments	Type of Modeling	Use of Human Subjects (Number of Subjects)	Main Findings Regarding Horizontal Distance
Jennison (1942)	Experimental	High-speed illumination for still photography	NA	Yes (not specified)	Majority of respiratory droplets, generated during sneezing, coughing, and talking, are expelled within 1 m (≈3 ft), the size of the filed of observation.
Zhu et al (2006)	Experimental and Modeling	Particle image velocimetry	Modeling coughing, at a maxim during each cough, af		More than 6.7 mg of saliva was expelled during coughing, at a maximum velocity of 22 m/s during each cough, affecting even area more than 2 m (≈6.5 ft) away from source.
Xie et al (2007)	Modeling	NA	Numerical Modeling	No	Expelled large droplets (>60 μ m) can travel more than 6 m (\approx 20 ft) for sneezing with an exhalatio velocity of 50 m/s and more than 2 m (\approx 6.5 ft) for coughing at an exhalation velocity of 10 m/s
Parienta et al (2011)	Modeling	NA	Mathematical Modeling	No	With a coughing velocity of 11.7 m/s droplets with a diameter of 16 μm can travel a distance more than 7 m (~23 ft).
Bourouiba et al (2014)	Experimental and Modeling	High-speed videography of human subject exhalations; Water tank physical experi- ments for model validation	Mathematical Modeling	Yes (not specified)	Droplets expelled during sneezing and coughing travel within a turbulent gas cloud and example of ranges, such as that of particle with 30-µm diameter, which can have a horizontal range of 2.5 m (≈8 ft).
Wei and Li (2015)	Modeling	NA	Numerical Modeling	No	Relative humidity (RH) plays an important role in the evaporation of the droplets and the distance a droplet can travel. At a RH of 80% and expira- tion velocity of 10 m/s, 95% of medium droplet (50 μm) were able to travel 4 m (≈13 ft).
Bourouiba (2016)	Experimental and Modeling	High-speed imaging	Mathematical Modeling	Yes (not specified)	The smaller and evaporating droplets are trapped the turbulent cloud, remain suspended, and car travel up to 6 to 8 m (≈20–26 ft). Based on mod eling validated in Bourouiba et al [17].
Wei and Li (2017)	Experimental and Modeling	Water tank experiments	Mathematical Modeling	No	Scaling relationships were used to scale the result of experiments in water with that of air. With mouth opening of 2 cm, large particles (96 μm) can travel a distance up to 1.4 m (≈4.5 ft).
Liu et al (2017)	Modeling	NA	Numerical Modeling	No	At 0% RH, 60- μ m droplets would dry out and become droplet nuclei with a diameter of 19 μ r and could fall out of the jet to reach a distance more than 4 m (~13 ft).
Lee et al (2019)	Experimental	Optical particle spectrometer	NA	Yes (10)	Particle sizer and optical particle spectrometer were used to measure cough particle concen- tration of 10 patients with cold symptoms in real time. Results showed that transmission ca spread more than 3 m (≈10 ft) from the patient.

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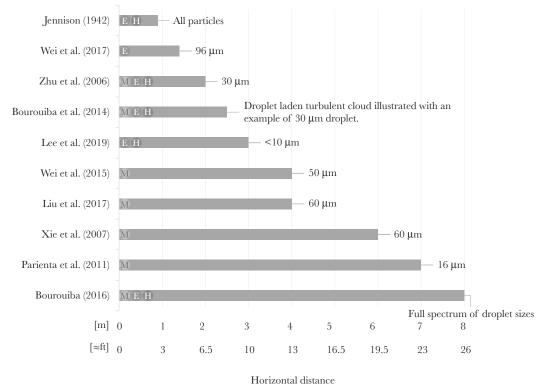


Figure 2. Extent of horizontal spread of droplets. Note that direct visualization of 8 meters also appears in [35]. E, experimental studies; H, human subjects; M, modeling (mathematical or numerical) studies.

tracheostomy, and cardiopulmonary resuscitation. All other situations are considered low risk. The WHO and CDC recommend respirators to protect from SARS in both low- and highrisk situations [24, 25]. For MERS, WHO recommends masks in low-risk situations and respirators in high-risk situations, CDC recommends respirators in both situations, and ECDC recommends a preassessment of workplace to decide between mask and respirator in low-risk situations and respirators for high-risk situations [26-28]. For COVID-19, the WHO recommends masks in low-risk situations and respirators in high-risk situations. The CDC and ECDC initially recommended respirators in both situations, but after personal protective equipment shortages, the CDC downgraded to use of masks in low-risk situations and the ECDC recommended use of mask in case of nonavailability of respirators [29-31]. The interim guidelines for COVID-19 appear to assume only droplet and contact spread, and the general risk limit defined for HCWs is 1 meter (\approx 3 feet) from the patient [10, 31].

DISCUSSION

The transmission of COVID-19 is not well characterized, but it is likely to be similar to SARS, which was spread by contact, droplet, and airborne routes [32]. Given the presence of SARS-CoV-2 viral loads in both the lower and upper respiratory tract [3], as well as the persistence of the virus in the air 3 hours after aerosolization in laboratory settings [33], airborne transmission is possible. A recent study showed that seasonal CoVs were more commonly emitted in aerosols than in droplets, even through normal tidal breathing [34]. It is timely to review the evidence informing the 1- to 2-meter (\approx 3–6 feet) rule of infection control, which drives guidelines for droplet precautions. Most studies of horizontal transmission of droplets show distances of greater than 2 meters (\approx 6 feet). The maximum distance recorded in the few available studies is 8 meters (\approx 26 feet) [19, 35]. We note that although the studies used very different methodologies and should be interpreted cautiously, they still confirm that the spatial separation limit of 1 meter (\approx 3 feet) prescribed for droplet precautions, and associated recommendations for staff at ports of entry [10], are not based on current scientific evidence.

The horizontal distance of droplet spread depends on various factors such as viscoelasticity of the expiration fluid, type of ventilation, velocity of expiration, rate of evaporation, and the dynamics of turbulent cloud generated during exhalations, sneezing, or coughing [15, 17–19]. The 1- to 2-meter (\approx 3–6 feet) limit is based on very limited epidemiologic and simulated studies of some selected infections [36]. Some studies cite Jennison [23] as the evidence in support of the 1- to 2-meter (\approx 3–6 feet) risk limit. This study used high-speed exposure to capture still photographs of the atomizing secretions generated

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	WHO		CDC		ECDC	
Pathogen	Low Risk	High Risk ^a	Low Risk	High Risk	Low Risk	High Risk
Severe acute respiratory syndrome coronavirus (SARS-CoV)	Respirator ^b	Respirator	Respirator	Respirator	-	-
Middle East respiratory syndrome coronavirus (MERS-CoV)	Mask	Respirator	Respirator	Respirator	Mask/Respirator ^c	Respirator
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	Mask	Respirator	Mask	Respirator	Mask/Respirator ^d	Respirator

Abbreviations: CDC, Centers for Disease Control and Prevention; ECDC, European Centre for Disease Control and Prevention; WHO, World Health Organization.

^aHigh risk are the situations involving an aerosol-generating procedure, ie, endotracheal intubation, bronchoscopy, open suctioning, administration of nebulized treatment, manual ventilation before intubation, turning the patient to the prone position, disconnecting the patient from the ventilator, noninvasive positive-pressure ventilation, tracheostomy, and cardiopulmonary resuscitation.

^bN/R/P 95/99/100 or FFP 2/3 or an equivalent national manufacturing standard (NIOSH [N, R, P 95, 99, 100] or European CE EN149:2001 [FFP2, FFP3] and EN143:2000 [P2] or comparable). ^cNo clear recommendation. Choice is based on the type of exposure risk defined after preassessment of workplace.

^dHealthcare workers in contact with a suspected or confirmed coronavirus disease 2019 (COVID-19) case should wear a surgical mask or, if available, an FFP2 respirator tested for fitting.

by human sneezing, coughing, and talking, imaged very close to the mouth. It was concluded that the distance to which the majority of droplets were expelled is 2–3 feet (\approx 1 meter), but no details were provided about how they reached this conclusion. The study acknowledges that the motion picture film used for the experiments was not sensitive enough to capture all the droplets. The lighting technique used inherently selects for the largest sizes of droplets and fluid ligaments, not capturing the rest of the emissions and gas cloud carrying them. The author used still photographs, in which many droplets move out of focus and become unrecordable very quickly, especially using photographic technology from the 1940s. More recent studies have shown the extent of droplet spread to be greater than 2 meters (\approx 6 feet) [16–21, 35], and that infection risk exists well beyond the recommended range of spatial separation.

Furthermore, there is no agreement on the definition of "droplet" route of transmission. There is some agreement that particles with diameters less than 5 μm are airborne particles, but there is significant variation in the literature when it comes to the classification of the lower size limit of droplets. Wells [37] considered 100 μ m as the cutoff limit for the droplet route. However, later studies considered a cutoff particle diameter of more than 10 μ m to more than 100 μ m [14, 15, 20]. The WHO uses a cutoff limit of 5 μ m to differentiate between aerosols ($\leq 5 \mu m$) and droplet (>5 μm) [38] transmission routes. However, even particles with a diameter of more than 10 μ m can remain airborne long enough to not fall under the framework of classification of "droplet" route [39]. In addition, the size of a droplet is dynamic and changes within seconds during the transit from the respiratory tract to the environment due to evaporation [39]. A large droplet expelled during coughing or sneezing can become an airborne particle in less than 1 second [39], and that timescale changes depending on the cloud dynamics of exhalation [17, 19]. Hence, it is not possible to characterize droplet and airborne spread as separate, mutually exclusive modes of transmission, and further studies of the risks accounting for combined ambient conditions and patient exhaled cloud are needed.

Indeed, another important consideration is the effect of temperature, relative humidity, ventilation, etc on the extent of droplet spread, which has been examined by only a few studies. To summarize, they have shown that relative humidity plays an important role in the evaporation of the droplets and the distance a droplet can travel. They report that as the relative humidity increases, the extent of droplet spread decreases [18, 20], yet the horizontal range of the cloud propelling the drops was found to increase with an increase in relative humidity, due to the role of buoyancy of the exhaled cloud [17]. For droplets less than 20 µm in diameter, local airflow field due to body heat is an important factor in determining the extent of spread because it can lift the droplets upwards into the breathing zone [40]. Studies have also shown that depending on the flow direction and airflow pattern, increasing ventilation rate can effectively reduce the risk of long-range, airborne transmission [41]. Most patients spend the majority of time in normal breathing and can saturate the room air with airborne particles expelled during breathing. Moreover, despite negative pressure isolation conditions, airflow due to door motion can cause breakdown in isolation conditions and as a result pathogen can escape the room, and there is a probability of infection spread outside the room [42]. In general, recent studies show distances reached by potentially pathogen-laden droplets of a continuum of sizes to be far greater than 2 meters (≈ 6 feet) [16–20]; therefore, the probability of infection well beyond the defined risk limit can be significant. For example, SARS was classified as predominantly transmitted through contact and droplet modes, but aerosolized transmission well beyond 2 meters (≈6 feet) was reported in the Amoy Gardens outbreak [32].

The ability of countries to respond effectively depends on the safety and confidence of the health workforce, especially in low-income countries with low ratios of HCWs per head of population, and protective measures are crucial to ensure a functional health workforce. We have previously shown that masks do not have clinical efficacy against respiratory infections [43, 44], and that intermittent use of respirators (which depends on HCWs to assess their own risk and use the device

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when they judge they are at risk) is as equally ineffective as mask use [44]. A recent trial confirmed there is no difference between targeted respirator use and surgical mask use, but it did not have a control arm and so it may have shown equal efficacy or inefficacy [45]. Proven efficacy of a respirator is seen when the device is worn continually during the shift [43]. The SARS-CoV-2 has been found in both upper and lower respiratory tract specimens, often early in the upper and later in the lower respiratory tract [3], which means it can potentially be dispersed in fine, airborne particles. Influenza studies show that in a busy emergency department or hospital ward, airborne particles with viable virus can persist for hours in the air [46]. A study of SARS-CoV-2 in a hospital in Wuhan found virus at least 4 meters (\approx 13 feet) within a hospital ward, and virus was identified in air samples and on multiple air outlet vents [47]. Other studies have also found SARS-CoV-2 on air vents in a patient room [48]. Another study found virus to be viable in air samples 3 hours after aerosolization in laboratory settings [33]. We have also shown that airborne precautions are more efficacious in protecting HCWs even against infections assumed to be spread by the droplet route [49]. This further supports the conclusion that transmission cannot be neatly separated into droplet versus airborne routes, and that it is likely driven by both airborne, and large droplets, carried by the respiratory gas cloud. In light of the lack of definitive transmission data for SARS-CoV-2, as well as persistence of the virus in the air 3 hours after aerosolization in laboratory settings [33], the precautionary principle in the initial CDC guidance was justified. This includes use of a mask by the patient, for which the limited evidence is supportive [11]. Guidelines should be precautionary in ensuring protection of the occupational health and safety of health workers treating COVID-19 [50]. Although the majority of the studies reviewed point towards horizontal spread of more than 2 meters (≈ 6 feet), these results cannot be translated directly to hospital settings, because the studies used a varying range of assumptions. The recent data on SARS-CoV-2 in a hospital ward shows a distance traveled by the virus of at least 4 meters (\approx 13 feet), double the assumed safe distance [47].

CONCLUSIONS

This review reveals the limited scientific data to inform spatial separation guidelines and a growing body of evidence that droplet precautions are not appropriate for SARS-CoV-2. Hence, future work on carefully documenting and studying the mechanisms shaping transmission distances are warranted, particularly with experiments over a large number of subjects and a variety of conditions, to update current spatial separation guidelines and the current paradigm of droplet and airborne respiratory transmission routes.

Notes

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Potential conflicts of interest. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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Exhibit 2

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Innovations in Care Delivery

ARTICLE

At the Epicenter of the Covid-19 Pandemic and Humanitarian Crises in Italy: Changing Perspectives on Preparation and Mitigation

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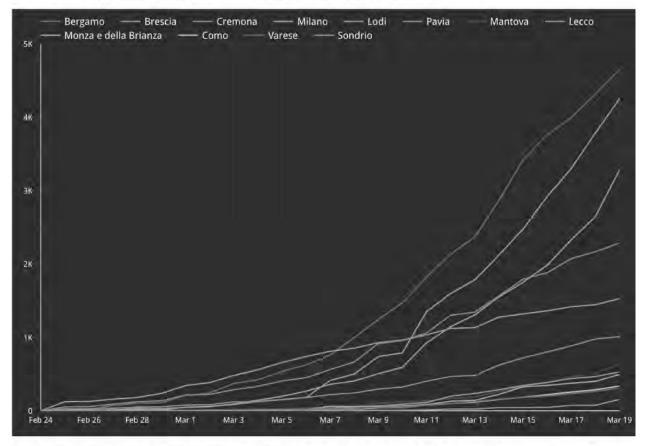
In a pandemic, patient-centered care is inadequate and must be replaced by communitycentered care. Solutions for Covid-19 are required for the entire population, not only for hospitals. The catastrophe unfolding in wealthy Lombardy could happen anywhere. Clinicians at a hospital at the epicenter call for a long-term plan for the next pandemic.

We work at the Papa Giovanni XXIII Hospital in Bergamo, a brand-new state-of-the-art facility with 48 intensive-care beds. Despite being a relatively small city, this is the epicenter of the Italian epidemic, listing 4,305 cases at this moment — more than Milan or anywhere else in the country (Figure 1). Lombardy is one of the richest and most densely populated regions in Europe and is now the most severely affected one. The World Health Organization (WHO) reported 74,346 laboratory-confirmed cases in Europe on March 18 - 35,713 of them in Italy.

FIGURE 1

Laboratory-Confirmed Cases of Covid-19 in the 12 Provinces of the Lombardy Region Since February 24, 2020.

Data from the Italian Ministry of Health, Civil Protection Department.



Source: https://datastudio.google.com/u/0/reporting/91350339-2c97-49b5-92b8-965996530f00/page/RdIHB NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

Our own hospital is highly contaminated, and we are far beyond the tipping point: 300 beds out of 900 are occupied by Covid-19 patients. Fully 70% of ICU beds in our hospital are reserved for critically ill Covid-19 patients with a reasonable chance to survive. The situation here is dismal as we operate well below our normal standard of care. Wait times for an intensive care bed are hours long. Older patients are not being resuscitated and die alone without appropriate palliative care, while the family is notified over the phone, often by a well-intentioned, exhausted, and emotionally depleted physician with no prior contact.

But the situation in the surrounding area is even worse. Most hospitals are overcrowded, nearing collapse while medications, mechanical ventilators, oxygen, and personal protective equipment are not available. Patients lay on floor mattresses. The health care system struggles to deliver regular services — even pregnancy care and child delivery — while cemeteries are overwhelmed, which

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will create another public health problem. In hospitals, health care workers and ancillary staff are alone, trying to keep the system operational. Outside the hospitals, communities are neglected, vaccination programs are on standby, and the situation in prisons is becoming explosive with no social distancing. We have been in quarantine since March 10. Unfortunately, the outside world seems unaware that in Bergamo, this outbreak is out of control.

Western health care systems have been built around the concept of *patient-centered care*, but an epidemic requires a change of perspective toward a concept of *community-centered care*. What we are painfully learning is that we need experts in public health and epidemics, yet this has not been the focus of decision makers at the national, regional, and hospital levels. We lack expertise on epidemic conditions, guiding us to adopt special measures to reduce epidemiologically negative behaviors.

For example, we are learning that hospitals might be the main Covid-19 carriers, as they are rapidly populated by infected patients, facilitating transmission to uninfected patients. Patients are transported by our regional system,1 which also contributes to spreading the disease as its ambulances and personnel rapidly become vectors. Health workers are asymptomatic carriers or sick without surveillance; some might die, including young people, which increases the stress of those on the front line.

This disaster could be averted only by massive deployment of outreach services. *Pandemic solutions are required for the entire population*, not only for hospitals. Home care and mobile clinics avoid unnecessary movements and release pressure from hospitals.2 Early oxygen therapy, pulse oximeters, and nutrition can be delivered to the homes of mildly ill and convalescent patients, setting up a broad surveillance system with adequate isolation and leveraging innovative telemedicine instruments. This approach would limit hospitalization to a focused target of disease severity, thereby decreasing contagion, protecting patients and health care workers, and minimizing consumption of protective equipment. In hospitals, protection of medical personnel should be prioritized. No compromise should be made on protocols; equipment must be available. Measures to prevent infection must be implemented massively, in all locations and including vehicles. We need dedicated Covid-19 hospital pavilions and operators, separated from virus-free areas.

This outbreak is more than an intensive care phenomenon, rather it is a public health and humanitarian crisis. It requires social scientists, epidemiologists, experts in logistics, psychologists, and social workers. We urgently need humanitarian agencies who recognize the importance of local engagement. WHO has declared deep concern about the spread and severity of the pandemic and about the alarming levels of inaction. However, bold measures are needed to slow down the infection. Lockdown is paramount: social distancing reduced transmission by about 60% in China. But a further peak will likely occur when restrictive measures are relaxed to avoid major economic impact.4 We strongly need a shared point of reference to understand and fight this outbreak.*We need a long-term plan for the next pandemic.*

Coronavirus is the Ebola of the rich and requires a coordinated transnational effort. It is not particularly lethal, but it is very contagious. The more medicalized and centralized the society,

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the more widespread the virus. This catastrophe unfolding in wealthy Lombardy could happen anywhere.

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Exhibit 3

Brazil Health Care System preparation against COVID-19

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ABSTRACT

Background: The coronavirus disease outbreak from 2019 (COVID-19) is associated with a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a highly contagious virus that claimed thousands of lives around the world and disrupted the health system in many countries. The assessment of emergency capacity in every country is a necessary part of the COVID-19 response efforts. Thus, it is extremely recommended to evaluate the health care system to prepare the country to tackle COVID-19 challenges. Methods and Findings: A retrospective and ecological study was performed with data retrieved from the public national healthcare database (DATASUS). Numbers of intensive care unit and infirmary beds, general or intensivists physicians, nurses, nursing technicians, and ventilators from each Regional Health Unity were extracted, and the beds per health professionals and ventilators per population rates were assessed. The accessibility to health services was also performed using a spatial overlay approach to verify regions that lack assistance. It was found that Brazil lacks equity, integrity, and may struggle to assist with high complexity for the COVID-19 patients in many regions of the country. **Conclusions:** Brazil's health system is insufficient to tackle the COVID-19 in some regions of the country where the coronavirus may be responsible for high rates of morbidity and mortality.

Keywords: Coronavirus; epidemiology; critical care; hospitalization; pandemic.

INTRODUCTION

The coronavirus disease 2019 (COVID-19) is associated with the novel severe acute respiratory syndrome coronavirus-2 (SARS-Cov-2) identified in December 2019 (1). As of May 9, 2020, COVID-19 has globally infected 4,018,342 people resulting in 278,756 deaths (2)[report 104]. The WHO declared COVID-19 a public health emergency of international concern (PHEIC) by the end of January 2020 under the International Health Regulations (IHR) (3). Few weeks after the PHEIC declaration, the COVID-19 outbreak was declared to be a pandemic, drawing attention worldwide (4).

The pandemic led to the adoption of several non-pharmacological interventions ranging from social distancing guidelines to national-level lockdowns by different countries (5). These stringent interventions have severely impacted the way of living of many people and disrupted the already precarious health system in many countries (6). In response to the COVID-19 pandemic, several countries undertook analyses for the necessary health system strengthening efforts. According to studies dedicated to characterizing the clinical evolution of the disease, 39% of the cases demand emergency care, with a subset of 5% needing ICU and 2.9 % demanding ventilator support to sustain life (33). In the U.S., the percentage of patients needing ventilator support was even higher, reaching up to 12,2%.

The response effort to tackle the COVID-19 requires a strong organization of the emergency network (7). The lack of beds, iniquities in the distribution of hospitals, and inadequate availability of ventilators could hamper the actions aiming to decrease the negative consequences of the COVID-19 (8). Unfortunately, usually, the distribution of the health resources within the countries are characterized by inequities (9). Due to the COVID-19 consequences, the scenario faced by low and medium-income countries is even more staggering (8). The historic challenges regarding an insufficient number of health professionals, iniquities in the distribution of human resources (10), low accessibility to emergency care services (11), and economic issues create additional pressures to be addressed, aiming is to achieve an adequate COVID-19 response.

As the COVID-19 spreads around the world, the hospital systems lack measures against the virus (12), and many countries are experiencing shortages of hospital supplies (13). For example, as of March 11, in Italy, where there were 12,462 cases of COVID-19 and 827 deaths, 1,028 of 5,200 beds in intensive care units (ICU) are occupied. A few days later, there were no more ICU beds available (14). In the United States of America, it is estimated that the disease will stress bed capacity, equipment, and health care personnel, as never seen before (15). The Brazilian case is not an exception (11). In order to reduce the burden of COVID-19, the hospital administrators, governments, policy-makers, and researchers must be prepared for a surge in the Healthcare System (16).

Brazil is characterized by severe social disparities and health inequities. On May 9 155,939 cases were confirmed and 10,627 deaths (17) (https://covid.saude.gov.br/). However, this number is under-reported, and the real number is estimated to be nine times greater,

according to some simulations (18). To further the concern, The Imperial College estimates that up to 1 million people will fall ill due to COVID-19 in Brazil (19).

During the last decade, Brazil is struggling to increase the funding of the public unified system (SUS). Despite the efforts performed in 2016, the Constitution Amendment 95 (E.C. 95 acronym in Portuguese) reduced the budget of the Ministry of Health by almost seven billion reais by year (20). Before the EC95, the Brazilian Health System was already underfunded (21). Two years after the EC95, the consequences regarding the lack of funding were aggravated by the COVID-19 pandemic. Additionally, Brazil is also facing a political crisis contributing to divergences between the administrative levels in the country.

The consequences of all these elements combined could hamper the response actions to tackle the COVID-19. The availability of information during a crisis is essential to support the decision-making process based on evidence. Taking this point into consideration the present work addresses critical aspects regarding the organization of the emergency network system in Brazil, jointly with the spatial expansion of COVID-19 cases within the country, and to highlight where the efforts currently performed in Brazil were capable of coping with the lack of access to emergency care needed to cope COVID-19 consequences.

METHODS

Study design and local

The present paper is an ecological, observational, and cross-sectional study using a spatial analysis approach. The data sources are based on secondary data from the Unified Health System (SUS) (22). To fulfill the defined objective, the adequacy parameters in terms of human resources, health care structure, and accessibility to emergency care services were analyzed in comparison with the reported incidence of COVID-19.

According to data from the Brazilian Institute of Geography and Statistics (IBGE), Brazil is located in South America with a territorial area of 8.510.820,623 km² and has a total of 210,147,125 inhabitants, with Human Development Index (HDI) of 0.51 with diversified values for the municipalities ranging from 0.41 to 0.86 (figure 1) (23). For the assessment of methodological quality, we followed the Guideline Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).

Data sources

To characterize the Brazilian emergency care services network, three sources were used: National Register of Health Facilities (CNES acronym in Portuguese), population data from the IBGE, and COVID-19 cases reported by Secretariat of Surveillance of the Ministry of Health (https://covid.saude.gov.br/).

Data regarding hospitals, professionals (nurses, nursing technicians, doctors, and physiotherapists), and equipment (ventilators, ICU, and infirmary beds) were obtained from

the CNES website using R through the microdatasus package (24). The population data and thematic maps were fetched from the IBGE (23).

The match between the number of health professionals and the recommended suitability parameters were compared using the guidelines from the National Health Surveillance Agency (ANVISA) Resolution of the Collegiate Board of Directors (RDC). The ANVISA RDC number 7 provides the minimum requirements for the operation of Intensive Care Units, in which ten ICU beds are required for each one intensive care physician and one physiotherapist, one intensive care nurse for every eight beds, and two nursing assistants for each bed (25)

The building of thematic maps was carried out by grouping the municipalities by Health Regions Unity (H.R.) using software QGIS 3.0. The (H.R.) is a continuous geographic space constituted by a group of bordering municipalities delimited by cultural, economic, and social identities, created by the Ministry of Health in order to mitigate the disparities in the country (26).

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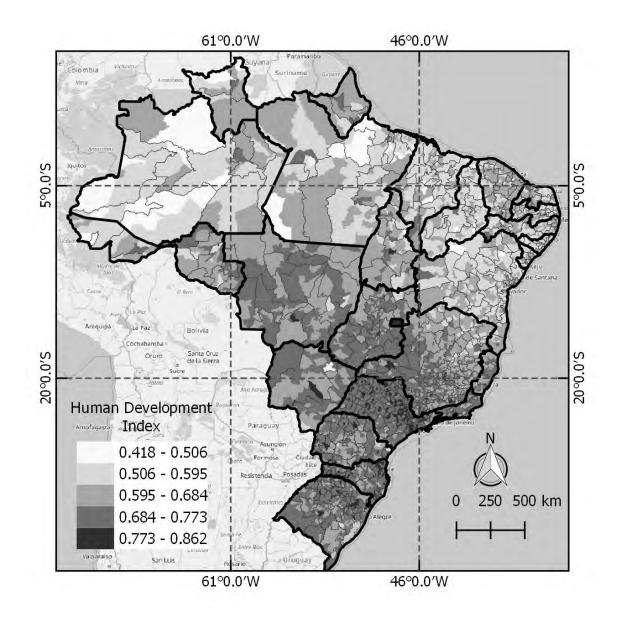


Figure 1. Location of Brazil and the distribution of human development index.

Spatial distribution of COVID-19 cases and the lack of emergency care

To identify regions with a high incidence of COVID-19, simultaneously presenting a lack of emergency network was used as a spatial overlay approach. The first step comprised the development of an emergency infrastructure index (EII). The EII was obtained computing the number of beds registered, by the ratio of professionals and equipment according to the last competence of February 2020 from CNES.

To evaluate the geographical accessibility to emergency care service care was used the two-step floating catchment area (2SFCA) technique. With this approach, it was possible to assess the accessibility to emergency care services by the interaction of two geographic characteristics: (a) the volume of available hospital beds weighted by population within 2 hours of travel distance, and (b) the proximity of hospitals within a 2 hours displacement from

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each municipality (11). The 2SFCA method generated two accessibility indexes for each municipality in Brazil, one regarding the network available in February 2020, and a secondary one highlighting where the COVID-19 new exclusive beds increased the access to emergency services. Both indexes created the conditions to identify regions with a lack of access to emergency care, as well as the regions being benefited by the expansion of the ICU beds dedicated to the CODVID-19 response. To highlight regions with a high incidence of COVID-19 and a lack of emergency structure, an overlap analysis was conducted to select the municipalities concurrently, showing a pattern of high incidence, jointly with a lack of access to emergency services.

Once the EII was computed, and the municipalities with high incidence within regions with low access to emergency care services care were identified, a Getis-Ord-Gi analysis was performed. Thus, it was possible to point out three spatial clusters: (1) emergency care services accessibility on February 20; (2) municipalities with low access to emergency care services and high COVID-19 incidence, (3) accessibility to ICU beds exclusively dedicated to COVID-19 response in March 2020.

Ethics

Following the Resolution No. 510/16 of the National Health Council and considering that we used secondary sources which are available in governmental and online databases, the dispensation of the consent form was requested to the Ethics Committee.

RESULTS

COVID-19 has shown a fast growth rate in Brazil. The total number of confirmed deaths in the country initially increased at a similar pace as Germany and Iran. However, differently than these countries, it has not yet shown a decrease in its growth rate (Figure 1A). Subnationally, the growth rate of confirmed deaths shows an unequal pattern. Likely due to different state-level isolation policies, the states of São Paulo, Rio de Janeiro, Ceará, and Amazonas have shown a much faster growth rate than the rest of the country (Figure 1B). Nonetheless, the country as a whole seems to be still far from its peak number of new deaths by COVID-19.

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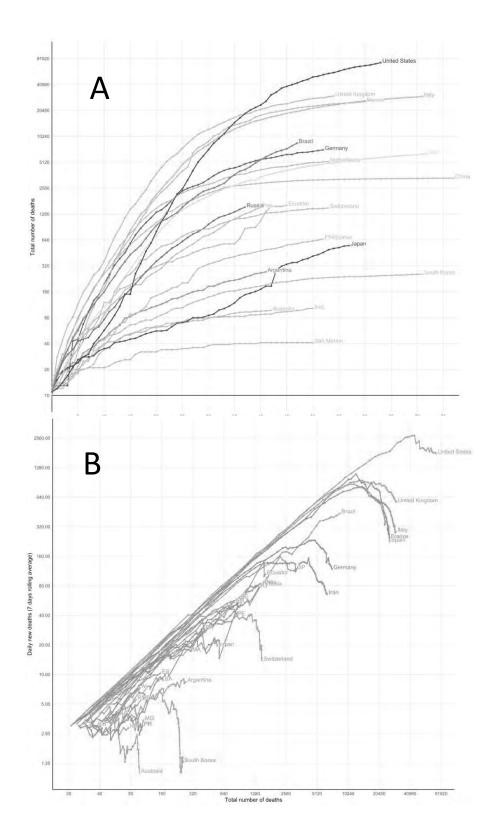


Figure 1. A. The total number of deaths in selected countries by days since 10th death. **B.** Total number of confirmed deaths and daily new deaths by COVID-19 by selected countries and Brazilian states (on 07-May-2020). Source: Data from the European Centre for Disease Prevention and Control (ECDC) and the Brazilian Ministry of Health.

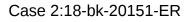
All of 5,570 municipalities are distributed in 5 regions and 438 Health Regions Unity in Brazil. Besides that, Brazil has a total of 35,682 ICU beds, 426,388 hospital beds, 65,411 ventilators, 18,716 intensivists, 564,529 general physicians, 2,768 intensive care nurses, 263,315 nurses, 710,846 nursing technician and 83,040 physiotherapists registered in the CNES database (February 2020). In terms of professionals and beds per 10,000 inhabitants, the southern region had the highest rates for ICU beds, ventilators, physicians, nurses, and technicians. In contrast, the northern region had the lowest ones (Table 1). Figure 2 shows the rates of beds and professionals per Health Regions. The ICU beds per intensivist varied from zero to 53, zero to 156.5 per intensive care nurse, zero to 0.21 per technician, and zero to 2 per physiotherapist. In addition, hospital beds per physician varied from 0.10 to 7.14, 0.52 to 11.26 per nurse, 0.19 to 2.58 per technician, and 1.32 to 31.28 per physiotherapist.

Figure 2 shows the distribution of professionals, beds, and ventilators throughout the territory, and classifies this distribution according to RDC number 7. In A, most H.R. is by the RDC, which determines up to 10 intensivists for each ICU bed. However, 132 HR do not have ICU beds and / or have no intensivist. In B, only 54 H.R. are working according to the recommended amount of 1 critical care nurse for each 8 ICU beds. C and D show that 322 HR are working correctly with the capacity of 1 nursing assistant and one physiotherapist for every 2 and 10 beds, respectively. In the second row of figure 1, F, G, and H show that there are nurses, nursing technicians and physiotherapists working above the limit of 1 nurse per 8 infirmary bed, one nursing technician for each two-infirmary bed and one physiotherapist per 10 infirmary bed.

Region	ICU beds	Infirmary beds	Physicians	Nurses	Technicians	Ventilators
South	1,70	24,33	31,72	13,21	35,46	3,13
Southern	2,11	19,46	34,70	14,14	38,57	3,82
Midwest	2,08	22,64	23,85	9,90	33,17	3,78
Northest	1,19	20,00	17,60	11,62	27,39	2,19
North	0,95	16,47	12,74	8,82	28,87	1,91
Brazil	1,70	20,29	26,86	12,53	33,82	3,11

Table 1. Rates of different types of beds and professionals per population in Brazil.

*According to the IBGE Cidades, it is estimated 210,147,125 inhabitants in Brazil.



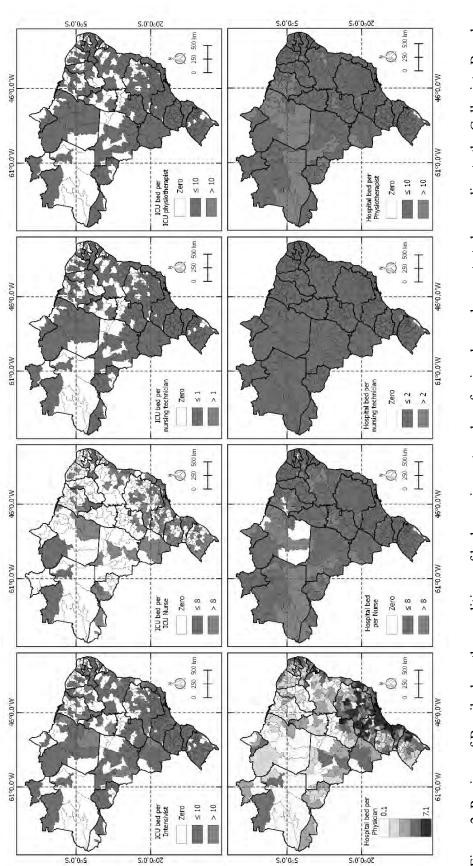


Figure 2. Regions of Brazil where the conditions of beds, equipment, and professionals are demonstrated according to the Collegiate Board Resolution.

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Figure 3 shows the distribution of 60,352 cases of COVID-19 and the location of 433 new adult and pediatric ICU beds on April 27. Most cases and new ICU beds are located in the southeast region, while the north region received few beds in comparison with other regions. Additionally, figure 4 presents the distribution of ICU beds per ventilator and shows that in the north, there are no ventilators available in some H.R.

Panel A in figure 5 depicts the COVID-19 incidence by the Brazilian municipality up to 04/29/2020. It is possible to observe that all states and regions currently are presenting COVID-19 cases with a highlight to the states of Amazonas, Amapá, Espírito Santo, and Santa Catarina, where it is already noted areas with hot colors. The hot colors indicate higher levels of incidence. In terms of deaths, all state capitals of the North, Northeast, and southeast regions are presenting high levels of mortality when compared with the rest of the country.

Figure 6 presents three maps characterizing the Brazilian situation in terms of emergency services and the COVID-19 incidence. Panel A exhibits the accessibility index to ICU beds by population. The map highlights a higher accessibility index close to the state capitals of the Brazilian states. The map B emphasizes the municipalities presenting a COVID-19 incidence higher than the national average of 16.49, simultaneously with an accessibility index lower than the national mean 21 per 100,000 inhabitants Thus, every municipality in the map B is facing challenges in terms of emergency care services and a high COVID-19 incidence for the Brazilian standards. Map C presents the accessibility index of the new beds created exclusively to offer intensive care to COVID-19 patients. Few beds with this specific purpose were open in the states of the North and Midwest region of the country.

Figure 7 shows the result of spatial clustering analysis to identify trends in access, as well as in the COVID-19 incidence. Panel A exhibits a hot spot covering the Southeast, Midwest, and South regions of the country. The states covered by the red layer presents the spatially significant group of municipalities with higher levels of access to ICU beds by population. On the opposite side, the blue layer highlights the regions facing geographical barriers to grant access to ICU beds to the population. To build the map B, the same approach was used, but this time only applied to the municipalities with high COVID-19 incidence and a low index of accessibility to ICU beds. The red color characterized a group of municipalities in the South and Midwest regions. Despite the higher availability of beds in these regions, it was possible to observe a statistically significant group of municipalities within these regions with barriers to access ICU beds. Map C illustrates the cluster of accessibility regarding the ICU beds created to tackle the COVID-19. The lack of overlay between the red color of maps B and C is pointing out a mismatch of the response efforts dedicated to addressing the COVID-19 challenge. The regions in map B characterized as hotspots were considered cold spots regarding the creation of ICU beds dedicated to COVID-19. The result suggests that the use of scarce resources needed to put in order ICU beds are not being directed to municipalities lacking access to emergency care services, despite their high levels of COVID-19 incidence.

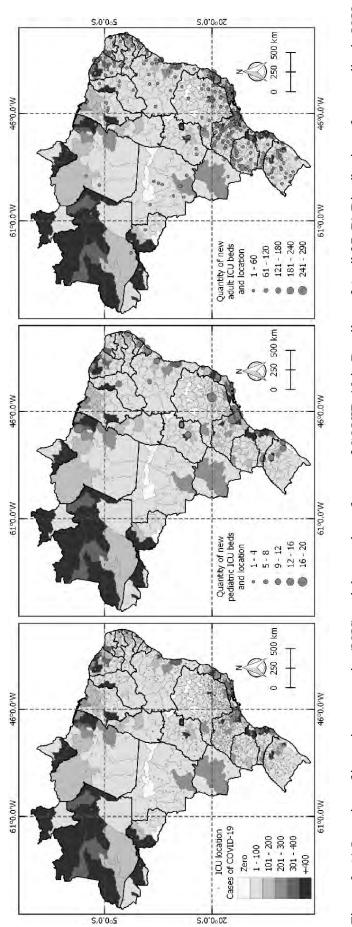
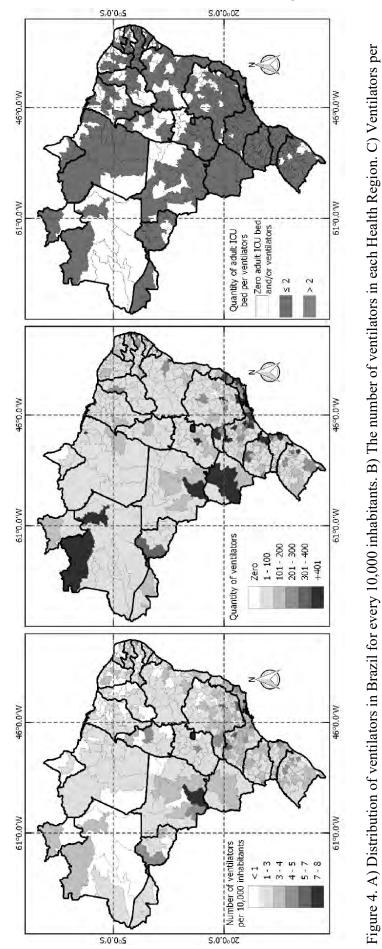


Figure 3. A) Location of intensive care units (ICU) and the number of cases of COVID-19 in Brazil as of April 27. B) Distribution of new pediatric ICU beds. C) Distribution of new adult ICU beds.

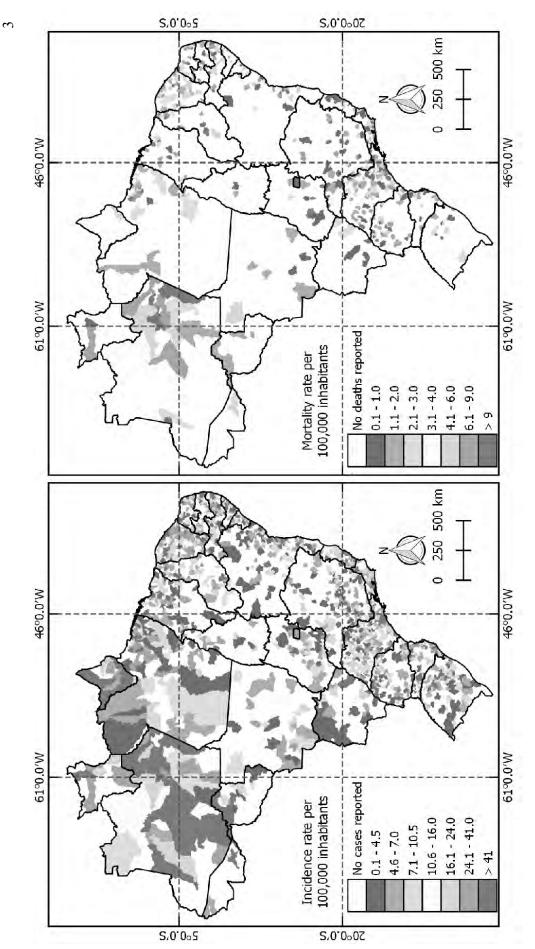
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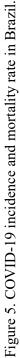
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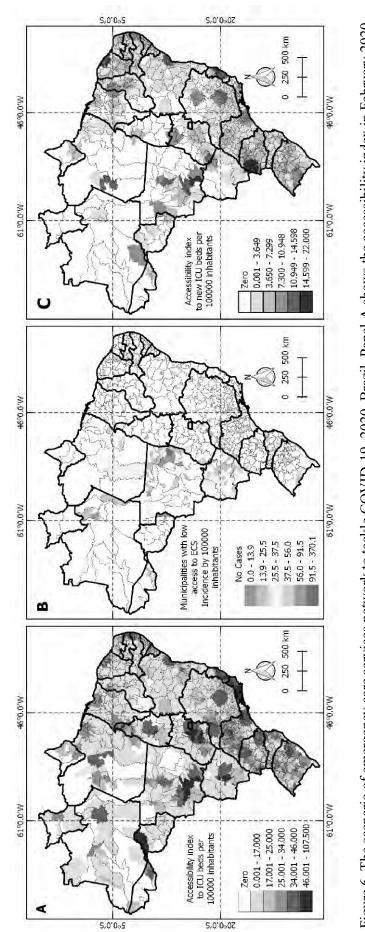
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B presents the high incidence of the disease and the lack of emergency care services. C exhibits the accessibility index of new beds created to tackle the Figure 6. The scenario of emergency care services network to tackle COVID-19, 2020, Brazil. Panel A shows the accessibility index in February 2020. COVID-19. Case 2:18-bk-20151-ER

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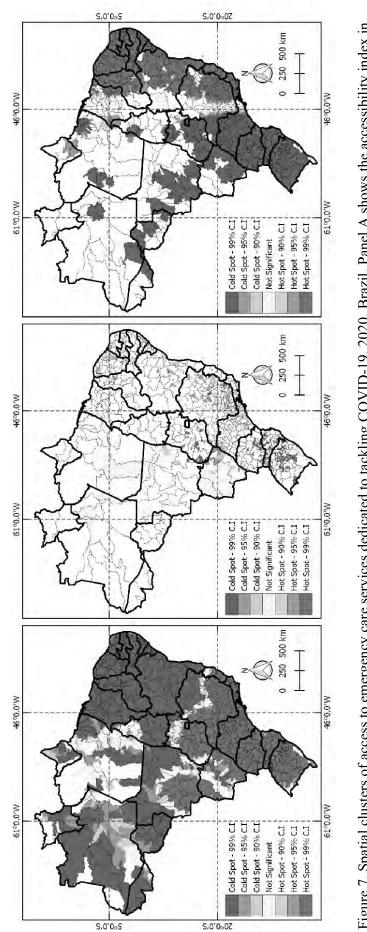


Figure 7. Spatial clusters of access to emergency care services dedicated to tackling COVID-19, 2020, Brazil. Panel A shows the accessibility index in February 2020. B presents the high incidence of the disease and the lack of emergency care services. C exhibits the accessibility index of new beds created to tackle the COVID-19.

DISCUSSION

The ongoing COVID-19 pandemic has caused nearly 4 million confirmed cases and claimed over 278,756 lives worldwide as of May 9, 2020 (2) [report 104]. It is noteworthy to mention that the COVID-19 outbreak is a challenge to the health systems worldwide (27), and although the outcome for the crisis caused by this disease is uncertain, SARS-CoV-2 will overwhelm health care infrastructure for months (28). In this study, the Brazilian health system was evaluated to verify its capacity to tackle the COVID-19 challenge.

According to the WHO, it is recommended one doctor and one nurse per 1,000 inhabitants as a parameter of health care for the population (29). To strengthen the WHO recommendations, the Brazilian Health Governments has established in the Resolution of the Collegiate Board of Directors number 7/2010, the quantities of ICU and infirmary beds per intensivists, general physicians, nurses, nursing technician and physiotherapists (25). Although Table 1 shows that in Brazil, there is a sufficient number of physicians in the country, figure 1 shows that these professionals are not evenly distributed to accomplish the WHO recommendations and CBR. In addition, the number of nurses does not meet the criteria in the north and midwest. To illustrate the problem, figure 1 shows that Brazil has desert zones of ICU assistance and regions where these professionals have to take care of beds far beyond the quantities stipulated by the RDC. Bahtt et al., 2017 verified that professionals in critical care that were caring for more patients per shift were more likely to experience burnout (30). Halpern et al., 2017 informed that intensivists are also in shortage in the United States of America, and this situation may be attributed to burnout (31). Therefore, the combat against the COVID-19 may be a difficult task in these regions, since providing access and affordable care for the large urban populations is already a challenge for many countries (32).

Experience from Lombardia has shown that 9% of patients with COVID-19 were admitted in the ICU treatment, whereas this number varied from 5 to 32% in some cities in China (33). On the other hand, in Brazil, there are no available large data of ICU patients at the moment, and supposing that those numbers might appear in the country as well, only 4 out of 438 Health Regionals could manage this number of patients.

In terms of nursing care in ICU accessibility, figure 1 shows that there are large regions of care voids, probably because there are low amounts of ICU nurses in Brazil (34). Besides that, it's possible to visualize that there are regions where ICU and generalist nurses are responsible for more than eight ICU and infirmary beds, which may represent a risk of unfavorable outcome for the COVID-19 treatment since that high amount of patients per nurse are associated with a range of negative patient outcomes (35, 36).

The pandemic has led to severe shortages of many essential supplies, such as ICU beds and ventilators (37). Based on Italy's numbers that 10 to 25% of hospitalized patients will require ventilation, the Centers for Disease Control and Prevention estimates that in the USA, there will be between 1.4 to 31 patients per ventilator this period (29, 37). Brazil, on the other hand, 2.5 to 3.4 million people will require hospitalization, according to The Imperial

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College of London (19), which represents 4 to 13 patients per ventilator if distributed equally. The numbers may represent a satisfactory amount of equipment. However, figure 1 shows that there are no ventilators in some H.R. that are potential places to have a high number of deaths.

The most staggering result was obtained through the spatial cluster analysis. Brazil is currently facing a double crisis. The political positioning of the president is going against the technical recommendations of the Ministry of Health and WHO. Consequently, there is a disagreement between the Federal administration, and the states and municipalities. On account of that situation, each administrative level is conducting several response actions against COVID-19 without country-level coordination. The spatial clusters analysis highlighted that new beds created to tackle the COVID-19 were misplaced. The hot spot clusters of municipalities with high incidence and lack of access are not overlapping with the hot spot cluster of new beds dedicated to the COVID-19. This situation calls attention for the misplacement of scarce resources during a pandemic. The scenario depicted is the result of a lack of coordination at the national level. The consequence of misplacing the new COVID-19 ICU beds is an increase in the chance of deaths due to a lack of emergency care services for municipalities currently presenting a COVID-19 incidence above the national average.

From now on, Brazil has several difficulties in treating patients in critical care. This paper shows that there is an insufficient number of ICU beds, ventilators, and a huge lack of professionals in healthcare. Additionally, the misplacement of the new beds aiming to fight the COVID-19 pandemic contributes to worsening the situation observed through the other indicators assessed. Developed countries like Italy and the United States demonstrate that COVID-19 can overwhelm the healthcare capacities of well-resourced nations very fast (16, 38). Therefore, the SARS-CoV-2 epidemic in middle-income countries, such as Brazil (39), may be devastating. Our findings suggest that strong leadership is needed to coordinate the response efforts against the COVID-19.

The limitations of this work rely on the complex data available. Health data from health information systems, including health-facility records, surveys, or vital statistics, may not be representative of the entire population of a country and, in some cases, may not even be accurate (40). The CNES database presents some limitations well known by the Brazilian scientific community (41). Despite this, the information regarding the availability of COVID-19 beds was published just a month ago, calling attention to the occurrence of efforts aiming to improve the quality of the data available to policymakers.

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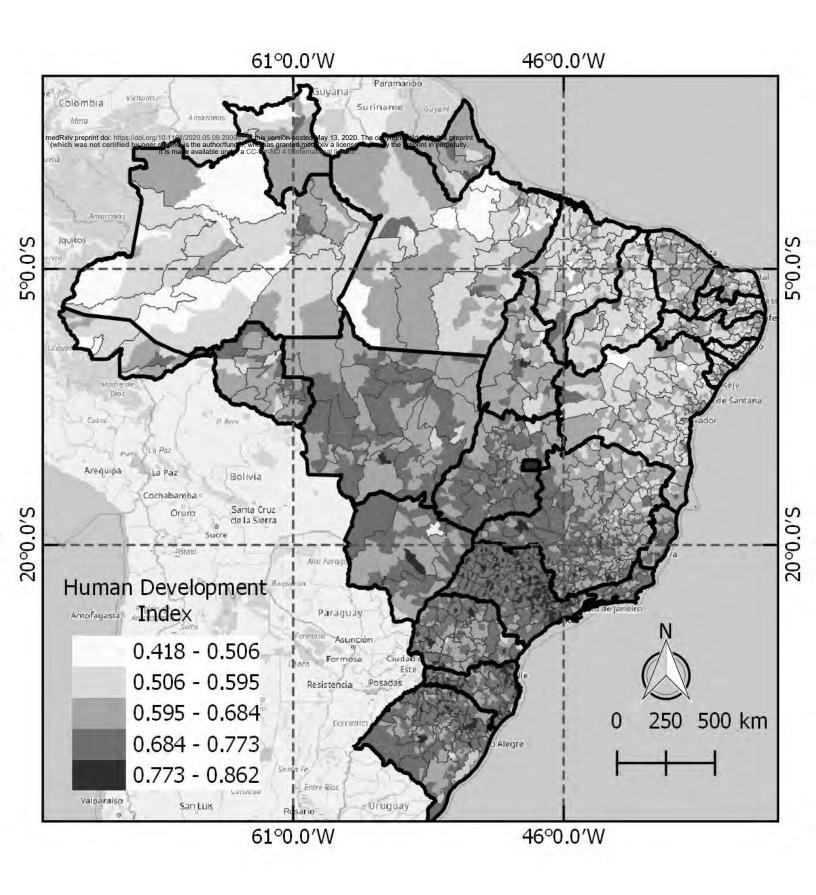
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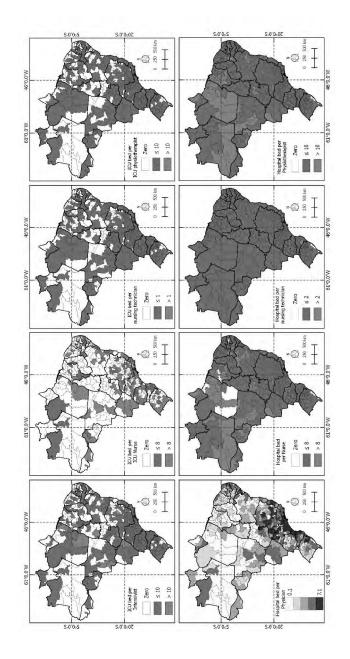
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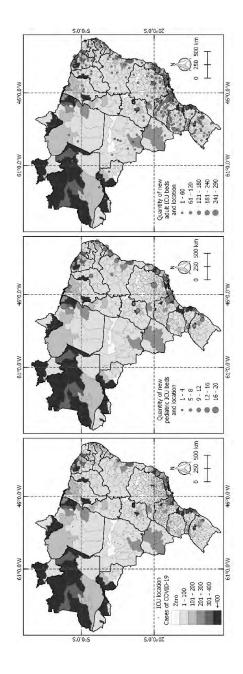
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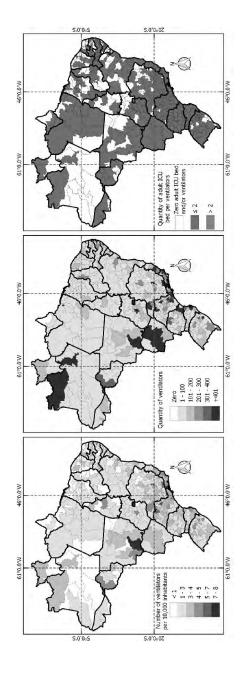
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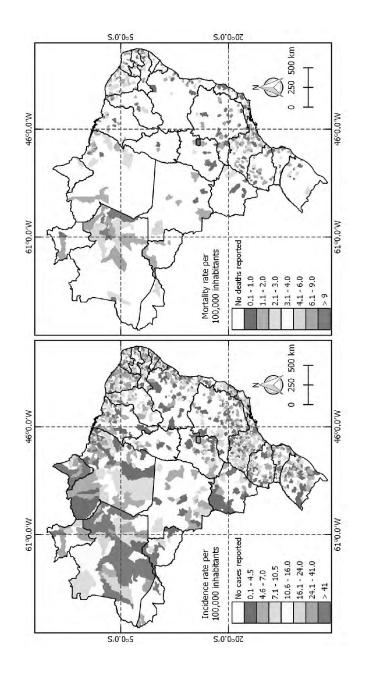
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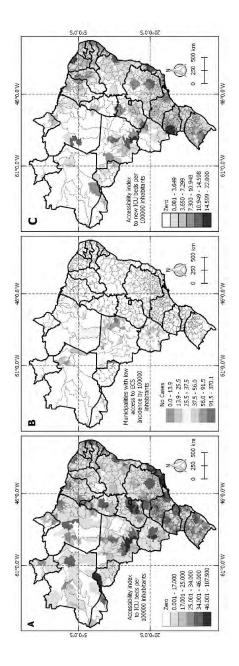


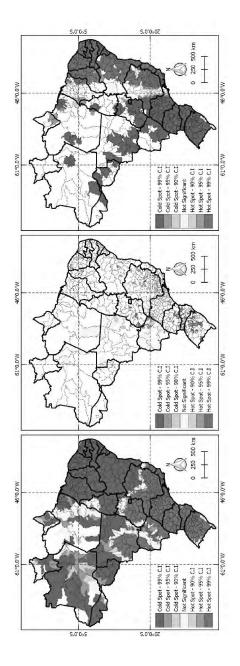












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Exhibit 4

Case 2:18-bk-20151-ER

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Coronavirus outbreak: the role of companies in preparedness and responses

As in previous health crises, the coronavirus disease 2019 (COVID-19) outbreak has raised questions about preparedness and emergency responses in many countries.

In this crisis, what role can companies play? Public and private companies must continue to produce or provide their services, but with consideration of the health context. Many companies are involved with the COVID-19 outbreak because they are established in or work with China (client or supplier), and most have already activated their business continuity planning or equivalent. During an infectious disease outbreak like COVID-19, most large companies around the world have a major part to play, especially in terms of preparedness and emergency response. Indeed, companies should be integrated into the governmental health contingency plan developed in many countries, and by WHO and the International Labor Organization.¹⁻³ Helped by their occupational practitioners, healthcare advisers, and safety professionals, companies that have a financial capacity and responsibilities (including governmental, federal, or state administrations) will thus have to prepare their business continuity planning for when cases of infected patients occur in the company. They also must be prepared for the potential psychosocial and psychological effects of outbreaks. All health professionals should be involved in the development and implementation of recommendations for companies and their environments.4

In practice, based on previous outbreak experiences and governmental contingency plans integrating workplaces as recommended by various organisations,¹⁻³ specific actions should be taken. First, prevention of discrimination of Chinese workers is crucial, as potential fears could arise around possible infectious cases, whether confirmed or not. Second, teleworking should be encouraged and developed. Third, we recommend that companies implement a dedicated response with medical screening, surveillance, and care, including psychological support.⁵ Companies are responsible for provision of optimal prevention to protect the health of their employees during their work. Fourth, regular follow-up of workers can also be done using telemedicine by the occupational health service to reduce in-person contact. Fifth, training and information on the responsibility of each employee in prevention of disease should be provided by health practitioners, such as basic hygiene rules and mask use. Finally, specific support for returning to work should be implemented, including assessment for eligibility for employment injury benefit. These recommendations should be included in occupational risk assessment.

Companies are and will be an important piece of global management of any outbreaks, including COVID-19, through the crucial involvement of their occupational, health, and safety practitioners.

We declare no competing interests. JS and AD contributed equally.

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Exhibit 5

ACP Journals

Letters 2Dune 2020

COVID-19 and the Risk to Health Care Workers: A Case Report

Kangqi Ng, MBBS, Beng Hoong Poon, MBBS, MPH, MMed (Family Med), ... View all authors + Author, Article and Disclosure Information

https://doi.org/10.7326/L20-0175

Background: Little is known about the effectiveness of personal protective equipment for health care workers who take care of patients infected with the novel coronavirus (SARS-CoV-2) that recently originated in China and has spread globally (1, 2).

Objective: To describe the clinical outcome of health care workers who took care of a patient with severe pneumonia before the diagnosis of COVID-19 was known.

Case Report: The patient was a middle-aged man with diabetes mellitus and hyperlipidemia who was hospitalized in February 2020 for community-acquired pneumonia. He had not traveled recently to China nor had had contact with anyone known to have COVID-19. He required supplemental oxygen on admission; the following day, he developed respiratory distress that required endotracheal intubation by the emergency airway team and mechanical ventilation in the intensive care unit (ICU). He was transferred to the ICU for intubation and had a difficult intubation that required use of a video laryngoscope and an airway bougie. He improved clinically after 3

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6/7/2020 Case 2:18-bk-20151c&R-19Dach4849o Hailed 06/09/20 calentered 06/09/20ml5v29:08 Desc Main Document Page 55 of 290 days of mechanical ventilation and was subsequently extubated to noninvasive ventilation.

On the day that the patient was extubated, a nasopharyngeal swab was sent as part of COVID-19 surveillance, and it was positive for SARS-CoV-2 on polymerase chain reaction (PCR) assay (3). Two other swabs obtained on subsequent days tested positive for SARS-CoV-2.

On the basis of contact tracing, 41 health care workers were identified as having exposure to aerosol-generating procedures for at least 10 minutes at a distance of less than 2 meters from the patient. The aerosol-generating procedures included endotracheal intubation, extubation, noninvasive ventilation, and exposure to aerosols in an open circuit (4). All 41 health care workers were placed under home isolation for 2 weeks, with daily monitoring for cough, dyspnea, and myalgia and twice-daily temperature measurements. In addition, they had nasopharyngeal swabs scheduled on the first day of home isolation, which could have been day 1, 2, 4, or 5 after last exposure to patient, and a second swab scheduled on day 14 after their last exposure. The swabs were tested for SARS-CoV-2 by using a PCR assay. None of the exposed health care workers developed symptoms, and all PCR tests were negative (Table).

Table. Number of Nasopharyngeal Swabs in Exposed Health Care Workers, by Type of Procedure, Day After Last Exposure, and Type of Mask*

Table. Number of Nasophar and Type of Mask*	yngear owabs in t	cxposed nearth	Care workers, c	by Type of Proce	oure, Day Aner	Lass Exposure,
Type of AGP (n = 41 HCWs)	PPE	Timing of First Swab From Date of Last Exposure				Timing of Second Swab From Date of Last Exposure
		HCWs With Swab Done on Day 1, n	HCWs With Swab Done on Day 2, n	HCWs With Swab Done on Day 4, n	HCWs With Swab Done on Day 5, n	HCWs With Swab Done on Day 14, n
Endotrichent intubition (a = 10)	Surgical mark	3	a	1	2	4
	N95 mask	1	K.	0	4	8
Extubition (n = 2)	Surgical milds	1	1	Ŭ.	0	2
	N95 mask	0	0	0	0	0
NPV (ICU/HDU) (n = 25)	Surgical mink	20	4	D	0	25
	N95 mask	-0	0	0	0	ů.

https://www.acpjournals.org/doi/full/10.7326/L20-0175?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub=pubmed

Discussion: The primary route for the spread of COVID-19 is thought to be through aerosolized droplets that are expelled during coughing, sneezing, or breathing, but there also are concerns about possible airborne transmission. In the situation we describe, 85% of health care workers were exposed during an aerosol-generating procedure while wearing a surgical mask, and the remainder were wearing N95 masks. That none of the health care workers in this situation acquired infection suggests that surgical masks, hand hygiene, and other standard procedures protected them from being infected. Our observation is consistent with previous studies that have been unable to show that N95 masks were superior to surgical masks for preventing influenza infection in health care workers (5). We emphasize, however, that nearly all experts recommend that health care workers wear an N95 mask or equivalent equipment while performing an aerosol-generating procedure.

We recognize the limitations of this single case report and acknowledge that additional studies are necessary to determine how best to protect health care workers from becoming infected with SARS-CoV while they are providing care for patients with COVID-19.

This article was published at Annals.org on 16 March 2020.

Comments

3/14

Kangqi Ng, Jagadesan Raghuram • Singapore • 29 April 2020

Authors' Response

We thank Vivian et al for for highlighting the multiple factors that influence viral transmission to HCWs. We agree that each AGP has different aerosolization risks (1). As provided in our article, 10 out of 41 HCWs were exposed to patient during intubation, which has been shown to be of high risk in various literature (2). Viral shedding is one of the factors that affect transmission, but it is variable with various viral loads at different timelines in the disease (3). While there are factors that are difficult to determine, our experience highlights the importance of personal protective equipment and hand hygiene in protecting HCWs. We thank Birati et al. and Dai et al for commenting on appropriate personal protective precautions. We also agree that protecting our HCWs is of paramount concern. As previously emphasized, we believe that the combination of surgical masks for all HCWs in all clinical areas in addition to strict hand hygiene and additional PPE requirements for HCWs taking care of suspected patients are of utmost importance. Finally, we would like to emphasize that the virus can be found on multiple surfaces including gown and gloves (3). Therefore, while the spotlight has been on the type of masks, we should never forget the need for good hand hygiene.

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Kangqi Ng, Troy Hai Kiat Puar; Jessica Li Shan Quah; Yu Jun Wong, Thean Yen Tan; Jagadesan Raghuram • Changi General Hospital, Singapore • 24 March 2020

Authors' Response

We thank Karolina et al. for highlighting the need to balance pre-emptive quarantine of asymptomatic exposed health care workers (HCWs) and sustainable healthcare. As reliable data on the risk of asymptomatic transmission of this novel virus was unknown, we elected to quarantine all exposed HCWs until we were certain that they were not infected [1]. Our strategy was disease containment to prevent further spread, as protecting HCWs prevents nosocomial transmission [2]. Such an approach has been

6/7/2020 Case 2:18-bk-20151c&R-19Date 4849.0 Hailed 20/09/20 calentered 406/09/20m15v29:08 Desc Main Document Page 58 of 290 adopted in areas which had "flatten the curve" such as Korea and Taiwan. We acknowledge this approach may strain the existing health care resources. However, it is also paramount to ensure the safety and trust of our HCWs, especially with the mounting pressure from the increased work demand, inadequate resources and stigmatization from the community [3].

To address Lee et al. query, none of the HCWs involved in endotracheal intubation used eye shields. Our recommendation for HCWs during aerosol generating procedures (AGP) for suspected cases, included a powered-air purifying respirator, N95 mask, gloves and a full-body gown. For non-AGPs for suspected cases, eye protection, N95 mask, gloves, and a full-body gown were recommended.

We thank Siu et al. for the comments, and we acknowledge that protecting health care workers (HCWs) with personal protective equipment (PPE) is paramount. It is important that readers were aware that during the exposure to our index patient, Singapore was at Disease Outbreak Response System Condition (DORSCON) alert level yellow [4]. However, without a travel history to China, or contact with COVID-19 patient, our patient did not meet national case definitions for COVID-19 testing. Following admission, enhanced testing for COVID-19 was initiated based on a revised national advisory for surveillance testing, and our patient subsequently found to be positive for COVID-19, 4 days after admission. During the early phase of the COVID-19 pandemic, several measures were set in place throughout Singapore, including ensuring excellent hand hygiene among HCWs, frequent disinfection of common areas, educating HCWs on PPE and restricting non-essential hospital visits for patients. Our hospital enforced standard droplet precautions and mandated the use of surgical masks in all clinical areas, with additional appropriate PPE (as stated above) when caring for suspect COVID-19 patients. We believe these measures collectively protected our HCWs in this exposure [5].

We appreciate Sedgwick et al. for highlighting a trial demonstrating the continuous use of N95 mask to prevent respiratory infections in HCWs. The practical use of PPE during a global pandemic, especially in a resource-limited setting, has been a point of debate. We must emphasize that adequate protection of HCWs should not be a debate on surgical masks or N95 masks alone, but rather a continuous, strict adherence to all protective measures, whenever possible. Finally, we emphasize that all institutions have the responsibility to equip all HCWs, our frontline warrior, with adequate PPE, in fighting this long-haul war against COVID-19.

(476 words)

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Lau CS, TC Aw • Department of Laboratory Medicine, Changi General Hospital • 30 April 2020

The use of protective equipment in intubation of COVID-19 patients

Adequate personal protective equipment (PPE) is a prerequisite for the emergency airway management of respiratory distress (1, 2). We are heartened and reassured that the health care workers (HCWs) in the case report recently described (3) did not contract SARS-CoV-2. In this report 6 HCW performed/assisted in a difficult intubation (including video laryngoscopy and airway bougie) wearing N95 masks and gloves only in February 2020. The patient diagnosed as community acquired pneumonia had no travel history to China. On a quick extubation 3 days later by 2 HCW wearing surgical masks the PCR test for SARS-CoV-2 was positive. All these 8 staff and 33 others in the unit were isolated for 14 days and tested negative for SARS-Cov-2 on two occasions. In another recent report (4) describing a simulation study using manikins in the emergency department, fluorescent markers demonstrated that aerosols can still contaminate exposed areas (skin and hair) and shoes of attending HCWs despite the use of recommended PPE measures (eye protection, N95 respirator, gloves and gown). They suggested that prevailing PPE recommendations (CDC, WHO) may not be fully adequate. We are aware of another instance in USA where the use of basic PPE resulted in no COVID-19 transmission to HCW (5). A woman returned from Wuhan in mid-January 2020 and was admitted for pneumonia and subsequently tested positive for SARS-CoV-2. Out of 195 HCWs who had contact with this patient 83 were not wearing full PPE and none of them contracted Cov-19.

While it is fortunate that basic PPE was adequate in both these instances. It is heartening and reassuring that learned societies have since augmented PPE standards in March 16 (1) and March 27 (2) in the face of COVID-19. While larger studies are awaited to establish the true infectivity of COVID-19 in intubation and other aerosol-generating procedures, the use of the N95 mask appears to be vital in the prevention of transmission of infection to HCWs. Further evidence-based research is also required before we can prove that SARS-CoV-2 is able to initiate infection at exposed skin in the face and neck. However, the full recommended PPE set with goggles, face shield, hair and foot coverings should always be used. Of course, strict hand hygiene remains paramount.

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Taiwan • 14 April 2020

A huge threat to health-care resource and global public health systems: COVID-19 of healthcare workers

Ng et al. described none of the 41 health care workers (HCWs) getting coronavirus disease 2019 (COVID-19) after taking care of a male patient before his confirmed diagnosis of COVID-19 (1). We have to emphasize that hospital populations are at significantly increased risk for COVID-19. With the presence of the healthcare-associated infection (HAI) of 2019 novel coronavirus (2019-nCoV) which may extremely damage the health-care resources reported in many countries globally, such as more than 150 employees at four Boston hospitals have tested positive for coronavirus reported recently (2), it's imperative to consummate a system protecting HCWs. With the previous experiences of the SARS-CoV outbreak in 2003 and mortality of Taiwanese HCWs caused by HAI, the Taiwanese government has established a system for hospital preparedness for highly infectious diseases and measures to curb infection outside and inside the healthcare facilities earlier (3). Until April 14, 2020, 393 laboratory-confirmed patients, significantly less than other countries were reported in Taiwan with two deaths after tests for 45,890 individuals (4). Currently, one nosocomial infection reported form one patient in Taiwan resulting in three nurses and one cleaner staff getting infected diagnosed 8 days ago after testing for 94 hospital personnel who have more close contacts with the index patient (4). Although all the 4 HCWs have contact history with this case, it is indeed a crisis that firstly the quarantine of the other HCWs who have contacts with the patients and these sick personnel will make the manpower of the health caring shortage. Fortunately, there is another nosocomial infection noted till now in Taiwan. With continuously increasing patient numbers reported in European countries and the United States, calling back the retired HCWs has been considered for the encountering shortage of manpower. Fewer patient numbers in Taiwan is as a result of 6/7/2020 Case 2:18-bk-20151c&Ro-19@@@4&49o н&ailecta@6/08/20 ca是mtexed/06/09/20m15v39ci08 Desc Main Document Page 61 of 290 effective measures for preventing an outbreak in communities and health care facilities.

As the recent report describing the quick response to COVID-19 in Taiwan (5), Taiwan's experience by far provides an exemplary model in earlier fighting COVID-19, particularly the nosocomial infection, and deserves to share around the world. Wearing masks is universally recommended for HCWs. With the community infection and transmission, all measures trying to keep the HCWs, especially in the internal medicine and healthcare facilities safe are crucial and fundamental for the global combating of the huge threat to global public health and the medical system.

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Yosefa Birati, Supriya Shore, Jeremy A. Mazurek, Lee R Goldberg and Edo Y. Birati. • University of Pennsylvania, Drexel University and University of Michigan • 5 April 2020

Appropriate Precautions for Healthcare Providers in the Era of COVID-19

Infection of healthcare providers (HCP) may have a tremendous effect on the normal function of every health care system. Ng et al. described a case of massive exposure of 41 HCP to a single COVID patient resulting in a need for 2 weeks' isolation of these providers [1]. In the current era, where the health system worldwide is handling high volume of patients with minimal manpower reserve, this may be detrimental. The field of occupational infection prevention and control for healthcare providers (HCP) has evolved over the years to promote universal safety for both HCP and individuals seeking medical care. More than thirty-three years ago HCP handled blood samples without using gloves or other personal protective equipment (PPE), and these precautions were used only for patients with known blood-borne infections. It was only in 1987 that the Centers for Disease Control (CDC) announced recommendations on universal precautions, stating that all bodily fluids, regardless of patient medical history, should be handled only with gloves [2]. Since then, use of gloves for handling bodily fluids has been the standard of care worldwide.

In December 2019, an outbreak of a severe respiratory viral illness was recognized in Hubei Province, China with the clinical disease subsequently being labelled as coronavirus disease-2019 (COVID-19) [3]. This virus is highly contagious, spread through droplets with possible aerosol and fomite transmission [4]. https://www.acpjournals.org/doi/full/10.7326/L20-0175?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub=pubmed 8/14

6/7/2020 Case 2:18-bk-20151; ER: 19 Do 0n 4 8 490 нь File Ca Do 0 420 case ntexted A 06 / Do 12 5 13 - Desc The current understanding is that although symptomatic patients are the most contagious, asymptomatic individuals may also transmit the infection [4]. Furthermore, symptoms can be atypical in a significant proportion leading to delayed or missed diagnosis. In a recently published study, 29% of infected individuals were HCP and at least 10 of them were infected by one patient who presented with non-specific gastrointestinal symptoms [5]. In Italy alone, it is estimated that so far at least 6,205 HCP were infected from COVID-19, and 37 physicians died as a consequence of the infection [6]. Furthermore, it is estimated that 12% of the COVID-19 patients were infected due to exposure to an infected HCP or from another hospitalized patient. Accordingly, in addition to the risk for these HCP, which may adversely affect provision of health care, HCP can act as vectors transmitting the disease forward [5]. Given the highly contagious properties of this virus [4] and lack of universal testing to detect asymptomatic individuals, at minimum, respiratory precautions using facemasks are critical to protect HCP and to prevent further downstream exposure to individuals seeking medical care. As in 1987, when the CDC guidelines were changed in an effort to protect HCP from HIV and Hepatitis infections, the ongoing COVID-19 pandemic mandates another update to recommend wearing, at minimum, facemasks for every patient encounter, even for individuals who are not considered at risk for COVID-19 infection.

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COVID-19: Protecting healthcare workers is first an d foremost

To the editor,

We read with interest the case report describing the favorable outcome (i.e., negative RT-PCR of nasopharyngeal swab) in 41 health care workers (HCW) who were inadvertently exposed to SARS-CoV-2 (COVID-19) after aerosol-generating medical procedures (AGMPs), where only 15% wore N95 masks and 85% surgical masks.[1] We are pleased to know of the wellbeing of all 41 HCW, but would like to highlight several issues which may make generalization of this case difficult. Details as to which HCW donned what level of personal protective equipment (PPE) for which specific type of AGMPs performed is needed to determine if the risk of exposure coincided with the level of PPE. Not all AGMPs have the same risk of infection as seen with the SARS epidemic, with the most consistent association across multiple studies being tracheal intubation.[2] Several factors influence infection to HCW, such as viral shedding by the patient, close-range aerosol transmission as in AGMPs or ventilation/air-flows.[3-4] Further, the possibility of recall bias by the HCW cannot be ruled out. Most importantly, this case should not be misinterpreted as N95 respirators and surgical masks having equal safety value for HCP, or a lack of close-range aerosol transmission,* especially in view of increased risk of COVID infection with lower level of PPE.** Rather it shows that 41 HCP could have been infected by one patient, and the requirement for guarantine. What also caught our attention was the seeming lack of heightened awareness for potential COVID-19 infection, when the patient presented in February 2020 with pneumonia amid the epidemic. Admittedly, missing a new disease could have happened anywhere. With COVID-19 a pandemic now, HCW should consider all patients presenting with influenza-like illness to be infected with COVID-19.[5] In other words, there is an urgent need for treating all untested patients as presumed infectious in the presence of increasing community spread.

HCW need to be extra vigilant in protecting themselves and others from infection. Proper PPE with N95 masks for AGMPs is paramount. While the present shortage of PPE world-wide amid the pandemic may make the use of surgical masks instead of N95 masks attractive, exposing HCW to infection due to potentially inferior PPE may be short-sighted and needs to be avoided. As production of PPE worldwide is increasing, together with sustainable strategies being developed to overcome shortages, HCW must be protected first and foremost to fight the pandemic.

Footnotes

* Alberta Health Services Response to Media reports about COVID-19 being airborne https://www.albertahealthservices.ca/assets/info/ppih/if-ppih-covid-19-response-airborne.pdf (Accessed 29 Mar 2020) 6/7/2020 Case 2:18-bk-20151c ER: 19 Docn 4849 or Hailed 26/08/20 calentered 406/09/20 mb 52:08 Desc ** Spinal anaesthesia for patients with coronavirus disease 2019 and possible transmission rates in anaesthetists: retrospective, single-centre, observational cohort study https://doi.org/10.1016/j.bja.2020.03.007 (Accessed 29 March 2020) *** FDA approved reusable respirator https://www.fda.gov/media/135763/download

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Jacqueline Sedgwick, MD, MPH • Primary Care Physician • 20 March 2020

Prior randomized clinical trial demonstrated N95 superiority -decreased infection transmission including influenza

Please review: "A randomized clinical trial of three options for N95 respirators and medical masks in health workers", Am J Respir Crit Care Med Vol 187, Iss. 9, pp 960-966, May 1 2013 by C. Raina MacIntyre, Quanyi Wang, et al which found continuous use (not just for procedures, but for all possible exposures) to result in significantly lower rates of clinical respiratory infection in HCWs compared with targeted use or medical (surgical) masks.

James Siu Ki Lau, Chi Kit Yuen • Ruttonjee Hospital, Hospital Authority, Hong Kong • 19 March 2020

Staying vigilant against COVID-19: Awareness and Proper Personal Protective Equipment

Dear editor,

We read the published article by Kangqi Ng et al [1] titled "COVID-19 and the Risk to Health Care Workers: A Case Report" with great interest.

However, we would like to voice some concerns regarding the infection control in severe acute respiratory disease in health care workers which is seemingly substandard in the study.

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Firstly, awareness of the COVID-19 is paramount. In Ng's case, the surveillance of COVID-19, which should have been done on the first day after admission, was performed only after the patient was mechanically ventilated for 3 days and after extubation.

The delay in surveillance for COVID-19 also results in delay in contact tracing and isolation of unprotected HCWs (2). By the end of January in the Asia Pacific region, the highly infectious virus with significant morbidity and mortality COVID-19 (novel coronavirus at that time) was already on the news daily. The lack of awareness of the possibility of COVID-19 by the team could have devastating consequences such as spreading the disease into the community by healthcare workers. In addition to not allowing family/friends to visit the hospitals except in very special circumstances, hospitals in Hong Kong have exercised an enhanced surveillance strategy very early on in February to combat the spread of the disease in hospital wards and community. It screens all patients admitted with the diagnosis of pneumonia for COVID-19 in designated isolation wards.

Secondly, according to guidelines of both CDC and WHO (3), N95 or higher-level respirators should be used during aerosol-generating procedures. A large proportion of the 41 healthcare workers involved in caring the index patient were not in proper personal protective equipment when performing aerosol generating procedures. It is an unacceptable risk to any healthcare worker worldwide. In Tran's study with WHO (4), they concluded aerosol generating procedures such as tracheal intubation, non-invasive ventilation, tracheotomy, and manual ventilation before intubation were associated with increased risk of SARS transmission to healthcare workers (4). Underlying reason for non-compliance to international guideline for proper application of PPE was not investigated in the study. Inadequate protection during aerosol generating procedures not just affects healthcare workers, but also their family, community, country and the world.

In conclusion, we agree with Ng that their negative yielding study is limited and we follow what most experts recommend so far on the use of N95 masks when performing aerosol generating procedures. We advocate staying vigilant against COVID-19 and not leaving our health and world to luck.

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6/7/2020 Case 2:18-bk-20151cを用: 19 @ 00 48 49 o H failed @ 6/08/20 catentered A06/09/20 mb 5/20 Desc Main Document Page 66 of 290 2019-nCov-IPCPPE_use-2020.1-eng.pdf on 19 March 2020.

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Jeffery Lee • Facey Medical Group • 19 March 2020

Eye shield

Could you comment on whether the healthcare workers were using eye shields or other eye protection?

Karolina Akinosoglou, Charalambos Gogos • Dept of Internal Medicine and Infectious Diseases, University Hospital of pATRAS • 17 March 2020

Self-isolation of COVID-19-exposed asymptomatic health care workers (HCW): Wise or Worrying ?

Ng et al describe the clinical outcome of health care workers (HCW) who took care of a patient with COVID-19 pneumonia (1). Following 14-day isolation and serial PCR testing, none of the HCW involved were infected. However, as the pandemic progresses, and the need for increased testing and mitigation of HCW shortages increases, a number of concerns rise reagrding HCW exposure.

Recent data has shown us that COVID-19 transmission can go undetected, by asymptomatic individuals (2). Exposed HCW could potentially become asymptomatic carriers, and, infect patients and/or colleagues. Hence, self-isolation is crucial to prevent transmission. However, in the case of HCW one should carefully weigh against the reality of the existing struggling health care system, that is required to respond to increased needs and workload. Where the fine line between risk to transmit to inpatient vulnerable groups, and establish the epidemic from "within", and risk to push the system beyond repairable damage from existing non-sufficient personnel burn out, lies, remains elusive. Either way, the result would be the same, while it has become clear that health care resource availability, including HCW shows a clear association with disease mortality. (3)

Even if one can afford asymptomatic exposed HCW self-isolation, timing of return to work is an open question, due to delayed virus shedding. Repeated negative testing has been adopted by many settings to optimize return to community, similar to follow up of discharged patients (4). However, in the case of exposed asymptomatic HCW, during the peak of a pandemic crisis, things can become more complex, since the actual risk and clinical impact of transmission via asymptomatic carriers still remains to be clearly quantified by mathematical models (5). Non-isolation and close monitoring via for example every other day screening of asymptomatic - high risk to develop symptoms - HCW could be an option in high income countries, that for example next-generation sequencing technology is available and affordable. Nonetheless, in the growing needs of an evolving epidemic, all settings should be managed as potentially resource-limited and any decision made should well justify its cost-effectiveness. Testing to confirm freedom-of-disease in asymptomatic individuals may come second, in view of the increased needs of diagnosis of symptomatic patients

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NEXT ARTICLE >

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Exhibit 6

Critical preparedness, readiness and response actions for COVID-19

Interim guidance 22 March 2020



This document is an update to the interim guidance document entitled 'Critical preparedness, readiness and response actions for COVID-19.' This version provides updated links to WHO guidance materials and provides the full list of WHO technical guidance available for COVID-19 and provides updated recommendations in the table.

Background

Several countries have demonstrated that COVID-19 transmission from one person to another can be slowed or stopped. These actions have saved lives and have provided the rest of the world with more time to prepare for the arrival of COVID-19: to ready emergency response systems; to increase capacity to detect and care for patients; to ensure hospitals have the space, supplies, and necessary personnel; and to develop life-saving medical interventions. Every country should urgently take all necessary measures to slow further spread and to avoid their health systems becoming overwhelmed as a result of seriously ill patients with COVID-19.

The <u>Strategic Preparedness and Response Plan for COVID-</u>19 aims to:

- Slow and stop transmission, prevent outbreaks, and delay spread
- Provide optimized care for all patients, especially the seriously ill
- Minimize the impact of the epidemic on health systems, social services, and economic activity

All countries should increase their level of preparedness, alert and response to identify, manage, and care for new cases of COVID-19. Countries should prepare to respond to different public health scenarios, recognizing that there is no one-sizefits-all approach to managing cases and outbreaks of COVID-19. Each country should assess its risk and rapidly implement the necessary measures at the appropriate scale to reduce both COVID-19 transmission and economic, public and social impacts.

Scenarios

WHO has defined four transmission scenarios for COVID-19:

- 1. Countries with no cases (No Cases);
- 2. Countries with 1 or more cases, imported or locally detected (Sporadic Cases);
- 3. Countries experiencing cases clusters in time, geographic location, or common exposure (Clusters of cases);
- 4. Countries experiencing larger outbreaks of local transmission (Community transmission).

Countries could experience one or more of these scenarios at the sub-national level and should adjust and tailor their approach to the local context.

Countries should prepare to respond to all transmission scenarios, following the framework laid out in the <u>Strategic</u> <u>Preparedness and Response Plan for COVID-19</u>. Prioritization and focus of resources for each technical area will depend on which transmission scenario(s) a country is managing.

COVID-19 is a new disease that is distinct from other SARS, MERS, and influenza. Although coronavirus and influenza infections may present with similar symptoms, the virus responsible for COVID-19 is different with respect to community spread and severity. There is still much to discover about the disease and its impact in different contexts. Preparedness, readiness, and response actions will continue to be driven by rapidly accumulating scientific and public health knowledge.

The Table describes the preparedness, readiness and response actions for COVID-19 for each transmission scenario. Hyperlinks to WHO Technical Guidance are provided.

All technical guidance for WHO can be found on the <u>WHO</u> website.

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Critical preparedness, readiness and response actions for COVID-19: interim guidance

Table 1. Critical preparedness, readiness and response actions for each transmission scenario for COVID-19

	No Cases	Sporadic Cases	Clusters of Cases	Community Transmission
Transmission scenario	No reported cases.	One or more cases, imported or locally acquired.	Most cases of local transmission linked to chains of transmission.	Outbreaks with the inability to relate confirmed cases through chains of transmission for a large number of cases, or by increasing positive tests through sentinel samples (routine systematic testing of respiratory samples from established laboratories.
Aim	Stop transmission and prevent spread.	Stop transmission and prevent spread.	Stop transmission and prevent spread.	Slow transmission, reduce case numbers, end community outbreaks.
Priority areas of work				
Emergency response mechanisms	Activate <u>emergency response</u> mechanisms.	Enhance <u>emergency response</u> mechanisms.	Scale up <u>emergency response</u> mechanisms.	Scale up <u>emergency response</u> mechanisms.
Risk communication and public engagement	Educate and actively communicate with the public through <u>risk communication</u> and community engagement.	Educate and actively communicate with the public through risk communication and community engagement.	Educate and actively communicate with the public through <u>risk communication</u> and community engagement.	Educate and actively communicate with the public through risk communication and community engagement.
Case finding, contact tracing and management	Conduct <u>active case finding</u> , contact tracing and monitoring: <u>quarantine of</u> <u>contacts</u> and isolation of cases.	Enhance <u>active case finding</u> , contact tracing and monitoring; <u>quarantine of contacts</u> and isolation of cases.	Intensify <u>case finding</u> , contact tracing, monitoring, <u>quarantine of contacts</u> , and isolation of cases.	Continue active case finding, continue contact tracing where possible, especially in newly infected areas, <u>quarantine of contacts</u> , and isolation of cases; apply self-initiated isolation for symptomatic individuals.
Surveillance	Consider testing for COVID-19 using existing respiratory disease surveillance systems and hospital-based surveillance.	Implement COVID-19 surveillance using existing respiratory disease surveillance systems and hospital-based surveillance.	Expand COVID-19 surveillance using existing respiratory disease surveillance systems and hospital-based surveillance.	Adapt existing surveillance systems to monitor disease activity (e.g. through sentinel sites).
Public health measures	Hand hygiene, respiratory etiquette, practice social distancing.	Hand hygiene, respiratory etiquette, practice social distancing.	Hand hygiene, respiratory etiquette, practice social distancing.	Hand hygiene, respiratory etiquette, practice social distancing.
IPC	Train staff in <u>IPC</u> and <u>clinical</u> <u>management</u> specifically for COVID-19.	Train staff in <u>IPC</u> and <u>clinical</u> <u>management</u> specifically for COVID-19.	Train staff in <u>IPC</u> and <u>clinical</u> <u>management</u> specifically for COVID-19.	Retrain staff in <u>IPC</u> and <u>clinical management</u> specifically for COVID-19.
	Prepare for surge in health care facility needs, including respiratory support and PPE.	Prepare for surge in health care facility needs, including respiratory support and PPE.	Advocate for home care for mild cases, if health care systems are overwhelmed, and identify referral systems for high risk groups.	Implement health facilities surge plans.

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Laboratory testing ¹	Test all individuals meeting the suspected <u>case definition</u> Test a subset of samples from SARI/ILI surveillance for COVID-19 Test patients with unexpected clinical presentation or an increase in hospital admissions in a specific demographic group that could be COVID-19	Test all individuals meeting the suspect case definition Considerations in the investigation of cases and clusters of COVID-19 Clinical management of severe acute respiratory infections when novel coronavirus is suspected. SARI/ILI surveillance for COVID-19 and reporting: see <u>Interim operational</u> considerations for COVID-19 surveillance using GISRS.	Test all individuals meeting the suspected <u>case definition</u> <u>Considerations in the investigation of</u> <u>cases and clusters of COVID-19.</u> <u>Clinical management of severe acute</u> <u>respiratory infections when novel</u> <u>coronavirus is suspected.</u> <u>SARI/ILI surveillance for COVID-19 and</u> <u>reporting: see Interim operational</u> <u>considerations for COVID-19</u> <u>surveillance using GISRS.</u>	 If diagnostic capacity is insufficient, implement prioritized testing and measures that can reduce spread (e.g. isolation), including priority testing of: people who are at risk of developing severe disease and vulnerable populations, who will require hospitalization and advanced care for COVID-19 (see <u>Clinical management of</u> <u>severe acute respiratory infections when</u> <u>novel coronavirus is suspected).</u> symptomatic health workers (including emergency services and non-clinical staff) regardless of whether they are a contact of a confirmed case (to protect health workers and reduce the risk of nosocomial transmission) the first symptomatic individuals in a closed setting (e.g. schools, long term living facilities, prisons, hospitals) to quickly identify outbreaks and ensure containment measures 	
Case management strategy ²	Set up screening and triage protocols at all points of access to the health system; Prepare to <u>treat</u> COVID-19 affected patients; Set up COVID-19 hotline and referral system; Ready hospitals for potential surge.	Screen and triage patients at all points of access to the health system; <u>Care</u> for all suspected and confirmed patients according to disease severity and acute care needs; Ready hospitals for surge; Ready communities for surge, including by setting up community facilities for isolation of mild/moderate cases.	Screen and triage patients at all points of access to the health system; <u>Care</u> for all suspected and confirmed patients according to disease severity and acute care needs; Activate surge plans for health facilities.	Screen and triage patients at all points of access to the health system; <u>Care</u> for all suspected and confirmed patients according to disease severity and acute care needs; Scale up surge plans for health facilities and ad-hoc community facilities, including enhancement of COVID-19 referral system.	
Case management recommendations by case severity and risk factors ²	 Test suspect COVID-19 cases according to diagnostic strategy¹ Mild cases and moderate cases with no risk factors: Isolation/cohorting in: Health facilities, if resources allow; Community facilities (i.e. stadiums, gymnasiums, hotels) with access to rapid health advice (i.e. adjacent COVID-19 designated health post, telemedicine); Self-isolation at home according to WHO guidance For moderate cases with risk factors, and all severe/critical cases: Hospitalization (in-patient treatment), with appropriate isolation and cohorting. 				

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Societal response	Develop all-of-society and business continuity plans.		Implement all-of-society resilience, repurpose government, business	Implement all-of-society resilience, repurpose government, business continuity, and		
		business continuity plans.	continuity, and community services plans.	community services plans.		
picitis.						

1 For full details, see WHO's guidance Laboratory testing strategy recommendations for COVID-19 available here: https://apps.who.int/iris/bitstream/handle/10665/331509/WHO-COVID-19-lab_testing-2020.1-eng.pdf

2 For full details, see: WHO Guidance: Operational considerations for case management of COVID-19 in health facility and community, available here: <u>https://apps.who.int/iris/bitstream/handle/10665/331492/WHO-2019-nCoV-HCF_operations-2020.1-eng.pdf</u>

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Critical preparedness, readiness and response actions for COVID-19: interim guidance

WHO Technical Guidance for COVID-19

Country-level coordination, planning, and monitoring

- Draft operational planning guidance for UN country teams.
- <u>COVID-19 Partners Platform based on Operational Planning</u> <u>Guidance</u>
- <u>Training modules: Operational Planning Guidelines and</u>
 <u>COVID-19 Partners Platform</u>
- <u>National capacities review tool for a novel coronavirus</u>

Surveillance, rapid response teams, and case investigation

- <u>Global Surveillance for human infection with coronavirus</u> <u>disease (COVID-19)</u>
- <u>Considerations in the investigation of cases and clusters of</u>
 <u>COVID-19</u>
- <u>Considerations for quarantine of individuals in the context of</u> <u>containment for coronavirus disease (COVID-19)</u>

Guidance for national laboratories

- WHO interim guidance for laboratory testing
- <u>WHO interim guidance for laboratory biosafety related to</u> <u>COVID-19 virus</u>
- Molecular assays to diagnose 2019-nCoV
- <u>WHO reference laboratories providing confirmatory testing for</u> <u>COVID-19</u>
- <u>Prioritized Laboratory Testing Strategy According to 4Cs</u> <u>Transmission Scenarios</u>

Clinical care for COVID-19 patients

- <u>Clinical management of severe acute respiratory infection when</u> novel coronavirus (nCoV) infection is suspected
- <u>Home care for patients with suspected novel coronavirus</u> (nCoV) infection presenting with mild symptoms and management of contacts
- Operational considerations for case management of COVID-19
 in health facility and community

Infection Prevention and Control for COVID-19

- Infection prevention and control during health care when novel <u>coronavirus (nCoV) infection is suspected</u>
- <u>Rational use of personal protective equipment for coronavirus</u> <u>disease (COVID-19)</u>
- <u>Q&A on infection prevention and control for health care workers</u> caring for patients with suspected or confirmed 2019-nCoV
- Health workers exposure risk assessment and management in the context of COVID-19 virus
- Water, sanitation, hygiene and waste management for COVID-19
- IPC guidance for long-term care facilities in the context of <u>COVID-19</u>

Risk communication and community engagement

 <u>Risk communication and community engagement (RCCE)</u> readiness and response to the 2019 novel coronavirus

- <u>A guide to preventing and addressing social stigma associated</u> <u>with COVID-19</u>
- Mental Health Considerations during COVID-19 Outbreak

Guidance for COVID-19 in schools, workplaces and institutions

- <u>Key Messages and Actions for COVID-19 Prevention and</u> <u>Control in Schools</u>
- Getting your workplace ready for COVID-19

Humanitarian operations, camps and other fragile settings

 Interim Guidance on Scaling-up COVID-19 Outbreak in Readiness and Response Operations in Camps and Camp-like Settings (jointly developed by IFRC, IOM, UNHCR and WHO)

Operational support and logistics

Disease commodity package

Points of entry and mass gatherings

- Q&A on Mass Gatherings
- <u>Management of ill travellers at Points of Entry international</u> <u>airports, seaports and ground crossings – in the context of</u> <u>COVID-19 outbreak</u>
- <u>Key planning recommendations for Mass Gatherings in the</u> <u>context of the current COVID-19 outbreak (Interim guidance)</u>
- Public health preparedness and response for aviation sector
- Operational considerations for managing COVID-19
 <u>cases/outbreak on board ships</u>
- Handbook for management of public health events on board ships

Online training courses available for COVID-19

- Introduction to COVID-19
- eProtect Respiratory Infections
- <u>Critical Care for Severe Acute Respiratory Infections</u>
- Infection Prevention and Control for COVID-19
- <u>Country Preparedness and response planning</u>
- Online course for public health preparedness for mass gathering events

Early investigation protocols

- <u>The First Few X (FFX) Cases and contact investigation protocol</u> for COVID-19 infection
- Household transmission investigation protocol for COVID-19
 infection
- Protocol for assessment of potential risk factors for COVID-19 infection among health care workers in a health care setting
- Surface sampling of coronavirus disease COVID-19 virus: A
 practical "how to" protocol for health care and public health
 professionals
- Global COVID-19 Clinical Characterization Case Record Form and new data platform for anonymized COVID-19 clinical data
- Population-based age-stratified seroepidemiological investigation protocol for COVID-19 virus infection

Critical preparedness, readiness and response actions for COVID-19: interim guidance

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

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WHO reference number: WHO/2019-nCoV/Community_Actions/2020.3

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Exhibit 7

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Editorial

Check for updates

Emergent Strategies for the Next Phase of COVID-19

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Conflict of Interest

No conflicts of interest.

Author contributions

Conceptualization: KRP, HSS. Writing – original draft: KH. Writing – review & editing: KRR, HSS.

"What's true of all the evils in the world is true of plague as well. It helps men to rise above themselves."

- Albert Camus, The Plague

About two months have just passed since the first report of patients with pneumonia of unknown cause in Wuhan, Hubei Province, China. The outbreak of infection with the novel coronavirus, now named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has spread to 25 countries since [1]. The global number of cases exceeded 70,000, of which more than 800 occurred outside China. Some suggest that the epidemic is showing signs of slowing down, as the number of new cases in China has been declining in recent days. However, it seems to be too early to relax; during the last two weeks troubling signs have been observed elsewhere in the world – cases without identifiable links are being reported in countries with close proximity and a high volume of traffic with China, including Korea.

Transmission dynamics from the earliest period of the outbreak showed the characteristics which might make containment difficult [2, 3]. A relatively large proportion of mild cases, high viral shedding at the symptom onset, and slowly progressive clinical course undermine the effectiveness of the classic "search and isolate" strategy. Characteristics of coronavirus disease 2019 (COVID-19) more closely resemble those of influenza A(H1N1) pdm09, which we failed to contain, than those of SARS-CoV in 2003. However, prevention and control strategies are more difficult than those for influenza pandemic, since morbidity is different and no vaccine or specific treatment agents against this new virus are expected in the near future. The recent identification of locally transmitted cases outside China without identifiable links suggests that the containment strategy might have reached its limit. While we have concentrated our effort on the containment of imported cases so far, what we have observed are calls for the preparation for the next stage: sustained transmission in countries outside China.

Even if a widespread epidemic does occur, the magnitude and velocity of the epidemic would be the critical factors determining its impact on society. Rapid spread with a high number of cases will saturate the capacity of healthcare system, resulting in excessively high toll of mortality and morbidity; in contrast, slower propagation will allow us time and resources for adequate preparation and management. Thus, efforts for mitigating transmission risk is still important even in the worst situation. Weak spots in systems and societies should be

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identified. History of recent epidemics - SARS, Ebola, and MERS - universally taught us that healthcare facilities, which comprise the pillars of our healthcare, are at particular risk at the time of epidemic. Hospitals have become stages of super-spreading events during SARS and MERS outbreaks [4, 5]. Outpatients and emergency departments, which serve as gatekeepers of hospitals, are expected to be most exposed. Facilities should formulate detailed plans for safe and effective screening, isolation, and testing of suspected cases (Table 1); otherwise, an increased number of patients and confusion on the front line may make those places epicenter of hospital-associated outbreaks. A dedicated triage area, perhaps makeshift, can serve as a safety barrier for a healthcare facility. Triage could utilize a clinical pathway to manage patients with symptoms of acute respiratory illness: for example, test and treat for influenza or other bacterial causes first with voluntary home isolation, then test for COVID-19 if unresponsive 3 - 5 days later [6]. Use of telemedicine or electronic prescription can be considered to reduce the need for outpatient visits. Hospitals should also build contingency plans for general wards and intensive care units. Care for numerous patients with COVID-19 would require a large number of airborne infections isolation rooms (AIIR) which greatly exceed the current capacity. Building temporary AIIRs with mobile negative-air machines or by adjusting ventilation systems can be useful alternatives, as demonstrated in Korea during the MERS outbreak. Heating, ventilation, and air conditioning (HVAC), along with sewage

Settings	Suggestions
Triage	Dedicated triage/walk-in clinic for patients with acute respiratory infections.
	• Room/area for specimen collection can be a delicate issue.
	 Transport and testing capacities should be provided.
Acute respiratory illness clinics	Test for influenza and consider preemptive oseltamivir.
	\cdot Advise to revisit 3–5 days later for further evaluation (SARS-CoV-2 test and chest X-ray) if no improvement seen.
Patient isolation in the healthcare settings	\cdot Operate dedicated wards, preferably in a building separated from the rest of the facilities.
	\cdot Separate route of movement, preferably with dedicated corridors and elevators.
	• Temporary airborne infections isolation rooms (AIIR) using mobile negative-air machines or by adjusting ventilation can be alternatives for fully equipped AIIRs.
Procedures and tests	Avoid unnecessary aerosol-generating procedures (AGP).
	\cdot If necessary, perform AGPs in AIIR by trained personnel with proper personal protective equipment (PPE).
	 Most radiologic test rooms are not equipped to meet the requirement for AIIR – separate dedicated radiology suites are ideal; if unavailable, consider adjusting ventilation to generate negative pressure. Advance knowledge on air change per hour would be helpful to determine safe interval between tests. Avoid futile care.
Personnel	• Train medical and non-medical personnel for adequate use of PPE and providing care with PPE donned.
	• Healthcare workers (HCW) who provides specialized care (e.g., intensive care, respiratory care, renal replacement) should be trained to perform expected activities with PPE.
	Consider differential level of PPE according to risk.
	\cdot Plan contingency work shifts with limited number of HCWs in case of mass isolation after unexpected exposure.
	 Vaccination for influenza and pneumococcus, as indicated.
Contact tracing	\cdot Prepare effective and easy methods for contact tracing.
	\cdot Prioritize effort to clusters and high-risk events.
	• Monitor human behavior.
	• Home quarantine of close contacts with financial and emotional support.
Healthcare system	• Telemedicine and/or electronic subscription for patients at risk.
	• Designating hospitals for COVID-19 care.
Public education	• Personal hygiene: hand hygiene, respiratory etiquette.
(nonpharmaceutical interventions)	• Staying home when feeling ill (voluntary home isolation).
	• Wearing facemasks when feeling ill or at crowded places.
	Cancellation of mass gathering.
	Social distancing: increase the distance between persons when possible.
	Cleaning frequently touched surfaces and objects.
	• Staying home for people who are old (>65 years) or who have chronic illnesses.
	Vaccination for influenza and pneumococcus, as indicated.

and waste handling, should be reviewed when general-purpose wards need be used for management of COVID-19 patients. Private practices and pharmacies face unique challenges, due to lack of capacity for isolation and testing. Effective workflow for screening and referral of patients are necessary, and public health authorities should work with the community to provide adequate support to this foundation of our healthcare.

Early diagnosis and isolation of cases will slow the transmission, mitigate the risk of outbreaks, and improve clinical outcomes. Most recent cases diagnosed in Singapore, Japan, and Korea demonstrate that the case definition based on travel history or contact with confirmed cases became insufficient. More systematic surveillance among acute respiratory illness is now required. United States Center for Disease Control and Prevention recently announced that it will consider adding SARS-CoV-2 to its existing influenza-like illness surveillance [7]. We believe that other countries should also prepare for implementing similar measures, and they could benefit from global coordination. Healthcare facilities need to conceive effective pathways to screen, test, and isolate patients with acute respiratory infections in various care settings. Surge capacity of laboratories is also of important concern and the development of rapid, point-of-care test will greatly relieve the laboratory burden and contribute to rapid diagnosis.

Sustained transmission of SARS-CoV-2 in the community will result in a surge of patients, both with and without COVID-19. Efforts should be made to provide adequate care for both groups of patients. Multiple media reports from Wuhan and Hubei province tell the story of sick people unable to access medical care. Overflow of healthcare system will unequivocally lead to suboptimal outcome in all patients regardless of their diagnosis. Surge capacities should be prepared, in terms of infrastructures, human and material resources, procedures, and organizations. Healthcare facilities should secure extra beds and instruments (e.g., ventilators) for surge capacity. Patients who could be cared at home or at long-term care facilities should be discharged, and elective medical care could be postponed. Resources for care of patients with COVID-19 needs to be checked and stocked. While their effects are yet to be proven by clinical trials, agents such as lopinavir/ritonavir, interferon, chloroquine, and remdesivir have been used for treatment [8, 9]. Antibiotics are expected to be administered to many patients, thus their stocks and contingency supply plan must be reviewed. Medical surge operation cannot be executed effectively by individual facilities alone. Public health authorities should coordinate joint operations to utilize limited resources in the most effective way. Designating hospitals for COVID-19 care would be more beneficial for the efficient use of limited resources and could maintain essential healthcare for patients requiring emergent or intensive management for other diseases.

Control of a large epidemic will require individual cooperation from the public [10]. Common sense etiquettes will help mitigate the risk of transmission: hand hygiene, cough etiquette, and avoiding crowded places for high-risk people (*e.g.*, elderly or immunocompromised). People with mild symptoms of acute respiratory illness are not likely to benefit from medical care, regardless of etiologic agents. Visiting healthcare facilities without proper protection will risk others if one has COVID-19, or risk oneself otherwise. The public should be advised to stay home if mildly ill, and seek medical care in a coordinated way if symptoms persist or aggravate. There still remains approximately a month until the flu season is expected to end and *Streptococcus pneumoniae* causes bacterial pneumonia year wise. Vaccination for influenza and pneumococcus, particularly for the high-risk population, should be recommended. Decrease in those conditions will reduce the burden on healthcare system and also lower the

risk of contracting COVID-19 in healthcare settings. Healthcare authorities should prepare a sufficient amount of influenza vaccines for the next season.

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Places of mass congregation, such as supermarkets, hotels, conferences, religious services, and schools, deserve special interest. They can serve as focal points of small outbreaks; even when they don't, patients visiting public places before isolation leads to massive contact tracing, which consumes precious resources and elicits public anxiety. Temporary closure of schools and non-critical services could be considered. At places staying open, observation of personal hygiene is likely to be helpful for lowering transmission risk.

As physicians working in the field of infectious diseases, it is heartbreaking to hear reports on the current situation in Wuhan. Much of the sufferings of people in the city are for the good of us outside, rather than for their own good. We are greatly indebted to their sacrifice; it has earned us valuable time to prepare for the next stage. We, as medical professionals and as a society, should not spend in vain the time earned with so much suffering.

Special thanks to the people in Wuhan and the great effort of China.

ACKNOWLEDGEMENTS

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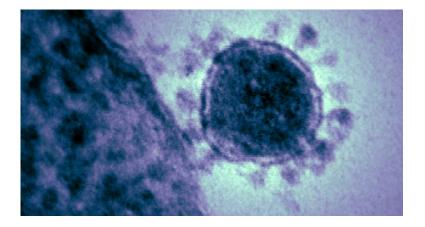
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Exhibit 8

Insights



Hospital Capacity and Operations in the Coronavirus Disease 2019 (COVID-19) Pandemic—Planning for the Nth Patient

Joseph J. Cavallo, MD^{1,2}; Daniel A. Donoho, MD³; Howard P. Forman, MD, MBA^{1,2,4}

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Introduction

The coronavirus disease 2019 (COVID-19) news coming from Italy should be sobering to health system leaders throughout the world. We are witnessing an advanced health system stretched beyond its capacity. When the capacity of the system is exceeded,

6/7/2020 Caseo 2014 State 2014 State Ethons Doe 4844 Quirus Filed 206/09/2020-1 Entered 206/09/2021 State 2014 Desc Care Me... Main Document Page 83 of 290 rationing decisions may need to be made that extend well beyond patients with COVID-19. On March 11, the Italian College of Anesthesia, Analgesia, Resuscitation, and Intensive Care was forced to publish guidelines for rationing care. Infectious disease and epidemiology experts¹ have been outlining the worst-case scenarios possible with the unchecked spread of a novel virus, both in terms of immunity and preparedness. Unfortunately, hospital systems are designed for average patient loads, not epidemics. Observations from Italy demonstrate what is at stake. When containment fails, the exponential growth of cases can transform a public health emergency into an operational crisis.

What Can We Learn?

Operationally, what can be gleaned from the dire situation in Italy to avoid a similar fate in other countries? The geographic and temporal clustering of outbreaks can overwhelm a health care system. Most Italian cases and deaths have been concentrated in the northern region of Lombardy, which should concern US states working to manage their own clusters, including Washington and New York. President Trump has imposed

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n visitors from China and Europe, but these restrictions will with widespread community transmission. Public

containment measures implemented in recent days will take a week or longer to have an effect; with an **incubation period of 2 to 7 days**² and a wait for test results of 2 to 3 days, new cases reflect infections from more than a week ago.

Patients with severe disease from COVID-19 require a mean of approximately <u>13 days of</u> <u>respiratory support</u>.² Such lengthy treatment time will further stress resources. This time in the system multiplied by the arrival rate (known as <u>Little's law</u>) is a simple but elegant formula for modeling system capacity before a queue develops. In manufacturing or customer service, queues may result in decreased profitability and/or the loss of customers; in critical care medicine, queues can be deadly. For example, take a large hospital with 100 beds in the intensive care unit. Assume that at any given time, 70% of these beds are occupied.³ The remaining 30 beds are the effective extra capacity to absorb patients with COVID-19. Because of the long treatment time (approximately 13 days), the number of new patients that can be accommodated per day during an 6/7/2020 Caseo 2016 2015 20 E Rons Doc 4849 irus Filed 00/09/20D-1E ntered 06/09/20r15:39 POEnt | Desc Care Me... Main Document Page 84 of 290 extended outbreak is low. Admitting more than 2.3 patients per day (30 beds divided by 13 days) with respiratory failure will lead to an unstable system and queues. Italy reported 7087 new cases during a 2-day period between March 14 and March 15, 2020. With as many as 15% of documented infections resulting in severe disease,² rationing decisions may quickly be required.

How Can We Prepare?

By observing regional outbreaks in the context of Italy's case growth, we can start to model and anticipate both what the ultimate capacity to provide care will be and when that capacity will be exceeded. Case **growth rates of 25% to 35% per day** are commonplace among affected regions. Based on trends in known cases in a specific locale, we can start to model caseloads under different scenarios. Tools designed for influenza epidemics, such as **the Centers for Disease Control and Prevention FluSurge**, can offer useful estimates. Preparations for expanding capacity should already be underway to address growing regional clusters of transmission (ie, so-called hotspots). Many hospitals have mass casualty protocols for catastrophic events; the COVID-19

al mobilization of staff and resources but during a ital systems should communicate early and often, given

that efficient case sharing and transport between hospitals could become essential. Regional networking among 15 hospitals was part of <u>Lombardy's early response</u> to the massive surge of patients with COVID-19 while individual hospitals increased capacity.⁴

Bed capacity may not be the most crucial bottleneck for providing critical care. Observing Italy, <u>experts are rightly concerned about the fixed number of ventilators</u>. However, there are many other key factors to consider. Given the risk of health care worker infection⁵ and quarantine, will there be enough staff to provide care? Are there <u>sufficient drug supplies</u> for effective respiratory and cardiovascular support? Are there adequate supplies of <u>personal protective equipment</u>? Hospitals have prided themselves on the efficiency that comes with <u>just-in-time supply management</u> and minimizing empty beds, but as a result, they may be ill equipped for an epidemic surge. 6/7/2020 Caseo2iile8:blke20150; ERons Doc 48:49 irusFile4:00/09/20D-1Entered:00/09/20r1E:309r0&rt | Desc Care Me... Main Document Page 85 of 290 Hospital administrators need to start preparing for worst case scenarios now, and thankfully, most are doing so. Toner and Waldhorn⁶ have assembled a comprehensive list of <u>preventive actions</u>. This planning and response will require a multidisciplinary effort; physicians, nurses, respiratory therapists, pharmacists, environmental services staff, supply chain managers, and many others possess needed expertise. Messaging from hospital leadership must be communicated often and clearly. The protection of staff from infection must remain a high priority.

What Lies Ahead?

Some countries, such as <u>Taiwan</u>,^Z have been successful at combating the virus through aggressive testing and containment measures. <u>South Korea</u>, while initially inundated with patients from a rapidly spreading cluster, has successfully mitigated spread (at least temporarily) with minimal associated mortality. These examples provide encouragement that a well-executed public health response can minimize the potential for operational crises. The common themes in success have been massive testing, adaptive policy recommendations for different regions, and communication by public officials that is

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nest. The public needs to trust public officials and see the

In our interconnected world, the life-and-death consequences of health care needs exceeding the system's capacity could hit any region at any time. It is imperative to learn the lessons of Italy and Hubei, China: waiting until an exponentially increasing epidemic becomes self-evident will ensure that draconian efforts will be required for control, and even with these measures, there will be a significant loss of life. Actions taken now by society and health care systems will determine whether history regards 2020 as a great public health achievement or an epic failure of our public health and health care infrastructure.

Article Information

Correction: This article was corrected on March 20, 2020, to fix errors in the authors' degrees and affiliations.

6/7/2020 Caseo2xiila83alke20150pERons Doc 4849virusEiled 06/09/20D-1Entered 06/09/20r15:39F0&nt | Desc Care Me... Main Document Page 86 of 290 Corresponding Author: Joseph Cavallo, MD, Yale Radiology and Biomedical Imaging, 330 Cedar St, TE 2-214, New Haven, CT 06520 (Joseph.Cavallo@yale.edu).

Conflict of Interest Disclosures: None reported.

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March 23, 2020

Suggestions for unconventional aids for coronavirus treatment

David Parish, BSME, MSEE | Design Engineer

I am a design engineer and would like to offer a couple free suggestions that perhaps could help our health care professionals.

d garments is in short supply at point of treatment facilities, perhaps existing masks and garbs could be decontaminated using ozone generators and UV light. Ozone generators are available for about \$100 and can be installed in a container like a dish washer, with masks or garbs in the pull out racks of the dishwasher, to infuse the used masks/garbs with ozone for an extended period to decontaminate them. Obviously not ...

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March 27, 2020

Suggestions

Leilei Li, Ph.D | West China Hospital of Sichuan University, Sichuan province, P.R.China

I am a staff who worked in emergency office in West China hospital of Sichuan university in China. I would to thank the authors for their consideration of the important topic of hospital surge capacity during a pandemic. What I think also needs more attention is how to balance normal care and control of the epidemic in the hospital. The practices in my hospital are (1) hospital layout adjustment; (2) care alteration; (3) medical and human resources optimization.

EXPAND ALL

CONFLICT OF INTEREST: None Reported

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Bella Mehta, MBBS, MS; Jane Salmon, MD; et al.

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Stuart M. Butler, PhD

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Exhibit 9

Hospital Emergency Management Plan During the COVID-19 Epidemic

Yubin Cao, MD^{1,2}, Qin Li, B.Nurs^{3,4,5}, Jing Chen, B.Nurs^{2,5,6}, Xia Guo, PhD⁷, Cheng Miao, MD^{1,2}, Hui Yang, B.Nurs^{2,5,6}, Zihang Chen, MD⁸, Chunjie Li, PhD^{1,2,9}, and Longjiang Li, PhD^{1,2}

The confirmed and suspected cases of the 2019 novel coronavirus disease (COVID-19) have increased not only in Wuhan, Hubei Province, but also China and the world. Enormous demand for handling the COVID-19 outbreak challenged both the health care personnel and the medical supply system. In West China Hospital, emergency department (ED) undertook the mission of clinical reception, primary diagnosis, and interim treatment for the suspected cases of COVID-19.

The pathogen of COVID-19, severe acute respiratory syndrome coronavirus 2, was confirmed to have human-to-human transmission.¹ Therefore, COVID-19 has expanded the infection risk from Wuhan to cities throughout China and even the world via case transportation.² Providing qualified personal protection equipment (PPE) to health care personnel plays an essential role in avoiding occupational exposure and infection. U.S. Centers for Disease Control and Prevention for COVID-19 infection control of health care personnel recommended gloves, gowns, respiratory protection, and eye protection as standardized PPE.³ However, protective clothing, N95 respirators, and goggles are not commonly used in clinical practice and hence are not in bulk stock. This brief report aims to present our interim hospital management measures on the health care personnel protection in West China Hospital under the condition of intense workload and PPE supply shortage after the outbreak of COVID-19.

We retrospectively reviewed the daily ED visits and PPE supply records from January 13 to February 1, 2020. The fever visits at the ED soared from January 20 to January 25. The ratio of fever patients at the ED exploded to a peak of over 40% on January 25 and then fluctuated at about 30% (Figure 1A). Protective clothing, N95 respirators, and goggles could only ensure the daily supply for < 15% ED personnel (Figure 1B). However, West China Hospital adopted a series of measures to achieve "zero infection" among health care personnel.

• First, the online clinic was set to facilitate the patient triage (Figure 1C). Through free online consultation, the hospital preliminarily judged the treatment urgency, recommended nonemergency patients to delay hospital appointments or visit other nonantiepidemic hospitals, provided low-

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YC, QL, and JC contributed equally to this work.

The authors have no relevant financial information or potential conflicts to disclose.

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Authors' contributions: YC—conception, literature search, figures, data analysis, data interpretation, writing, and final approval; QL—conception, data collection, data analysis, data interpretation, and final approval; JC—conception, data collection, data analysis, data interpretation, and final approval; JC—conception, data collection, data analysis, data interpretation, and final approval; XG—writing, major revision, and final approval; CM—major revision and final approval; HY—major revision and final approval; ZC—conception, data interpretation, writing, and final approval; CL—conception, major revision, and final approval; LL—supervision, major revision, and final approval.

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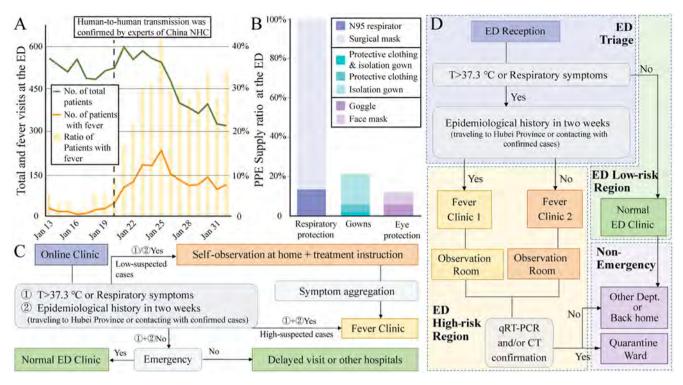


Figure 1. ED workload, PPE shortage, and hospital management plan during the COVID-19 epidemic. (A) The daily number and ratio of fever visits at the ED from January 13 to February 1, 2020. (B) The PPE supply ratio at the ED of West China Hospital on January 25. (C) The illustration of online clinic triage of West China Hospital. (D) The illustration of ED triage and region separation. NHC = National Health-care Commission; T = temperature.

suspected patients treatment instruction when selfisolating at home, and invited high-suspected patients to the Fever Clinic via the green channel. The online clinic effectively alleviated the ED workload and facilitated early detection of potential cases.

- Second, the interim visit triage and ED region separation were established (Figure 1D). The assigned personnel conducted preexamination and triage to divide visits into low-suspected, high-suspected, and other patients and required different patients to follow the specified routines to enter ED and separate the intra-ED space into high-risk and low-risk regions. For suspected cases, the hospital assigned an independent fever clinic room, fever observation room, and CT examination room. Cases confirmed through gRT-PCR and/or CT were transferred to quarantine ward while excluded patients went to other departments or back home. The ED region separation triage system reduced the cross-infection by restricting the activity ranges of both patients and ED personnel.
- Third, the ED requirement had the highest priority. The hospital established a capable command system, implemented effective coordination mechanisms,⁴ provided the ED with PPE and medical devices

preferentially, equipped the triage and high-risk-region personnel with standardized personal protection, withdrew or postponed nonurgent appointments and operations, and dispatched aid personnel from other departments to ED. These measures concentrated the limited supply through the hospital on the staff who mostly needed protection.

Emergency- and disaster-preparedness was an important issue and a global problem. Most hospitals could not maintain their routine work for a week due to the disaster-related resource shortage.⁵ A previous review highlighted the challenge of the emergency ordering of standardized PPE supply.⁶ The hospital invested greater efforts to establish an emergency management system based on the anticipated hazard.⁷ However, the unpredictable epidemic rendered the interim PPE preparedness impossible, especially for less-used PPE, protective clothing, and N95 respirators in daily work. It might be more practical to prepare a flexible hospital contingency plan than abundant PPE preparedness.

Our hospital adopted interim measures, including online consultation, region separation, and epidemic priority, to alleviate the pressure in the clinical work, reduce the cross-infection, and strengthen the protection

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of high-risk staff. Our hospital held the "zero infection" record, which was far lower than the simultaneous outside-Hubei mean level of 3.4% in late January.⁸ The zero infection indicated the flexibility and validity of our interim hospital management strategy.

However, there were still some limitations. First, the supply protocol compromised the health protection of low-risk personnel without standardized PPE. Second, the interim management strategies could not resist large-scale outbreak and long-term PPE shortage. Nevertheless, our management strategies, as a temporary emergency plan, created the biggest benefits of extremely limited resources to meet the emergency need. The long-term solution should be a sustainable supply chain. Fortunately, the government of China recovered the PPE production supply in February, which alleviated the supply shortage significantly.

In conclusion, the hospital emergency management plan of West China Hospital could alleviate the ED workload, protect health care personnel, and control the cross-infection during the COVID-19 epidemic. We advocate that every hospital should create the contingency plan suited to their conditions.

We acknowledge the colleagues at Emergency Department of West China Hospital and also all the colleagues combating COVID-19.

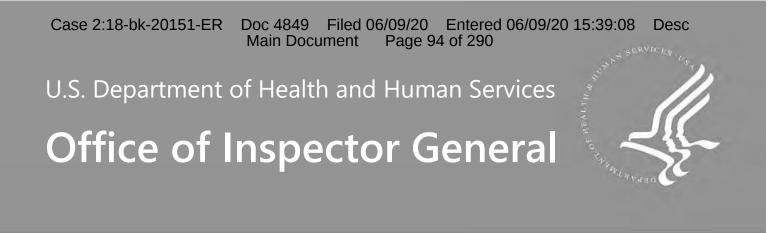
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Exhibit 10



Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020

Christi A. Grimm Principal Deputy Inspector General April 2020, OEI-06-20-00300



Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020

Purpose of the Review

This review provides the Department of Health and Human Services (HHS) and other decision-makers (e.g., State and local officials and other Federal agencies) with a national snapshot of hospitals' challenges and needs in responding to the coronavirus 2019 (COVID-19) pandemic. This is not a review of HHS response to the COVID-19 pandemic. We have collected this information as an aid for HHS as it continues to lead efforts to address the public health emergency and support hospitals and other first responders. In addition, hospitals may find the information about each other's strategies useful in their efforts to mitigate the challenges they are facing.

The hospital input that we describe reflects their experiences and perspectives at a point in time—March 23–27, 2020. The pandemic is fast-moving, as are the efforts to address it. We recognize that HHS, Congress, and other government entities across the Federal, State, local, and Tribal levels are taking substantial actions on a continual basis to support hospitals in responding to COVID-19. HHS has already taken and continues to take actions related to each of the challenges that hospitals identified in our survey, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act provides the basis for additional actions. We present this information for HHS's and other decision-makers' consideration as they continue to respond to the COVID-19 pandemic.

Key Takeaway

Hospitals reported that their most significant challenges centered on testing and caring for patients with known or suspected COVID-19 and keeping staff safe. Hospitals also reported substantial challenges maintaining or expanding their facilities' capacity to treat patients with COVID-19. Hospitals described specific challenges, mitigation strategies, and needs for assistance related to personal protective equipment (PPE), testing, staffing, supplies and durable equipment; maintaining or expanding facility capacity; and financial concerns.

How OIG Did This Review

This information is based on brief telephone interviews ("pulse surveys") conducted March 23–27, 2020, with hospital administrators from 323 hospitals across 46 States, the District of Columbia, and Puerto Rico, that were part of our random sample. Our rate of contact was 85 percent. Interviews focused on three key questions:

- 1. What are your most difficult challenges in responding to COVID-19?
- 2. What strategies is your hospital using to address or mitigate these challenges?
- 3. How could government best support hospitals responding to COVID-19?

Respondent hospitals included Special Pathogen Centers, critical access hospitals, and a range of hospitals nation-wide of various sizes and characteristics. At the time of our surveys, most hospitals reported they were treating patients with confirmed or suspected COVID-19, but some were not currently treating any patients with confirmed or suspected COVID-19, but some were not currently treating any patients with confirmed or suspected COVID-19, but some were not currently treating any patients with confirmed or suspected COVID-19.

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Findings at a Glance: Hospital Challenges

Severe Shortages of Testing Supplies and Extended Waits for Results

Hospitals reported that severe shortages of testing supplies and extended waits for test results limited hospitals' ability to monitor the health of patients and staff. Hospitals reported that they were unable to keep up with COVID-19 testing demands because they lacked complete kits and/or the individual components and supplies needed to complete tests. Additionally, hospitals reported frequently waiting 7 days or longer for test results. When patient stays were extended while awaiting test results, this strained bed availability, personal protective equipment (PPE) supplies, and staffing.

Widespread Shortages of PPE

Hospitals reported that widespread shortages of PPE put staff and patients at risk. Hospitals reported that heavier use of PPE than normal was contributing to the shortage and that the lack of a robust supply chain was delaying or preventing them from restocking PPE needed to protect staff. Hospitals also expressed uncertainty about availability of PPE from Federal and State sources and noted sharp increases in prices for PPE from some vendors.

Difficulty Maintaining Adequate Staffing and Supporting Staff

Hospitals reported that they were not always able to maintain adequate staffing levels or offer staff adequate support. Hospitals reported a shortage of specialized providers needed to meet the anticipated patient surge and raised concerns that staff exposure to the virus may exacerbate staffing shortages and overwork. Hospital administrators also expressed concern that fear and uncertainty were taking an emotional toll on staff, both professionally and personally.

Difficulty Maintaining and Expanding Hospital Capacity to Treat Patients

Capacity concerns emerged as hospitals anticipated being overwhelmed if they experienced a surge of patients, who may require special beds and rooms to treat and contain infection. Many hospitals reported that post-acute-care facilities were requiring negative COVID-19 tests before accepting patients discharged from hospitals, meaning that some patients who no longer required acute care were taking up valuable bed space while waiting to be discharged.

Shortages of Critical Supplies, Materials, and Logistic Support

Hospitals reported that shortages of critical supplies, materials, and logistic support that accompany more beds affected hospitals' ability to care for patients. Hospitals reported needing items that support a patient room, such as intravenous therapy (IV) poles, medical gas, linens, toilet paper, and food. Others reported shortages of no-touch infrared thermometers, disinfectants, and cleaning supplies. Isolated and smaller hospitals faced special challenges maintaining the supplies they needed and restocking quickly when they ran out of supplies.

Findings at a Glance: Hospital Challenges (continued)

Anticipated Shortages of Ventilators

Anticipated shortages of ventilators were identified as a big challenge for hospitals. Hospitals reported an uncertain supply of standard, full-feature ventilators and in some cases used alternatives to support patients, including adapting anesthesia machines and using single-use emergency transport ventilators. Hospitals anticipated that ventilator shortages would pose difficult decisions about ethical allocation and liability, although at the time of our survey no hospital reported limiting ventilator use.

Increased Costs and Decreased Revenue

Hospitals described increasing costs and decreasing revenues as a threat to their financial viability. Hospitals reported that ceasing elective procedures and other services decreased revenues at the same time that their costs have increased as they prepare for a potential surge of patients. Many hospitals reported that their cash reserves were quickly depleting, which could disrupt ongoing hospital operations.

Changing and Sometimes Inconsistent Guidance

Hospitals reported that changing and sometimes inconsistent guidance from Federal, State, and local authorities posed challenges and confused hospitals and the public. Hospitals reported that it was sometimes difficult to remain current with Centers for Disease Control and Prevention (CDC) guidance and that they received conflicting guidance from different government and medical authorities, including criteria for testing, determining which elective procedures to delay, use of PPE, and getting supplies from the national stockpile. Hospitals also reported concerns that public misinformation has increased hospital workloads (e.g., patients showing up unnecessarily, hospitals needing to do public education) at a critical time.

Findings at a Glance: Hospital Strategies

Secure Necessary PPE, Equipment, and Supplies

To secure the necessary PPE, equipment, and supplies, hospitals reported turning to new, sometimes un-vetted, and non-traditional sources of supplies and medical equipment. To try to make existing supplies of PPE last, hospitals reported conserving and reusing single-use/disposable PPE, including using or exploring ultra-violet (UV) sterilization of masks or bypassing some sanitation processes by having staff place surgical masks over N95 masks. Hospitals also reported turning to non-medical-grade PPE, such as construction masks or handmade masks and gowns, which they worried may put staff at risk.

Ensure Adequate Staffing

To ensure adequate staffing to treat patients with COVID-19, hospitals were training medical staff such as anesthesiologists, hospitalists, and nursing staff to help care for patients on ventilators.

Support Staff

To support staff, some hospitals reported assisting staff to access services such as childcare, laundry, grocery services, and hotel accommodations to promote separation from elderly family members.

Manage Patient Flow and Hospital Capacity

To manage patient flow and hospital capacity, some hospitals were providing ambulatory care for patients with less severe symptoms, offering telehealth services when possible, and setting up alternate facilities such as fairgrounds, vacant college dorms, and closed correctional facilities as additional spaces for patient care.

Secure Ventilators and Alternative Equipment to Support Patients

In anticipation of increased needs for ventilators, hospitals tried to obtain additional machines by renting ventilators, buying single-use emergency transport ventilators, or getting ventilators through an affiliated facility. Some hospitals reported converting other equipment, such as anesthesia machines, to use as ventilators.

Findings at a Glance: Hospital Requests for Assistance

The hospital input and suggestions in this report reflect a specific point in time—March 23–27, 2020. We recognize that HHS is also getting input from hospitals and other frontline responders and has already taken and continues to take actions toward each of these suggestions. For example, on March 28, 2020, the Centers for Medicare & Medicaid Services (CMS) announced the availability of advanced payments to hospitals and other providers, and on March 30, 2020, CMS announced an array of regulatory changes to increase hospitals' and other health care providers' flexibility in responding to this pandemic, including changes to support facility capacity and workforce, among many others.

We present hospitals' suggestions for ways that the government could assist them for HHS's and other decision-makers' consideration as they continue to respond to COVID-19. We note that authorities for some of the assistance sought by hospitals may reside with entities outside of HHS (e.g., other Federal agencies or States).

Testing, Supplies, and Equipment

Many hospitals noted that they were competing with other providers for limited supplies, and that government intervention and coordination could help reconcile this problem nationally. For example, hospitals wanted the government to ensure that they have access to test kits and swabs, make tests faster by allowing more entities to conduct and produce tests, and help hospitals obtain PPE supplies and other equipment such as ventilators.

Workforce Allocation

Hospitals requested that government allow reassignment of licensed professionals and realignment of duties as needed, provide flexibility with respect to licensed professionals practicing across State lines, and provide relief from regulations that may restrict using contracted staff or physicians based on business relationships.

Capacity of Facilities

Hospitals asked for relaxed rules around bed designations, the ability to establish surge facilities in non-traditional settings, and expanded flexibilities in telehealth, such as the types of services, caregivers, and modalities eligible to receive reimbursement.

Financial Assistance

All types of hospitals, and especially small rural hospitals, requested financial assistance, including faster and increased Medicare payments, and loans and grants.

Communication and Information

Hospitals sought centralized communication and public information, including evidence-based guidance, reliable data and predictive models, and a central repository for all COVID-19-related guidance, data, and information.

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FINDINGS

Hospitals reported that their most significant challenges centered on testing and caring for patients with COVID-19 and keeping staff safe

Hospitals across the country reported facing similar challenges, regardless of which stage of the process they were in—treating patients with coronavirus 2019 (COVID-19), testing patients who were potentially infected, or preparing to treat COVID-19 patients in the near future. The most commonly reported challenges centered on hospitals' efforts to confirm cases of COVID-19, to keep health care staff safe, and to provide needed services to patients requiring hospital care for a wide array of medical reasons, including COVID-19. Challenges included difficulties related to testing, lack of personal protective equipment (PPE), and staffing, including specialized staffing.

Hospitals reported that severe shortages of testing supplies and extended waits for test results limited hospitals' ability to monitor the health of patients and staff

Hospitals explained that they were unable to keep up with testing demands because they lacked complete kits and/or the individual components and supplies needed to complete tests, such as nasal swabs, viral transfer media, and reagents used to detect the virus. These shortages left hospitals unable to effectively test staff, patients, and others in the community who reported that they were concerned about possible exposure. One hospital administrator said that across the industry, "millions [of tests] are needed, and we only have hundreds." Without access to needed testing materials, some hospitals described dividing the media in COVID-19 kits in half to double their capacity and resorting to using the transfer media in flu and strep kits to provide testing.

Hospitals described extended waits for COVID-19 test results. Hospitals reported frequently waiting 7 days or longer for test results. According to one hospital, 24 hours would typically be considered a long turnaround time for virus testing. Hospitals' reliance on external laboratories contributed to delays, particularly as these laboratories became overwhelmed with tests to process from around the State or country. Hospitals also reported delays related to infrequent specimen pickups, mailing delays, and labs' restrictive business hours. Some hospitals described success getting results more quickly by using commercial labs, whereas others received more timely results from public sources. Still others experienced inconsistent turnaround times, leaving them unable to predict when results would arrive or advise patients on how long they should self-quarantine or undertake other measures while awaiting results.

Testing challenges exacerbated other challenges, including bed availability, PPE supplies, and staffing shortages. Hospitals reported that to prevent the spread of the virus in the hospital and community, they were treating symptomatic patients as presumptive positive cases of COVID-19 (i.e., an individual with symptoms that strongly indicate COVID-19 and tests have ruled out

similar conditions, but without a positive COVID-19 test result). The scarcity of COVID-19 tests and length of time it took to get test results back meant presumptive positive patients greatly strained bed availability, PPE supplies, and staffing, as noted in Exhibit 1.

Exhibit 1: Hospitals reported that the lack of testing supplies and delays in receiving test results caused additional challenges.

Patients stayed in beds Staff used PPE in Staff may not have known whether they were exposed to patients with longer and experienced interactions with delays in transfers while patients that they the virus or if they had the virus. To they waited for tests may not have avoid potentially spreading the and/or test results. needed to use. virus, staff may have stopped providing clinical care while unsure if they were contagious.

Hospitals reported that some presumptive positive patients remained in the hospital for days while awaiting test results, which reduced the hospitals' availability of beds for other patients. One hospital that was holding presumptive positive patients in intensive care unit beds reported that testing with a quick turnaround would free up bed availability and increase patient and staff safety. An administrator at another hospital noted that the sooner the hospital knows whether patients are negative, the faster it can move them to a lower level of care that consumes fewer resources. As one administrator put it, "sitting with 60 patients with presumed positives in our hospital isn't healthy for anybody."

Hospitals reported that extended patient stays while awaiting COVID-19 test results also depleted PPE supplies used by staff in treating those patients during those additional days. One hospital reported that its staff, at the time of our interview, used (on average) 307 masks per day for its 23 patients with suspected cases of COVID-19. Another hospital administrator said, "The testing turnaround presents a challenge, especially for our 'rule-out' patients...we have to use a lot of PPE on those rule-outs. And especially when it's a negative, we basically used all that PPE for nothing."

The inability to quickly identify confirmed cases exacerbated challenges with hospital staffing. In one hospital, between 20-25 percent of staff were determined to be presumptively positive for COVID-19. Due to the lack of quick test results, staff who ultimately were not positive were prevented from providing clinical services for longer than necessary, causing a substantial strain on staffing availability. Another hospital noted that it wanted to set up a separate testing clinic to keep potentially infectious patients from exposing staff, but it did not have enough testing kits and/or related components and supplies to set up such a clinic.

Delays in receiving test results also made it more challenging for hospital staff to provide patients with the most appropriate care. One hospital reported that these delays put patients at risk because physicians were unable to make effective treatment decisions without the test results. Another said that some patients faced unnecessarily long hospital stays because some long-term-care facilities and nursing homes will not accept patients without a confirmed negative COVID-19 test.

Testing challenges hampered hospitals' efforts to reduce community spread, protect staff, and care for patients. Hospitals reported that their inability to test patients quickly was affecting their efforts to limit the transmission of COVID-19 within the wider community. Given supply

shortages and uncertainty about future access, hospitals reported prioritizing testing for their employees and for patients with more severe symptoms. Prioritized testing meant that many hospitals reported they were currently unable to conduct widespread testing of patients and community members to help contain the spread of COVID-19.

Hospitals raised concerns that widespread shortages of PPE put staff and patients at risk

Hospitals across the country reported that a shortage of PPE was threatening their ability to keep staff safe while they worked to treat patients with COVID-19. The most commonly needed PPE items reported were masks (including N95 masks, surgical masks, and face shields), followed by gowns and gloves.

Hospitals reported that heavier than normal use of PPE contributed to shortages. The administrator of one hospital stated that before COVID-19, the hospital's medical center used around 200 masks per day and that it was now using 2,000 per day. Delays in test results led to heavier use of PPE until a patient's status was confirmed. Another hospital administrator noted the "fear factor" associated with COVID-19, which led to all staff wearing masks instead of only a subset. One hospital administrator reported that some supply distributors limited the quantity of supplies that any one hospital could order, which meant that even with no COVID-19 patients, the hospital was depleting PPE faster than it could restock. Even among hospitals that reported that they currently had enough PPE, some noted that a surge in patients would quickly deplete their supplies. One hospital noted that with its high "burn" rate (i.e., rate of use), its inventory of PPE would last only 3 more days. Another hospital administrator expressed a common concern: not wanting to put employees in a position that "endangers their lives and the lives of their families because [they] do not have PPE."

Hospitals pointed to the lack of a robust supply chain as delaying or preventing them from restocking the PPE needed to protect staff. Hospitals reported that the supply chain for medical equipment had been disrupted because of increased demand for PPE from health care providers and others around the country. As one administrator said, everyone is "trying to pull [PPE] from the same small bucket." Another administrator stated that their hospital's purchaser was reporting delays of 3-6 months in being able to replenish key supplies, including surgical and N95 masks. Another hospital made the point that this competition for supply was unusual in that it involved not only health care providers, but also the public. An administrator at this hospital reported apprehending a person trying to steal face masks from the hospital lobby.

Hospital administrators expressed uncertainty about availability of PPE from Federal and State sources. Some hospitals noted that at the time of our interview they had not received supplies from the Strategic National Stockpile, or that the supplies that they had received were not sufficient in quantity or quality. One administrator stated that getting supplies from the stockpile was a major challenge, saying that the supplies the hospital received "won't even last a day. We need gloves, we need masks with fluid shields on—N95 masks—and we need gowns. It's the number one challenge all across the system." One health system reported that it received 1,000 masks from the Federal and State governments, but it had been expecting a larger resupply. Further, 500 of the masks were for children and therefore unusable for the health system's adult staff. One hospital reported receiving a shipment of 2,300 N95 masks from a State strategic reserve, but the masks were not useable because the elastic bands had dry-rotted. Another hospital reported that the last two shipments it had received from a Federal agency contained PPE that expired in 2010. The shipment contained construction masks that looked different than traditional masks and did not contain a true N95 seal.

Hospitals noted sharp increases in prices for some equipment. Multiple hospitals reported concerns that prices of equipment, particularly masks, had increased significantly. One administrator noted that masks that originally cost 50 cents now cost \$6 apiece. Other hospitals reported concerns about vendors buying up supplies and selling them to the hospital at a higher cost. As one hospital administrator noted, "We are all competing for the same items and there are only so many people on the other end of the supply chain." Another administrator reported being concerned about poor quality products despite high-prices and "...wonder[ing] if you get what you paid for."

Hospitals reported that they were not always able to maintain adequate staffing levels or to offer staff adequate support

Many hospitals reported that they did not have enough staff to meet current or anticipated needs for COVID-19 patients, which put a strain on existing staff. Some hospitals reported that they were already struggling with staffing limitations prior to COVID-19, which made any additional demand particularly challenging. One hospital administrator explained that their hospital would have significant staffing shortages if faced with a surge of COVID-19 patients because the hospital relies heavily on traveling nurses. Another administrator stated, "Unlike a disaster where the surge is over in a matter of days, with this situation we have to prepare for this to last many months. We have to scale up in equipment and staff, and prepare for this to last a long, long time. This is very challenging for staff."

Hospitals reported a shortage of specialized providers needed to meet the anticipated

patient surge. Several hospitals emphasized a particular need for specialized staff, such as infectious disease providers, respiratory therapists, and physicians and nurses who can provide intensive and critical care. Many hospitals also stated that they lacked trained staff that can operate ventilators and treat patients receiving that level of care. One hospital administrator said his hospital has only one ventilator and only one respiratory therapist, adding that the therapist can't work 24 hours a day monitoring the ventilator. Another administrator said, "You can build thousands of ventilators, but you need an army to manage that equipment and care for those patients."

Hospitals raised concerns that staff exposure to the virus may exacerbate staffing

shortages and overwork. Several hospitals reported that they would struggle to maintain hospital operations if even a few staff were exposed to the virus. The administrator for one small, rural hospital explained that if one patient tested positive for COVID-19 the hospital would have to put 16 staff members in quarantine, which would essentially halt its operations. Administrators in two hospitals described how staffing levels in their facilities had been significantly impacted after a large number of staff had contracted or been exposed to the virus.

Hospital administrators expressed concerns that fear and uncertainty were taking an emotional toll on staff, both professionally and personally. Hospitals reported that fear of being infected, and uncertainties about the health and well-being of family members, were impacting

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morale and creating anxiety among staff. As one administrator put it, "The level of anxiety among staff is like nothing I've ever seen." Another hospital administrator explained that staff were carrying a heavy burden both professionally and personally. Professionally, staff were worried about the security of their jobs and the difficult choices they must make regarding their patients, such as who should get one of a limited number of tests. They also feared contracting the virus. At one hospital, a staff member who tested positive exposed others on staff, but the hospital did not have enough kits to test those exposed. Personally, staff were worried about spreading the virus to their family members and ensuring that their families were cared for, especially with schools and daycare centers being closed. As one administrator said, "Health care workers feel like they're at war right now...[they] are seeing people in their 30s, 40s, 50s dying...This takes a large emotional toll."

Hospitals also reported substantial challenges maintaining and expanding capacity to care for patients

The other most prominent concerns reported by hospital administrators centered on maintaining facility operations while receiving and treating patients with known or suspected cases of COVID-19. These challenges included concerns about bed availability, particularly specialized beds such as intensive care unit beds, and supplies, as well as maintaining financial solvency given reductions in routine patient care and elective surgeries.

Hospitals were concerned about their capacity to treat a surge of patients who may require special beds and rooms to treat and contain infection. Hospitals anticipated being overwhelmed by a surge in COVID-19 patients, who would need specialty beds and isolation areas for effective treatment. Specifically, hospitals reported concerns about potential shortages of intensive care unit beds, negative pressure rooms, and isolation units. Hospitals also reported that, given the limitations to bed availability, it was challenging to sufficiently separate COVID-19 and non-COVID-19 patients within their facilities. Separating patients is thought to allow health care workers to better coordinate and direct needed treatment specific to COVID-19 patients as well as reduce the spread of infection. One hospital administrator observed that: "Being a rural hospital, we have to be ready to convert beds to prepare for surge capacity. We still have to take care of our non-COVID situations. We have to make people feel like we can still take care of them if they have [an] emergent situation."

Hospitals reported being unable to discharge patients to certain post-acute facilities while awaiting COVID-19 test results. Many hospitals reported that some post-acute facilities, such as skilled nursing facilities or facilities with lower-level care, were requiring negative COVID-19 tests before accepting patients discharged from hospitals. As such, patients who no longer required acute care were taking valuable bed space while waiting to be discharged. One hospital reported a case in which a post-acute-care facility refused to take a patient unless the hospital sent them a week's worth of masks for the patient and for the staff who would care for the patient, even though the patient was not positive for COVID-19. Delays in receiving test results contributed to delays in transferring patients to these lower level facilities and in freeing beds in the hospitals for incoming COVID-19 patients.

Hospitals reported concerns about securing other critical supplies, materials, and logistic support

Hospitals reported they do not have a reliable source for the equipment and supplies they use to support patient care. One hospital reported that, in addition to beds, it needed to source the materials that accompany additional beds and did not know where to order them. For example, hospitals described the supplies that support a patient room, such as intravenous therapy poles, medical gas, linens, and food. Multiple hospitals also cited a shortage of toilet paper. Hospitals discussed the need for supportive services, such as sanitation services, staffed mobile field hospitals, and mortuary services, as well as the construction work and maintenance needed to convert rooms.

Hospitals reported shortages of no-touch, infrared thermometers needed for

temperature screening. One hospital reported an inability to implement a policy to screen all hospital entrants because it did not have enough no-touch thermometers to allow for timely testing and avoid long lines at entrances. (No-touch thermometers use infrared technology to rapidly provide accurate temperature results.) This hospital reported it resorted to only screening patients, staff, and vendors on a random basis. Similarly, another hospital explained that it was unable to monitor employee temperatures in a timely manner, given it had a 700-plus person staff and had just a few of the no-touch thermometers that could be devoted to staff testing rather than patient care.

Hospitals faced shortages of disinfectants and cleaning supplies. Hospitals reported insufficient inventory of essential cleaning supplies, such as disinfectant wipes, hand sanitizer, and hand soap. One hospital described being unable to buy disinfectant cleaning supplies and not knowing when supplies will be available. Another hospital described making disinfectants, such as bleach, out of on-hand chemicals, such as chlorine.

Isolated or smaller hospitals reported that they have a harder time accessing necessary

supplies. Isolated and smaller hospitals reported that they were facing special challenges maintaining the supplies they need to continue their operations. One hospital noted that its island location made it difficult to restock quickly when it runs out of supplies. Another hospital reported that it was not able to request the amounts of disinfectants and other supplies that it needed from the State. Instead, products were "divvied up" by the State, and because the hospital is small, it received fewer of the products and supplies than larger hospitals.

Hospitals cited anticipated shortages of ventilators as a potential challenge

Many hospitals reported concerns that they would not have enough ventilators if faced with a surge of COVID-19 patients. One administrator explained the difficulty of predicting whether a surge would come and how many ventilators would be needed, "[We] just don't know two weeks down the road what we will need." Hospitals pointed to overall supply shortages and the unavailability of ventilators in other facilities, as well as the scarcity of ventilator components such as tubes.

Some hospitals' concerns about the supply of ventilators were exacerbated by their small

size. Small hospitals reported that they were able to maintain few, if any, ventilators. Some of these hospitals described contingency plans to repurpose alternative machines from other hospital

departments or to transport patients to other facilities, if needed. However, one hospital with no ventilators expressed concern that if a patient needs ventilation, neighboring hospitals may not have the space to take them. Another hospital noted that larger hospitals may be given priority in receiving ventilators.

Hospitals also explained that potential ventilator shortages would pose difficult

decisions about ethical allocation and liability. As hospitals planned for a surge of patients, many reported that they were either developing or revising guidelines regarding ventilator utilization decisions, although at the time of our survey no hospital reported limiting ventilator use. Some administrators noted that with difficult decisions about ventilator allocation also come concerns about liability. For example, one hospital administrator described concerns about the liability embedded in decisions regarding which patients would receive assistance from a ventilator and which would not, concluding that: "Government needs to provide guidelines on ethics if health resources are limited and decisions need to be made about which patients to treat. Are physicians liable for their decisions if that happens?"

Hospitals described increasing costs and decreasing revenues as a threat to their financial viability

Hospitals reported that the increased costs and loss of revenue were quickly depleting cash reserves and could be disruptive to ongoing hospital operations. Hospitals reported having essentially ceased performing elective procedures and many other services, which many hospitals said accounted for a substantial portion of their revenue. Meanwhile, hospitals explained that their costs have increased as they prepare for a potential surge of patients by purchasing extra equipment (such as PPE and ventilators), remodeling rooms for negative pressure, or setting up drive-through clinics and tents. One administrator explained that having cash on hand was becoming an urgent issue with the specialty clinic volume down 80 percent, primary care volume down 50 percent, and cancellation of all elective surgeries. One administrator said their hospital is in a favorable financial position, but it is concerned it could be overwhelmed if other hospitals close. Another administrator said their hospital is tracking all of its costs for treating COVID-19 patients or potential cases, so that it can be reimbursed in the future. Other hospitals reported laying off staff due to financial difficulties, which further exacerbated workforce shortages and the hospitals' ability to care for COVID-19 patients and the routine patient population. One administrator stated that it had been "an absolute financial nightmare for hospitals."

Hospitals that were part of a larger health system reported that they considered themselves to be better situated to absorb financial losses compared to smaller independent and rural hospitals. Being part of a larger health system enabled hospitals to distribute losses from the hardest hit hospitals to the other hospitals in the system. Smaller, independent hospitals, such as rural hospitals and critical access hospitals, reported that they were at greater financial risk than those in larger systems and that they could face more financial uncertainty. As one hospital administrator observed, "There is no mothership to save us."

Hospitals reported circumstances in which insurance reimbursements were not covering hospitals' costs for providing services in the midst of the COVID-19 crisis. Hospital administrators reported that insufficient reimbursement for some services and a lack of flexibility in

billing rules that affect reimbursement amounts have created financial challenges. For example, some hospitals were using telehealth to provide services without patients having to come to the hospital, but reported that reimbursement amounts for telehealth services often do not cover the hospitals' costs. In another example, hospitals reported facing resistance from health plans to paying for patients' additional days in the hospital while the patients were awaiting COVID-19 test results. Negative test results were needed for the patients to be accepted for admission or re-admission at post-acute-care facilities and nursing homes.

Further, hospitals reported difficulty in getting reimbursed for treating patients in non-traditional spaces because there were no qualifying billing codes when treating patients in these locations. For example, to mitigate COVID-19 spread, one hospital relocated speech, occupational, and physical therapy services off-site. However, the hospital said it was unable to bill for these services because it does not own the building housing the relocated services, or meet billing requirements.

Hospitals reported that changing and sometimes inconsistent guidance from Federal, State, and local authorities posed challenges and confused hospitals and the public

Hospitals reported that it was sometimes difficult to remain current with CDC guidance when training staff on PPE and safety precautions. To reduce the spread of COVID-19 and prepare staff for patient surges, hospitals reported providing training regarding proper use of PPE, procedures for putting on and taking off PPE, and isolation practices. As new information about the virus becomes available and circumstances on the ground change, the Centers for Disease Control and Prevention (CDC) has changed its guidance over time. However, some hospital administrators expressed that it was challenging to stay up to date with CDC guidance and re-educating staff on changes to the guidance (e.g., who needs PPE, when to remove it, and when to reuse it). Some hospitals reported that the multiple changes in guidance contributed to a greater sense of confusion, fear, and distrust among staff that they could rely on hospital procedures to protect them.

Hospitals reported instances of receiving conflicting guidance from different Federal, State, and local authorities. Hospitals reported receiving conflicting guidance on criteria for testing, defining elective procedures to delay, use of PPE, and getting supplies from the national stockpile. For example, on proper use of PPE, one hospital administrator reported that CDC guidelines at that time called for use of an N95 mask for all patients suspected of COVID-19 infections, while at the same time, one State said that using a surgical mask and face shield was sufficient for staff treating patients with COVID-19. The hospital noted "[The inconsistency] makes everyone nervous. It would have been better if there was coordination and consistency in guidance among the different levels of government." Another administrator said, "It's difficult when a doctor or nurse shows you legitimate information from legitimate sources and they're contradictory."

Hospitals also reported concerns that misinformation had proliferated among the public, unnecessarily increasing workload on hospitals at a critical time. Many hospital administrators reported needing to spend time responding to fear, lack of information, and lack of understanding in their public communities, which they attributed to an absence of clear, accurate, and

consistent information. These hospitals reported having to dispel misinformation and unrealistic

expectations among patients about testing and other issues, as well as having to work to educate the community about proper steps to prevent the spread of COVID-19 and when to seek medical attention versus self-isolating at home. One hospital administrator reported the challenge of taking on a public health advocacy role with mayors and county commissioners to advocate implementing social distancing at beaches, restaurants, and the like to slow the spread of COVID-19, in addition to performing normal duties. Another hospital administrator reported that employers were telling employees they cannot return to work without testing negative and that the hospital was having a difficult time educating employers that only certain people can be tested. One administrator stated: "The misinformation that is out there, and the lack of serious understanding about what we could be facing, is extraordinary. It is not helping the situation at all. We need to take this seriously."

Hospitals reported using a range of strategies to maintain or expand their capacity to care for patients and to keep staff safe

Hospital strategies often attempted to address multiple challenges. These efforts included broad-scale ideas that involved multiple providers and suppliers across the country, as well as smaller-scale, community-based efforts that rose in some cases from hospital leadership and staff, other public health stakeholders, and the general public. For a more detailed list of operational strategies that hospital administrators shared, see Appendix A.

Hospital administrators turned to alternative practices and unconventional sources to secure necessary PPE, equipment, and supplies for their staff

In an attempt to get needed equipment and supplies, hospital administrators turned to new, sometimes un-vetted, and non-traditional sources. The lack of PPE caused hospitals to consider new and un-vetted sources for PPE of whose reputability they were sometimes unsure. One hospital reported that in working with new vendors, some ordered items did not show up, were expired, or were different than what was ordered. The administrator also stated that the hospital did not have the ability to evaluate the quality of the equipment in a meaningful way.

Some facilities stated that they turned to non-traditional sources of medical equipment and supplies to combat supply chain disruptions. For instance, some hospitals considered sources for PPE that they would not normally use—such as online retailers, home supply stores, paint stores, autobody supply shops, and beauty salons.

To try to make existing supplies of PPE last, hospitals reported conserving and reusing

PPE. Hospital administrators discussed implementing or considering new procedures to conserve PPE, including physically securing PPE to prevent theft or misuse, educating staff on appropriate use and conservation, and limiting PPE use according to patient condition. Other hospitals reported reducing the extent and frequency of patient interaction to reduce PPE burn; this included doing as much for a patient as possible in one interaction, having multiple providers see a patient together, or removing equipment like intravenous pumps from patients' rooms so that it could be prepped elsewhere without

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PPE. At one facility, staff tested patients at remote sites to, in part, reduce PPE use. Hospitals indicated that staff performing testing remotely can remain in PPE all day, whereas staff who test inside hospitals typically change PPE frequently when moving from suspected COVID-19 patients to other patients. Another hospital described being in 'war mode' and abandoning the typical standard of care by only using N95 masks for certain higher-risk procedures for COVID-19 patients such as aerosolized procedures, which can send the virus into the air and put health care workers at risk.

Conservation strategies included reusing PPE, which is typically intended to be single-use. To reuse PPE, some hospitals reported using or exploring ultra-violet (UV) sterilization. Other hospitals reported bypassing some sanitation processes by having staff place industry masks over N95 masks so that the N95 mask could be reused. As one administrator characterized the situation, "We are throwing all of our PPE best practices out the window. That one will come back and bite us. It will take a long time for people to get back to doing best practices."

Hospitals also reported turning to non-medical-grade PPE, which they worry may put

staff at risk. Instead of reusing medical-grade equipment, some hospitals reported resorting to non-medical-grade PPE such as construction masks or handmade masks and gowns, but were unsure about the guidelines for how to safely do it. For example, one hospital administrator noted that recommendations were not clear about whether cloth masks were good enough, stating, "But if that's what we have, that's what we're going to have to use." One hospital reported using 3D printing to manufacturer masks, while another hospital reported that its staff had made 500 face shields out of office supplies.

Other hospitals reported using community resources to make ends meet, including accepting homemade cloth gowns from a quilter's guild, asking volunteers to make masks, and asking for donations on their website. One hospital administrator described a plan for the local distillery to blend 100 liters of the hospital's ultrasound gel with the distillery's alcohol to produce CDC-compliant hand sanitizer.

Hospital strategies also focused on ensuring adequate staffing to treat patients with COVID-19

Hospital administrators reported using strategies aimed at ensuring they had sufficient staff with the needed skills to treat COVID-19 patients where most needed. For example, some administrators shared that their hospitals were training certain medical staff, like anesthesiologists, hospitalists, and nursing staff, to help care for patients on ventilators. Further, hospitals touted partnerships with large health care systems as beneficial because they can deploy medical staff, like nurses, to other hospitals in the health care system that may be experiencing a staff shortage.

Hospitals reported providing resources to help reduce employee burden as well as anxiety and stress

To ease anxiety and reduce outside burdens on staff that could distract them or prevent them from working, some facilities reported assisting staff to access services such as childcare, laundry pick up and drop off, grocery services, and hotel accommodations to promote separation from elderly family members. Hospitals also reported offering or expanding resources to provide employees with

emotional and psychological support. One hospital shared that it recruited external mental health clinicians and engaged its own psychiatry staff to help alleviate anxiety among hospital staff.

Some strategies focus on managing patient flow and hospital capacity to receive and treat patients

Hospital administrators reported using several strategies to manage patient flow as they respond to their communities' needs during the COVID-19 pandemic. Strategies included promoting the use of ambulatory care for patients with less severe symptoms to help relieve the pressure on emergency departments, and the use of telehealth services when possible to help protect both patients and staff through social distancing measures. In addition, to help triage patient flow into the hospitals, hospital administrators described efforts to educate community members about COVID-19 screening or testing processes to avoid patients entering the hospital if not advised under guidelines.

To address potential bed and facilities shortages, some hospitals reported converting or creating space to house a surge of additional patients. This included expanding their intensive care units, repurposing existing space, using tents, and utilizing other network facilities to separate COVID-19 patients when possible. One hospital administrator explained their strategy: "I've emptied the hospital and I'm waiting for it to come. Which it may or may not." Some hospital administrators described plans to make use of other facilities, such as local fairgrounds, vacant college dorms, and closed correctional facilities as additional space for patient care in the event of a surge.

With an uncertain supply of standard, full-feature ventilators, hospitals sought new sources and turned to alternative equipment to support patients

In anticipation of increased needs for ventilators, hospitals tried to obtain additional machines by renting ventilators, buying single-use emergency transport ventilators, or getting ventilators through an affiliated facility. Hospitals also discussed sharing supplies of ventilators between hospitals. Where these options were not available, some hospitals planned to transfer patients in need of a ventilator to a nearby hospital.

Some hospitals reported converting other equipment to use as ventilators. For example, adapting anesthesia machines and bilevel positive airway pressure machines. One hospital reported considering "doubling up on ventilators – that is, adding another hose to the ventilator so that it can push oxygen to two patients from a single machine." Another hospital detailed its staff's efforts at both converting anesthesia machines and using them to support more than one patient: "Our staff had figured out that we could transition some anesthesia machines using t-connectors and viral filters to turn them into ventilators. You jerry-rig the anesthesia machine by using a t-connector, you can support four patients off one of these."

Hospitals reported pressing needs for government assistance to meet COVID-19 challenges

Faced with the magnitude and diversity of challenges described above, hospital officials identified a range of government assistance that could support their COVID-19 response. One common theme was

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the need for swift action to respond to the COVID-19 crisis. Broadly, the actions they described fall into five categories: 1) assistance with testing, supplies, and equipment (e.g., PPE); 2) assistance with workforce allocation; 3) assistance with capacity of facilities; 4) financial assistance; and 5) communication and public information.

The hospital input and suggestions reflect a specific point in time—March 23–27, 2020. We recognize that the Department of Health and Human Services (HHS) is also getting input from hospitals and other frontline responders and has already taken and continues to take action to alleviate many hospital challenges and implement suggestions. The Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law on March 27, 2020, and provides HHS with additional funding and authorities to combat and respond to the COVID-19 pandemic, including in ways that address challenges and suggestions raised by the hospitals we surveyed.^{1, 2}

We present the following hospital suggestions on ways that the government could assist them for HHS's and other decision-makers' consideration as they continue to respond to COVID-19.

Assistance with testing, supplies, and equipment

In discussing potential government assistance related to testing, supplies, and equipment, hospitals often stated that they were in competition with other providers for limited supplies, and that government intervention and coordination could help reconcile this problem at the national level to provide equitable distribution of supplies throughout the country.

Hospitals wanted the government to:

- provide test kits and swabs, or for the government to take steps to ensure that supply chains can provide hospitals with a sufficient supply of tests;
- make testing faster by allowing more entities to produce tests and related supplies or to conduct tests;
- help in obtaining a range of supplies, such as N95 masks, surgical masks, gloves, and other protective gear;
- provide equipment such as ventilators, triage tents, and beds, among others, or take steps to bolster supply chains to provide needed equipment; and,
- loosen restrictions around the transfer or gifting of equipment and supplies (e.g., when providers want to send supplies necessary for treatment with patients when transferring them to another facility).

Assistance with workforce allocation

Given their concerns about staffing shortages, hospitals reported that they needed the government to enable maximum flexibility among their care-giving workforce.

Hospitals wanted the government to:

- enable reassignment of licensed professionals and realignment of duties within the hospital and throughout their health care networks;
- provide flexibility with respect to licensed professionals practicing across State lines,
- provide relief from regulations that may restrict using contracted staff or physicians based on business relationships.

Assistance with capacity of facilities

Hospitals reported concerns with their capacity to house a surge of COVID-19 patients. They described a range of government actions that they believe would help them on this front.

Hospitals wanted the government to:

- relax rules around the designation of bed types;
- take steps that enable hospitals to establish surge facilities in non-traditional settings such as hotels and civic centers; and
- allow more patients to be treated at home by expanding access to telehealth through flexibilities in the types of services, caregivers, and modalities eligible to receive reimbursement.

Financial assistance

Hospital representatives across all types of hospitals (and in particular small, rural hospitals) reported that they need financial assistance. Notably, some hospitals reported needing assistance in a matter of weeks in order to avoid insolvency.

Hospitals wanted the government to:

- speed up Medicare payments by dropping the 14-day wait period;
- increase Medicare payments; and
- offer loans and grants.

Communication and information

Hospitals told us that they thought the Federal Government could play a central role in messaging and communications to mitigate what they perceived to be conflicting or inconsistent guidance across levels of government, as discussed in the challenges.

Hospitals wanted the government to:

- provide evidence-based guidance (and as an example, they highlighted the usefulness of CDC's guidance on conserving N95 masks);
- provide reliable predictive models and data that would help them plan and prepare; and
- provide a single place to find the information they need, including information on the COVID-19 disease, guidance from agencies, and instructions for processes they need to follow, such as how to apply for waivers from certain requirements.

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CONCLUSION

This report provides information about hospitals' experiences and perspectives in responding to COVID-19 at a point in time—March 23–27, 2020. The pandemic is fast-moving, as are the efforts to address it. Since our interviews, some hospital challenges may have worsened and others may have improved. Hospitals reported that their most significant challenges centered on testing and caring for patients with known or suspected COVID-19 and keeping staff safe. Hospitals also reported substantial challenges maintaining or expanding their facilities' capacity to treat patients with COVID-19.

We recognize that HHS, Congress, and other Federal, State, local, and Tribal entities are taking substantial action on a continual basis to support hospitals as they work on the frontlines to treat patients, ensure the safety of the health care workforce, and protect communities. We present this information for HHS's and other decision-makers' consideration as they continue to respond to the COVID-19 pandemic. In addition, hospitals may find the practical information about other hospitals' strategies useful as they confront the many challenges they face in fulfilling their mission.

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BACKGROUND

Hospital Response to the COVID-19 Pandemic

The emergence of COVID-19 has created unprecedented challenges for the U.S. hospital system.³ As frontline responders, hospitals have significant responsibilities for identifying and treating patients with COVID-19. Hospitals around the country are adapting to the constantly changing face of the COVID-19 pandemic by adopting both expected and novel strategies to tackle the crisis. (See Appendix A on pages 21–25 for a list of hospital strategies reported.)

The Emergence of COVID-19

Four main sub-groupings of coronaviruses commonly circulate among humans worldwide, typically causing mild to moderate upper respiratory tract illnesses, and their incidence usually peaks annually in the United States during the winter months.^{4, 5, 6} COVID-19 is a highly contagious coronavirus.⁷ Common symptoms include fever, tiredness, dry cough, and shortness of breath, and it can be fatal in some cases.⁸

The first reported instances of COVID-19 occurred in Wuhan, Hubei Province, China, in December 2019 and January 2020.⁹ On January 13, 2020, the first patient with COVID-19 was reported outside of China, and the first patient in the U.S. was reported 7 days later.¹⁰ In late-February 2020, a hospital in California documented the first community spread transmission of COVID-19, meaning the illness was acquired through an unknown exposure in the community in the U.S.¹¹

On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic, which refers to an epidemic that has spread over several countries or continents, usually affecting a large number of people.^{12, 13} As of April 3, 2020, CDC reported 239,279 confirmed cases in the U.S. and 5,443 deaths.¹⁴

Role of HHS in Emerging Infectious Disease Preparation and Response

HHS is the lead federal agency responsible for medical support and coordination during public health emergencies, such as emerging infectious disease (EID) outbreaks. HHS operating divisions involved in the Federal response to EIDs, including the current COVID-19 response, include the Office of the Assistant Secretary for Preparedness and Response (ASPR), CDC, CMS, and the Food and Drug Administration (FDA).¹⁵

ASPR coordinates HHS's response to public health emergencies with other Federal agencies, such as the Federal Emergency Management Agency. ASPR also maintains the Strategic National Stockpile, which supplements State and local stocks of life-saving pharmaceuticals and medical supplies for use in a public health emergency.¹⁶ Since 2010, ASPR has managed the Hospital Preparedness Program, which provides grants to States and localities to distribute to hospitals and health care coalitions for improved preparedness. Health care coalitions are groups of health care providers and public health entities that

work together to prepare for, respond to, and recover from emergencies.^{17, 18} ASPR also created the Technical Resources, Assistance Center, and Information Exchange to provide information and technical assistance to health care coalitions, health care providers, and other stakeholders during public health emergencies.¹⁹

Following the Ebola outbreak in 2014, ASPR designated 10 hospitals as Ebola and Other Special Pathogen Centers.^{20, 21} ASPR defines "special pathogens" as highly infectious agents that produce severe disease in humans.²² These centers are to maintain capability to accept patients with suspected or diagnosed illness from special pathogens within 8 hours of notification and to conduct quarterly exercises to prepare for an EID outbreak.²³ During 2017–2018, all 10 Special Pathogen Centers participated in on-site readiness consultations conducted by the National Ebola Training and Education Center, which is a collaborative effort involving ASPR, CDC, and several academic institutions. The results of these assessments indicate that Special Pathogen Centers have higher levels of operational readiness to provide care to patients with special pathogens.²⁴

In response to COVID-19, ASPR is working with its partners to develop medical countermeasures and to provide resources to support the U.S. health care system's response. On March 24, 2020, ASPR indicated that it will provide \$100 million to support U.S. health care systems in getting ready for an increase in patients with COVID-19.²⁵

CDC monitors and responds to public health emergencies, such as EIDs, conducts research, and provides guidance to health care providers, government entities, and the public.²⁶ In response to COVID-19, CDC recently released interim guidance for U.S. health care facilities on preparing for community transmission of COVID-19,²⁷ along with strategies for optimizing the supply of N95 respirators,²⁸ and steps health care facilities can take to prepare for COVID-19.²⁹

CMS oversees hospitals participating in Medicare and Medicaid by requiring them to meet Conditions of Participation, a set of minimum health and safety standards.^{30, 31} To help to address challenges presented by COVID-19, CMS has waived some requirements under the emergency authority set forth in Section 1135 of the Social Security Act.³² In addition, under its 1135 waiver authority and the Coronavirus Preparedness and Response Supplemental Appropriations Act, CMS expanded the telehealth benefit for Medicare beneficiaries to allow beneficiaries to "receive a wider range of services from their doctors without having to travel to a health care facility."³³

FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.³⁴ FDA is working with hospitals and the medical industry to develop vaccines, drugs, and diagnostic tests while monitoring the medical supply chain during the COVID-19 outbreak.³⁵ FDA is also issuing emergency use authorizations for ventilators and other medical devices to treat patients.³⁶

Personal Protective Equipment

PPE is protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury or infection. PPE also includes a variety of types of respirators and face

masks.³⁷ Most relevant to the types of PPE that hospitals are commonly using in treating patients with known or suspected cases of COVID-19 is the N95 respirator mask, a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles.³⁸

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METHODOLOGY

Data Collection and Scope

We conducted a "pulse survey" (i.e., quick, point-in-time questions) by telephone (or in a few cases, by email) with administrators from a random sample of Medicare-certified hospitals across the nation and in some cases, their parent corporations. These conversations focused on three key issues regarding their COVID-19 response: 1) challenges responding to the COVID-19 pandemic, 2) strategies to mitigate the challenges, and 3) needs for government assistance.

We conducted the surveys on March 23–27, 2020 with one or more administrators. The positions of these hospital administrators were typically Chief Executive Officer, Chief Medical Officer, or representatives from teams and departments dedicated to emergency preparedness or incident command. In some cases, leadership from the relevant hospital networks participated in the interviews alongside hospital administrators or on the hospitals' behalf.

Hospital selection and response

We had previously selected a stratified random sample of 410 hospitals for an October 2018 report examining hospital preparedness for EIDs.³⁹ We selected the 410 hospitals from 4,489 Medicare-certified hospitals with emergency departments in 2016, located in 47 States, the District of Columbia, and Puerto Rico. The sample was comprised of two strata: (1) all 10 ASPR-designated Special Pathogen Centers, and (2) 400 other hospitals with emergency departments.

For this review, we used the same sample, but removed 12 hospitals that were no longer in operation or no longer providing inpatient care, and 18 hospitals that were under investigation by OIG. This left a total sample of 380 hospitals that we attempted to survey.

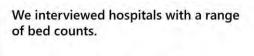
We received responses from 323 of these 380 hospitals, for an 85 percent rate of contact. Among the hospitals that did not respond, 9 chose not to participate, and we were unable to contact 48 after a minimum of three attempts during the 5-day data collection period.⁴⁰

The responding hospitals are located across 46 States, the District of Columbia, and Puerto Rico. Most survey responses were provided directly by an administrator for a single hospital. However, for 46 sampled hospitals, we spoke with administrators from their parent corporation instead of, or in addition to, the hospital administrators. We considered the interviews with the administrators from the parent companies to be responses for each of the hospitals in our sample that were owned by those companies. These 46 hospitals were spread across 16 hospital networks.

The following two pages provide additional information about the hospitals that responded.

Exhibit 2: Hospital Respondents, March 23–27, 2020.

Most hospitals that we interviewed were currently treating patients with **confirmed** or **suspected** coronavirus disease 2019 (COVID-19).



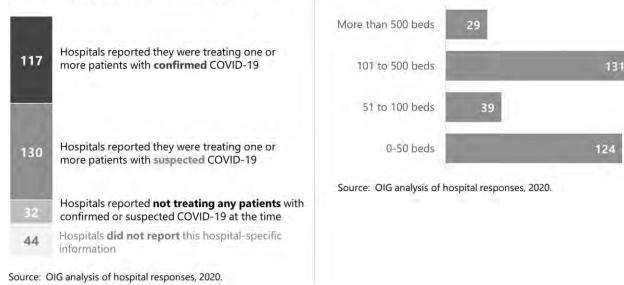


Exhibit 3: The 323 hospitals that we interviewed were located in 46 States, as well as the District of Columbia and Puerto Rico.



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Exhibit 4: Among the 323 hospitals that we interviewed, some are designated as

specialized hospitals.

Special pathogen centers are designated to treat patients with infectious diseases. We talked to all 10.	Major teaching hospitals are affiliated with medical schools. We talked to 24.	Critical access hospitals are smaller hospitals in rural communities. We talked to 100.
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Limitations

We have three limitations: 1) hospital responses reflect a point in time (March 23–27, 2020), but the pandemic is fast-moving, as are efforts to address it. Since our interviews, some hospital challenges may have worsened and others may have improved; 2) we did not independently verify the information reported by hospital administrators. Rather, we report on hospitals' experiences and perceptions as they were conveyed to OIG; and 3) our analysis found some evidence of response bias. Specifically, larger hospitals appear to be under-represented in the pool of respondents and as a result, their views may be under-represented.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

APPENDIX A – STRATEGIES REPORTED BY HOSPITALS

The following are specific strategies reported by hospitals divided by topic areas: 1) securing PPE, other equipment, and supplies for staff; 2) ensuring adequate staffing to treat patients with COVID-19; 3) reducing employee anxiety and stress; 4) managing patient flow and hospital capacity; and 5) securing ventilators and alternative equipment to support patients. We note that these strategies are self-reported by the hospitals and OIG has not validated their effectiveness or safety.

Strategies to secure the necessary PPE, equipment, and supplies for staff

Seeking Alternative Sources of PPE

To supplement limited supplies, hospitals reported improvising PPE and reaching out to non-traditional sources or the community to acquire PPE.

- Using non-traditional sources of PPE, such as online retailers, home supply stores, paint stores, autobody supply shops, and beauty salons.
- Using 3D printers and office supplies to make PPE (e.g., masks).
- Repurposing masks from other industries such as dentists, veterinarians, construction workers, nail salons, etc.
- Purchasing expired PPE.
- Considering other materials to substitute for needed supplies (e.g., sandwich bags as thermometer covers, blending ultrasound gel and alcohol from a local distillery to make hand sanitizer).
- Creating supply by accepting handmade gowns and masks from community volunteers or local businesses.

Implementing Methods to Extend PPE Usage

To conserve existing PPE, hospitals reported implementing procedures to extend and/or reuse PPE.

- Reusing PPE (e.g., disposable masks, face shields, and gowns).
- Sanitizing PPE (e.g., face shields and masks) between use.
- Reducing the extent and frequency of patient interaction to reduce PPE burn.
- Physically securing PPE to prevent theft or misuse.
- Limiting use of PPE to certain staff or patients (e.g., intensive care unit staff or patients).

Strategies to ensure adequate staffing to treat patients with COVID-19

Maintaining Staffing Levels

To keep operations going, hospitals reported "cross-training" staff or bringing on additional medical staff.

- Supplementing medical staff with contractors, retired providers, nurse aides, and medical and nursing students.
- Training medical staff to support or play other roles (e.g., anesthesiologists, hospitalists, and nurses are being trained on how to operate ventilators and care for patients on the machines; non-Emergency Department physicians are being trained to triage in the Emergency Department).

Implementing Screening Procedures

To control the spread of COVID-19, hospitals reported implementing procedures to screen and monitor staff and patients.

- Monitoring the temperature of staff, patients, and visitors who come into the hospital.
- Establishing screening centers outside of the hospital.

Partnering and Collaborating

To aid in their delivery of care, hospitals reported leveraging their partnerships and collaborating with those in the community.

- Being part of a large health care system enables hospitals to deploy staff to other hospitals and share supplies (e.g., PPE).
- Rural hospitals working with other rural hospitals to share supplies and pass information about vendors.
- Working with the local emergency and health departments (e.g., fire department) to prepare and help with patient flow.
- Coordinating with local health authorities to find proper placement for people that need to isolate but do not have homes.
- Working with local community businesses and organizations (e.g., factories, fashion schools, and distilleries) to assist with supplies, such as PPE and cleaning supplies.

Strategies to help reduce employee anxiety and stress

Providing Social Support and Services

To ease anxiety and reduce outside burdens on staff, hospitals reported providing emotional and psychological support and other support services.

- Assisting staff to find childcare, grocery, and laundry services.
- Providing hotel accommodations to promote separation from elderly family members.
- Expanding Employee Assistance Program services.
- Recruiting mental health clinicians and psychiatry staff to provide emotional and psychological support.

Strategies to manage patient flow and hospital capacity

Using Ambulatory Care and Telehealth Services

To limit foot traffic, hospitals reported increasing their use of ambulatory care services and telehealth.

- Using ambulatory care clinics in the community and telehealth to triage patients in the clinic, in the car, or over the phone to limit Emergency Department visits.
- Establishing hotlines for education and advice.

Social Distancing and Restricting Access

To control the spread of COVID-19, hospitals reported restricting access to the hospital and across different parts of the hospital.

- Limiting the number of entrances to the hospital.
- Limiting the number of visitors and/or restricting visitors to attend only births and end-of-life situations.
- Dismissing hospital volunteers.
- Restricting access to common areas (e.g., making cafeterias "grab and go," closing gyms).
- Splitting the Emergency Department into separate areas one area for patients with respiratory symptoms and another area for those without respiratory symptoms.
- Constructing temporary walls in the Emergency Department to isolate patients and create negative pressure space.
- Turning the ambulance bay into a respiratory assessment unit with portable X-rays and negative air pressure to keep unscreened patients from going through the Emergency Department.

Increasing Bed Availability

To address potential bed and facilities shortages, hospitals reported converting or creating space to house a surge in patients.

- Expanding intensive care units, repurposing existing space or using tents, and utilizing other network facilities to separate COVID-19 patients.
- Establishing alternate care sites at local fairgrounds and other spacious facilities.
- Converting nonoperational facilities in the community (e.g., prisons and college dorms) into temporary critical care units.

Conducting Community Outreach and Education

To keep communities informed and reduce public panic, hospitals reported conducting outreach and education activities to answer questions about COVID-19.

- Sending internal and external hospital communications, such as a daily newsletter; sharing information on employee health and human resources.
- Holding senior leadership meetings often with other hospitals and communicating with local and State governments.
- Partnering with local government to educate the public on the COVID-19 screening process, including indicating which potential patients should go to the emergency department and when, based on criteria such as symptoms.
- Developing ways for hospital leaders to hear hospital staff concerns, such as through daily webinars.

Eliminating Elective Surgeries and Other Procedures

To reduce risk of exposure and conserve PPE, hospitals reported eliminating elective surgeries and reducing other services such as ambulatory services, outpatient services, physical therapy, and medical imaging.

- Conserving the PPE and blood supply that would be used for elective procedures in preparation for a COVID-19 patient surge.
- Using surgery units and beds for potential COVID-19 patients.
- Reassigning surgical clinicians and staff to assist with COVID-19 response.

Activating Hospital Command Centers

To coordinate the hospitals' emergency plans, hospitals reported activating their incident command centers.

 Setting up hospital contingency plans to prepare for patient surge and demand for services (e.g., using clinic-based physicians to assist in hospital acute care, using a buddy system that pairs intensive care unit and non-intensive care unit providers together, plans for evacuating patients, as needed, to alternate settings.

Managing Financial Viability

To continue providing needed care and retain staff, hospitals reported assessing ways to manage their cash flow.

- Opening a line of credit to keep payroll going.
- Evaluating pay cuts and layoffs.
- Implementing mandatory and voluntary time off for staff that are not busy or essential, during which time staff would not be paid but would stay on staff.
- Using flexible staffing and furloughing staff.
- Identifying grants and other funding opportunities.
- Reducing inventory not related to COVID-19.

Strategies to secure ventilators and alternative equipment to support patients

Securing Ventilators and Alternative Equipment

To address a shortage in ventilators, hospitals sought new sources and alternative equipment to support patients.

- Renting ventilators, buying single-use emergency transport ventilators, or obtaining ventilators from an affiliated facility.
- Sharing supplies of ventilators between hospitals.
- Planning to transfer patients in need of ventilator to a nearby hospital.
- Converting medical equipment to use as ventilators (e.g., anesthesia machines and bi-level positive airway pressure machines).
- Fitting ventilators with additional hoses to connect more than one patient to a single machine.

APPENDIX B - GLOSSARY OF KEY TERMS

Office of the Assistant Secretary for Preparedness and Response (ASPR): HHS staff division that leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR is assisting organizations to prepare for and respond to the COVID-19 outbreak.

Centers for Disease Control and Prevention (CDC): HHS operating division tasked with protecting the public health and safety through the control and prevention of disease, injury, and disability in the U.S. and internationally. CDC is studying COVID-19 worldwide and helping communities prepare and respond locally.

Centers for Medicare & Medicaid Services (CMS): HHS operating division that administers the Medicare program and works in partnership with State governments to administer Medicaid, the Children's Health Insurance Program, and health insurance portability standards. CMS is issuing clinical and technical guidance for providers and beneficiaries about COVID-19.

Community spread: Spread of an illness for which the source of the infection is unknown.

Coronavirus disease 2019 (COVID-19): An illness of the respiratory tract that is highly contagious. Symptoms include a cough, a high temperature (fever), and shortness of breath, and can be fatal in some cases. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is the virus that causes COVID-19 and is often called the COVID-19 virus; its prior name was the 2019 novel coronavirus (2019nCoV).

Critical Access hospital (CAH): Rural primary health care hospital that gives limited outpatient and inpatient hospital services to people in rural areas. CAHs are designated by CMS, and to qualify these facilities must meet certain conditions such as: furnishing 24-hour emergency care services 7 days a week, having no more than 25 inpatient beds, and having an average length of stay of 4 days or less per patient for acute-care services. CMS is waiving requirements that CAHs limit the number of beds to 25 and length of stay of 4 days.

Emerging infectious disease (EID): Infections that have recently appeared within a population or those whose incidence or geographic range is rapidly increasing or threatens to increase in the near future.

Epidemic: Refers to an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area.

Federal Emergency Management Agency (FEMA): Federal agency under the U.S. Department of Homeland Security that coordinates responses to natural disasters with State and local governments and provides Federal assistance.

Food and Drug Administration (FDA): HHS operating division that is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological

products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. FDA is working with hospitals and the medical industry to develop vaccines, drugs, and tests while monitoring the medical supply chain during the COVID-19 pandemic.

Intensive care unit (ICU): Specialized hospital or facility department that provides critical care and life support for acutely ill and injured patients.

Intravenous (IV) pump: Medical device that delivers fluids, such as nutrients and medications, into a patient's body in controlled amounts.

Isolation room: Negatively pressurized room to control the airflow so that the number of airborne contaminants is reduced to a level that makes the chance of cross-infection to other people within a health care facility unlikely (also see negative pressure room).

Middle East Respiratory Syndrome (MERS): Illness caused by a virus (more specifically, a coronavirus) called Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and was first reported in Saudi Arabia in 2012. Most MERS patients develop severe respiratory illness with symptoms of fever, cough and shortness of breath and many people who are infected die.

N95 respirator mask: Respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. The 'N95' designation means that when subjected to careful testing, the respirator blocks at least 95 percent of very small (0.3 micron) test particles. If properly fitted, the filtration capabilities of N95 respirators exceed those of face masks.

Negative pressure room: Room in a hospital or facility that is used to contain airborne contaminants within the room.

Outbreak: Carries the same definition as "epidemic," but usually refers to a more limited geographic area.

Pandemic: Epidemic that has spread over several countries or continents, usually affecting a large number of people.

Personal protective equipment (PPE): Protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury or infection. This includes respirators and face masks.

Positive COVID-19 test: Test has laboratory confirmation, either from a State or local laboratory or the CDC.

Powered air purifying respirators (PAPRs): Type of PPE used to safeguard workers against contaminated air. It includes a battery-powered blower that pulls air through filters then moves filtered air towards the facepiece. PAPRs are sometimes called positive-pressure masks, blower units, or just blowers (compare with elastomeric respirators).

Presumptive positive: someone with symptoms that strongly indicate COVID-19 and tests have ruled out other conditions like the flu, but there hasn't been an initial positive COVID-19 test result or

confirmatory test result. This term can also be used when an individual whose initial COVID-19 test has been positive, but the CDC or other laboratories have not confirmed it.

Pulse survey: Type of short feedback survey, typically narrow in scope and can be administered on an ongoing basis to track the same topic.

Quarantine: Condition that separates and restricts the movement of people who were exposed to a contagious disease. If the person in quarantine is determined to have contracted the disease, the person should seek treatment, as necessary, or go into isolation until they are no longer contagious.

Reagent: Substance that is used to produce a chemical reaction that allows researchers to detect, measure, produce, or change other substances. For RNA extraction tests that detect the COVID-19 virus, this is an essential component that is lacking in many health care facilities.

Respirator: Masklike device, usually of gauze, worn over the mouth, or nose and mouth, to prevent the inhalation of noxious substances. There are two main types: air-purifying respirators which remove contaminants from the air and air-supplying respirators which provide a clean source of air. "Respirator" is sometimes used interchangeably to refer to "ventilators." (Also see powered air purifying respirators and N95 respirators)

Severe Acute Respiratory Syndrome Virus (SARS): Viral respiratory illness caused by a coronavirus called SARS-associated coronavirus (SARS-CoV). SARS was first reported in Asia in February 2003. The illness spread to more than two dozen countries in North America, South America, Europe, and Asia before the SARS global outbreak of 2003 was contained.

Single-use (disposable or emergency) ventilator: A small, lightweight ventilator used outside of the hospital, typically for emergency care situations and intended only for short-term, single patient use, with no cleaning or calibration needed.

Social distancing: Limits human interaction to lower the risk of human-to-human transmission. Recommended measures can include keeping 6' away from others, avoiding social gatherings, and working from home.

Special Pathogen Centers: 10 hospitals designated by ASPR following the Ebola outbreak in 2014 to maintain capability to accept patients with suspected or diagnosed illness from special pathogens within 8 hours of notification and to conduct quarterly exercises to prepare for an EID outbreak. They receive annual assessments from the National Ebola Training and Education Center, which is a collaborative effort involving ASPR, CDC, and several academic institutions.

Special pathogens: Highly infectious agents that produce severe disease/illness in humans.

Strategic National Stockpile: Supplements State and local stocks of vaccines, medicines, and supplies for emergencies.

Surge: When patient volumes challenge or exceed a hospital's servicing capacity to effectively treat individuals.

Telehealth: Use of electronic information and telecommunications technologies to support longdistance clinical health care, patient and professional health-related education, public health and health administration.

Thermometer (no-touch): No-touch thermometers use infrared technology to rapidly provide accurate temperature results.

Traveling nurse: Nurses employed on a short-term or periodic basis. They include temporary staff, independent contractors, and seasonal hires.

Triage: Process of sorting, classifying, and assigning priority to patients based on degree of sickness or severity of injury.

Ventilator: Machine that supports breathing when a patient is having surgery or cannot breathe on their own due to a critical illness. The patient is connected to the ventilator with a tube that goes in their mouth or nose and down into their main airway.

WHO: World Health Organization, a United Nations agency that directs and coordinates international public health efforts.

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This report was prepared under the direction of Blaine Collins and Ruth Ann Dorrill, Regional Inspectors General for Evaluation and Inspections in the San Francisco and Dallas regional offices, and Abby Amoroso and Amy Ashcraft, Deputy Regional Inspectors General.

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ABOUT THE OFFICE OF INSPECTOR GENERAL

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ENDNOTES

¹ Coronavirus Aid, Relief and Economic Security (CARES) Act of 2020, P.L. No. 116-136 (enacted Mar. 27, 2020).

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Exhibit 11



Anaesthesia 2020, 75, 928-934

Review Article

Hospital surge capacity in a tertiary emergency referral centre during the COVID-19 outbreak in Italy

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Summary

The first person-to-person transmission of the 2019 novel coronavirus in Italy on 21 February 2020 led to an infection chain that represents one of the largest known COVID-19 outbreaks outside Asia. In northern Italy in particular, we rapidly experienced a critical care crisis due to a shortage of intensive care beds, as we expected according to data reported in China. Based on our experience of managing this surge, we produced this review to support other healthcare services in preparedness and training of hospitals during the current coronavirus outbreak. We had a dedicated task force that identified a response plan, which included: (1) establishment of dedicated, cohorted intensive care units for COVID-19-positive patients; (2) design of appropriate procedures for pre-triage, diagnosis and isolation of suspected and confirmed cases; and (3) training of all staff to work in the dedicated intensive care unit, in personal protective equipment usage and patient management. Hospital multidisciplinary and departmental collaboration was needed to work on all principles of surge capacity, including: space definition; supplies provision; staff recruitment; and ad hoc training. Dedicated protocols were applied where full isolation of spaces, staff and patients was implemented. Opening the unit and the whole hospital emergency process required the multidisciplinary, multi-level involvement of healthcare providers and hospital managers all working towards a common goal: patient care and hospital safety. Hospitals should be prepared to face severe disruptions to their routine and it is very likely that protocols and procedures might require re-discussion and updating on a daily basis.

[Correction added on 1 May 2020, after first online publication: Affiliations for A. Protti and M. Cecconi have been updated from 6 to 8.]

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Introduction

As of 11 April 2020, there have been 152,271 officially reported confirmed cases of the 2019 novel coronavirus (nCoV) infection causing coronavirus disease 2019 (COVID-19) in Italy. Of these active cases, 57,592 are from the

Lombardy region, with 1174 (2%) currently admitted to an intensive care unit (ICU) [1]. The first person-to-person transmission in Italy was reported on 21 February 2020 and led to an infection chain that represents one of the largest known COVID-19 outbreaks outside Asia [2]. From previous

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reports and current data, we anticipated a critical care crisis due to a shortage of intensive care beds similar to that reported in China [3]. Considering the rapid spread of the disease, it was then paramount for hospitals, units and providers to plan ahead and prepare as much as possible while the infection had not reached uncontrolled rates [4]. As a response to the COVID-19 outbreak in the Lombardy region, a regional critical care task force was created on 21 February 2020 [5]. The aim of the task force was to develop governance guidelines for the emergency response and to co-ordinate the allocation of resources for all patients with COVID-19 requiring a critical care bed among hospitals in the region. The task force, which is led by the intensive care team at the Policlinico Maggiore Hospital in Milan, is active 24 h a day, 7 days a week and is staffed by a group of consultant intensivists. It receives bed request calls for COVID-19-positive patients and makes the calls to COVID-19 intensive care units asking for beds on a regional basis. This is also co-ordinated with the regional pre-hospital emergency medical service which manages all pre-hospital and interhospital transfers [6]. A regional directive required hospitals, as of 23 February 2020, to urgently prepare for a mass influx of COVID-19-positive critically ill patients. The choice was to cohort these patients at the ward or unit level and the receiving hospitals were asked to create dedicated wards and ICUs.

In this review, we report our experience of preparing the reception, assessment and critical care areas of our hospital to admit a large number of COVID-19 critically ill patients. Our aim was to increase hospital surge capacity to offer the appropriate level of care to the maximum number of patients, doing our best to maintain biocontainment of confirmed and suspected cases while still providing safe critical care to non-COVID-19 patients and ensuring a safe working environment for the healthcare providers involved.

Our setting

Our centre is a large, multidisciplinary, academic hospital in the south of Milan. It has a strong surgical prepondrance with a focus on cancer and immune disorders. It also has a third level emergency department and is part of the extracorporeal life support network. Totalling more than 700 beds, it usually operates two ICUs: a general neurotrauma ICU with 15 beds and a cardiothoracic ICU with 9 beds. Under normal conditions, the ICU bed usage is always above 90%. It is worth mentioning that although there is a team of clinical microbiologists and infectious disease specialists, the hospital does not usually have dedicated infectious disease beds. Anaesthesia 2020, 75, 928-934

A dedicated task force of our hospital experts was created on 24 February 2020 with the task of increasing the hospital surge capacity, defined as the combination of space, staff and supplies needed for safely admitting a large number of critically ill patients with COVID-19 [7]. The task force was guided by two key principles: increased surge capacity for COVID-19–positive patients and strict containment of the suspected and positive cases. Isolation of patients and working areas planning was guided by the European Centre for Disease Control Coronavirus Hospital guidance [8].

The task force was formed of physicians, senior critical care nurses and representatives from the medical directorate, hospital management and hospital infection control. Following this initial meeting, the team split into three working groups: operations; procedures; and training. Each group was tasked with one of the above-mentioned items. Each team had direct involvement with a group of support teams from different departments including: pharmacy; diagnostics; logistics and procurement; building engineering; biomedical technologies; information technologies; waste management; and medical education and simulation. Representatives from each department were asked, through hospital management, to be constantly available for on site and on call availability during the whole unit activation process.

A meeting was held on the morning of that same day, and also following a review of the literature [9–13], a response plan was designed as follows:

- 1 Establishment of cohorted ICU(s), emergency department and wards dedicated to the treatment of COVID-19–positive patients while maintaining clinical care of non-COVID-19 patients in other dedicated ICUs and wards
- **2** Design of appropriate procedures for reception, assessment, isolation and movement of suspected and confirmed cases
- **3** Training of all staff expected to work in this dedicated ICU on personal protective equipment (PPE) usage and patient management in this special situation

On the same day, the hospital shut down 85% of its elective surgical activity. It was decided that the dedicated COVID-19 ICU would be located in one of the temporarily closed day surgery units. It was decided to observe a stepup approach starting with four operational bays by the early morning of 27 February 2020. We received the first patient on the afternoon of 1 March 2020 and have since implemented a median increase of 2 beds per day reaching the capacity of 12 occupied beds as of 6 March 2020, with a further expansion into our anaesthetic rooms in the Anaesthesia 2020, 75, 928-934

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operating theatres and 39 occupied level 3 beds as of 25 March 2020.

Space

This first cohorted ICU was selected on the ground floor for its proximity to the emergency department and the computed tomography (CT) scanner; the ability to maintain negative pressure within its premises; and the limited number of access points allowing easy to control access to the new unit. Negative pressure for all involved areas was created ad hoc by the building engineers. The selected area consists of a surgical area of five operating theatres, all with a common pre-operative area, which is also connected to a large 24-bay recovery area, which was selected as the main area for the COVID-19-dedicated ICU. Access to the area was confined to one entry and one exit point for staff and one entry-exit point for patients. All other doors leading outside were locked or zip-tied from the inside, and access badges for non-authorised staff members were disabled. The men's changing room in the theatre area was chosen as the donning area, and the women's changing room became the doffing area. Both led to the same corridor to the isolated unit. Personal protective equipment was stockpiled in a locked cabinet within the locked changing room to prevent theft.

Two medical wards, both on the ground floor with 25 beds each, were initially dedicated to patients not requiring level 3 care. Negative pressure was generated in these areas similar to that produced in the ICU. Daily operations in these wards were run by respiratory consultants with the support of a multidisciplinary internal medicine team. Approximately 20% of the ward beds were dedicated to level 2 care (high dependency unit), with monitors and the capacity to deliver non-invasive ventilation with the support of a critical care outreach team. Clear goals of care were instituted and discussed early during the admission to these wards to avoid any delay in escalation to level 3 care if appropriate and needed.

Available beds, both on the ICU and in medical wards, were activated gradually, trying to forecast daily needs over a period of 2–3 days each time and predicting an average 15–20% unplanned additional cases every day. This proved particularly challenging as the set-up of new bays had to be performed wearing full PPE. After saturation of the isolated intensive care, the escalation plan was as follows: closure of the cardiothoracic intensive care; reduction in the overall non-COVID-19 critical care beds to 10 beds; and the opening of a second dedicated COVID-19 ICU in the cardiothoracic ICU (with six occupied beds as of 13 March 2020). After saturation of the two medical wards, a further

two wards with the same characteristics as above were opened to patients not requiring level 3 care with a total of 106 patients admitted as of 13 March 2020.

Supply

Each bay of the new ICU was fitted with basic intensive care equipment including a bed, a monitor, a ventilator and syringe drivers. Most of these items did not have appropriate stands but were placed on surgical tables or laparoscopic shelves which served as suitable alternatives. Ergonomics of this area were a concern during set-up. Moreover, as the equipment had to be procured from different locations within the hospital (i.e. from other closeddown surgical areas), doctors and nurses working here needed to use a broad range of devices from different manufacturers. For example, the ventilators in the unit come from three different interfaces. This must be considered, especially when admitting patients who will require frequent ventilator manipulation.

As with the Chinese experience, a list of dedicated medical equipment was prepared and the relevant equipment permanently moved and exclusively assigned to that unit [10]. These items were left in the unit at all times. These included: disposable bronchoscopes; a videolaryngoscope; a blood gas machine; a portable X-ray machine; a three-probe ultrasound machine; a laptop and tablets for staff; and a refrigerator. A limited quantity of consumables was stockpiled within the infected areas and restocking of consumables had to be planned accordingly. Due to the high anticipated work-load during the response, we decided not to routinely offer extracorporeal membrane oxygenation (ECMO). We aimed to offer standard intensive care to all critically ill patients rather than very resourceconsuming treatments only to some of them (with the inherent risk of being unable to adequately treat some others). We maintained a case-by-case screening of potential ECMO patients for very select cases, that would be referred to the regional ECMO network after shared decision-making.

Staff

Departmental administrators worked on designing dedicated rotas (shifts) for these newly created areas. Staffing was planned with a one-to-two nurse-to-patient ratio and one-to-five or six physician-to-patient ratio. A common shift system was agreed among all those working in the new ICU. Considering the discomfort of working in PPE, including overheating and the inability to access food, water or bathroom facilities, we developed a four-shifts-a-

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day system, with teams handing over every 6 h. At this stage we planned two physicians for each one of the daytime shifts (6 am–12 pm; 12 pm–6 pm and 6 pm–12 am) and only one for the night shift (12 am–6 am). The COVID-19 team on shift was not allowed to leave the unit to assess or consult patients; this was allocated to an independent team. Only confirmed cases of COVID-19 were brought to the unit.

The core critical care consultant team staffed the COVID-19 ICU and some shifts on the general ICU, while anaesthetists covered the remaining general ICU shifts which remained unchanged in terms of number and structure. The pool of experienced critical care nurses was moved to the new COVID-19 ICU, with the general ICU being staffed by a large pool of nurses from the surgical operating theatres having been made available by the drastic reduction in elective surgical activity. Nurses and doctors had to be relocated from their usual places of work to allow full staffing of the ICU and wards.

Ward staffing had to be adapted to the new cohort model. Rotas of nurses dedicated to COVID-19 wards were reinforced with personnel from other areas, such as outpatient clinics or diagnostic services, that were shut down. On average, ward staffing was increased by 33% to meet the increased demands of care of these patients and to allow proper resting times between shifts. Medical doctors no longer involved in elective hospital activities were assigned to cohorted wards, regardless of their specialty. The hospital retained a small amount of elective non-deferrable oncologic cases, amounting to < 10% of the usual surgical volume. Surgeons not involved in these activities assisted with the management of COVID-19 patients, supported other medical areas and put in place one COVID-19 operating room and dedicated surgical pathways [14].

 Table 1
 COVID-19 healthcare workers training scheme.

Open communication and appropriate shift design and mixing experienced and unfamiliar personnel were fundamental to the sustainability of the process. The communication strategy involved emails every evening by hospital managers to present what had been achieved that day. These were complemented by departmental meetings held in the evening which were extremely well attended. Meetings were used to present protocols and answer questions. Subsequent significant changes in protocols and procedures in accordance with the developing national or regional law and guidelines were communicated and adopted by all staff members. It should be noted that, as in any disaster response, communication plays a key role in response success.

Training

Training of medical doctors, nurses and healthcare assistants consisted of lectures with live demonstrations and in-situ simulation. Not only was every staff member due to work in the COVID-19 ICU required to attend the training but it was also required for other staff members who might intervene in case of escalation as second-line healthcare providers. The first cohort of staff was chosen from critical care consultants and experienced critical care nurses and healthcare assistants. The 60-min training programme was designed and delivered by a group of critical care consultants and infection control nurses with the support of a simulation specialist from the simulation centre. It was designed so that it could be attended by all the healthcare providers during their shift, either while on a break or while being covered by a colleague. The training curriculum was designed ad hoc, balancing educational needs and time, and was also inspired by a number of previous works on emergency and pandemic training through simulation [15,

Training sessions	Activities	Duration	Participants numbers	Involved personnel
Lectures with live demonstrations	PPE donning and doffing	1 h 3 times a day	Small groups < 25 persons	ICU medical staff ICU nurses Healthcare assistants
	PPE explanation			
In-situ simulation	PPE donning Airway management of suspected or confirmed COVID-19 patients Isolated patient handling (low-resource prone positioning) Doffing of PPE	1 h All day rotations	1–2 doctors 2–3 nurses	
Random calls	Surprise assessment with PPE checklists	20 min	1 person at the time	

PPE, personal protective equipment; ICU, intensive care unit.

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16]. Over the two core training days we trained 28 critical care physicians, 39 critical care nurses and 10 healthcare assistants. Protocols on how to use PPE, precautions to be adopted during tracheal intubation and how to rapidly turn a patient from supine to prone or the other way around with only three healthcare workers, were presented to all staff, disseminated via email and displayed in the emergency department and in the COVID-19 ICU. Details of the training programme are presented in Table 1.

Critical care area operations

The workflow for the management of suspected or confirmed COVID-19 patients is presented in Figure 1. Any patient presenting to the emergency department was subject to a pre-triage assessment, either directly in the parked ambulance or in a shelter unit created ad hoc at the entrance of the emergency department. The objective of the pre-triage was to separate patients with respiratory symptoms from all others. Patients were classified into three

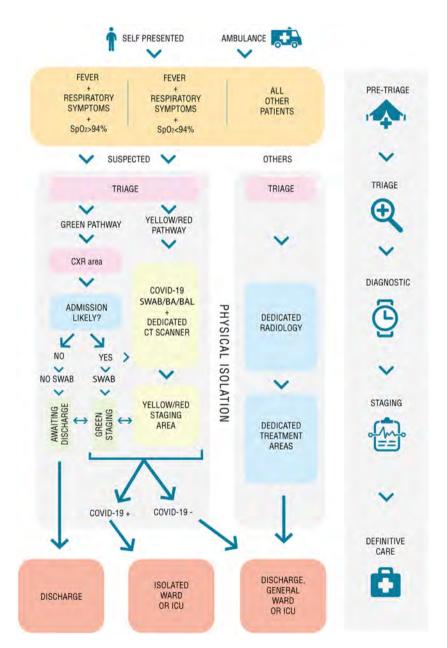


Figure 1 Patient flow within the hospitals from presentation through assessment to final disposition. Green (minor), yellow (moderate) and red (immediate) triage codes based on local emergency department triage protocol. CXR, chest X-ray; BA, bronchial aspirate; BAL, bronchoalveolar lavage; CT, computed tomography; ICU, intensive care unit.

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subsets: (1) with respiratory symptoms and $S_pO_2 \ge 94\%$ on room air; (2) with respiratory symptoms and $S_pO_2 < 94\%$; and (3) without respiratory symptoms. A structural redesign of the emergency department was performed. Two physically separated areas were created: one dedicated to any respiratory case and the other for non-respiratory cases. The emergency department CT scanner was dedicated exclusively to respiratory patients, and central radiology was used for all the other emergency department patients. Walking patients with respiratory symptoms underwent portable chest X-ray in a dedicated area just after triage and were then assessed by a physician who decided whether they required admission or could be discharged.

It was decided that patients requiring critical care would enter the dedicated ICU only with a confirmed laboratory diagnosis of COVID-19 either via the emergency department or using secondary transport through the regional COVID-19 coordination network.

For this reason, a fully isolated 'pending-confirmation' staging area was prepared in the emergency department for patients with respiratory symptoms, separating those with hypoxaemia from the others. The emergency department staging for the most severe hypoxaemic patients (red area) was equipped with mechanical ventilators and staffed by critical care nurses from the unit, with the medical support of a critical care consultant on call for the emergency department. Once a diagnosis of COVID-19 was confirmed, patients were transferred directly from the ambulance or the emergency department staging area via a dedicated pathway to their assigned unit by fully donned staff members. If indicated, CT scan of the chest was performed during the same transfer as patients passed next to the dedicated scanner. The patient was then handed over to the ICU team. The hallway connecting the emergency department and the ICU could not be locked down at all times for hospital logistics. Hospital security with lightweight PPE secured each end of the hallway before any transport. After each patient move, the hallway was sanitised with chlorine-based disinfectants.

Due to limited staffing within the COVID-19 ICU and the complexity of these patients, a telemedicine system was deemed essential for the running of the critical care service. Two tablets were prepared with teleconferencing software; one was placed in the COVID-19 ICU and the second in the general non-COVID-19 ICU. Two other tablets were given to the co-ordinators of the unit who were alternately on call during the night from home. This was an easy, cheap and practical solution, as it allowed the physicians to move around and show clinical findings, screens and monitors to the outside team. A daily ward round was run at 12 pm with all consultants on duty, and external consultations took place 24 h a day. Other tablets were prepared for awake patients to communicate with their relatives who were not allowed to enter the unit and who were themselves either self-isolated or admitted to hospital.

At the same time, hospital managers and clinicians worked to increase the overall safety and surge capacity of the whole hospital, including areas other than critical care. All entrances were check-pointed and any person entering the facility, including healthcare professionals, was questioned about recent illnesses and contacts with subjects with respiratory symptoms; their body temperature was measured via a contactless device. Those screened as 'at risk' were either asked to return home with appropriate instructions or sent to the emergency department as appropriate. Access to the hospital was limited to emergency patients or outpatients with an urgent clinic appointment.

Conclusions

We have reported our brief experience with the process of opening a new dedicated cohorted COVID-19 ICU while also guaranteeing a safe option for patients admitted with other pathologies. This manuscript was prepared during the actual response while increasing our bed surge capacity on a daily basis and experiencing a constant increase in affected patients and healthcare needs. On 6 April 2020 our hospital has used the approach described here to open other ICUs for invasive ventilatory support and level 2 areas for non-invasive ventilatory support. At this date our capacity was: 45 level 3 beds for COVID-19 patients; 10 level 3 ICU beds for non-COVID-19 patients; 40 level 2 beds and 200 level 1 beds for COVID-19 patients outside of the ICU. We have prepared another level 3 area ready to be open for another 10 beds and another level 2 area in case of need. Our data and experience suggests that hospitals have to prepare for at least for a 4-5 times increase in ICU capacity compared with baseline.

Opening our intensive care units and adapting the whole hospital emergency process required multidisciplinary, multi-level involvement of healthcare providers and hospital managers all working towards a common goal: patient care and hospital safety. As the infection moves around the world, certain areas which are not affected yet should use the time to prepare and train, stockpile necessary equipment and prepare their staff for sudden disruptions in their work–life balance for the upcoming weeks, including the very likely possibility of enforced in-hospital quarantine. Hospitals should be

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prepared to face severe disruptions in their routine. It is very likely that protocols and procedures will require revision and updates on a daily basis. We hope this review will be useful to anyone who may have to face a similar challenge.

Acknowledgements

We are in debt to all the colleagues who worked so hard to cope with this unprecedented emergency. We acknowledge the COVID-19 Lombardy ICU Network for their remarkable efforts to provide care for the critically ill patients with COVID-19. We would like to dedicate this work to all professionals involved in the response of COVID-19 in Italy and the world. No competing interests declared.

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Exhibit 12

ACP Journals

Ides and Opinions | 5 May 2020 Annal Society of Internal Medicine How Should U.S. Hospitals Prepare for Coronavirus Disease 2019 (COVID-19)?

Vineet Chopra, MD, MSc, Eric Toner, MD, Richard Waldhorn, MD, Laraine Washer, MD

Author, Article and Disclosure Information https://doi.org/10.7326/M20-0907



"...make them believe, that offensive operations, often times, is the surest, if not the only (in some cases) means of defence."

-George Washington (1799)

Coronavirus disease 2019 (COVID-19) is on the verge of being declared a pandemic. As of 7 March 2020, a total of 423 cases and 19 deaths, including several non-travel-related cases, areas of sustained community transmission, and a nursing home outbreak, have been reported (1). Bestcase estimates suggest that COVID-19 will stress bed capacity, equipment, and health care personnel in U.S. hospitals in ways not previously experienced (2). How can health systems prepare to care for a ...

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Exhibit 13

EDITORIAL

Open Access

How to risk-stratify elective surgery during the COVID-19 pandemic?



Philip F. Stahel

Keywords: Coronavirus, COVID-19, Resource utilization, Emergency preparedness, Elective surgery

On March 11, 2020, the World Health Organization (WHO) declared the novel coronavirus disease 2019 (COVID-19) a global pandemic, which classifies the outbreak as an international emergency [1]. At the time of drafting this editorial, COVID-19 has swept through more than 115 countries and infected over 200,000 people around the globe [2-4]. More than 7000 individuals have died during the early phase of the pandemic, implying a high estimated case-fatality rate of 3.5% [2–4]. The rapidly spreading outbreak imposes an unprecedented burden on the effectiveness and sustainability of our healthcare system. Acute challenges include the exponential increase in emergency department (ED) visits and inpatient admission volumes, in conjunction with the impending risk of health care workforce shortage due to viral exposure, respiratory illness, and logistical issues due to the widespread closure of school systems [5]. Subsequent to the WHO declaration, the United States Surgeon General proclaimed a formal advisory to cancel elective surgeries at hospitals due to the concern that elective procedures may contribute to the spreading of the coronavirus within facilities and use up medical resources needed to manage a potential surge of coronavirus cases [6]. The announcement escalated to a nationwide debate regarding the safety and feasibility of continuing to perform elective surgical procedures during the COVID-19 pandemic [7, 8]. Many health care professionals erroneously interpreted the Surgeon General's recommendation as a "blanket directive" to cancel all elective procedures in the Country [9]. This notion was vehemently challenged in an open letter to the

Surgeon General on behalf of United States hospitals [10]. The letter outlined a significant concern that the recommendation could be "interpreted as recommending that hospitals immediately stop performing elective surgeries without clear agreement on how we classify various levels of necessary care "[10]. Notably, the Surgeon General's recommendation was based on a preceding statement by the American College of Surgeons (ACS) with a call to prioritize appropriate resource allocation during the coronavirus pandemic as it relates to elective invasive procedures.

The ACS bulletin stated the following specific recommendations [11]:

- Each hospital, health system, and surgeon should thoughtfully review all scheduled elective procedures with a plan to minimize, postpone, or cancel electively scheduled operations, endoscopies, or other invasive procedures until we have passed the predicted inflection point in the exposure graph and can be confident that our health care infrastructure can support a potentially rapid and overwhelming uptick in critical patient care needs.
 - Immediately minimize use of essential items needed to care for patients, including but not limited to, ICU beds, personal protective equipment, terminal cleaning supplies, and ventilators. There are many asymptomatic patients who are, nevertheless, shedding virus and are unwittingly exposing other inpatients, outpatients, and health care providers to the risk of contracting COVID-19.

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infection [12].

Importantly, the notion to "thoughtfully review all

scheduled elective procedures "does not reflect on a presumed imperative to cancel all elective surgical cases across the United States [11]. The uncertainty on the predicted time course of COVID-19 beyond a critical inflection point implies that patients may be deprived of access to timely surgical care likely for many months to come. Arguably, the potential fallout from inconsiderate elective surgery cancellations may have a more dramatic and immeasurable impact on the health of our communities than the morbidity and mortality inflicted by the novel coronavirus disease. For the sake of this discussion, it is imperative to understand that the term "elective "surgery does not mean optional surgery, and rather implies that a procedure is not immediately indicated in response to a limb- or life-threatening emergency. A current estimate suggests that more than 50% of all elective surgical cases have a potential to inflict significant harm on patients if cancelled or delayed [12]. The physiological condition of a vulnerable cohort of patients may rapidly worsen in absence of appropriate surgical care, and the resulting decline in patients'health will likely make them more vulnerable to a coronavirus Table 1 Examples of surgical case types stratified by indication

Indication	Urgency	Case examples
Emergent	< 1 h	 Life-threating emergencies Acute exsanguination / hemorrhagi shock Trauma level 1 activations Acute vascular injury or occlusion Aortic dissection Emergency C-section Acute compartment syndrome Necrotizing fasciitis Peritonitis Bowel obstruction / perforation
Urgent	< 24 h	 Appendicitis / cholecystitis Septic arthritis Open fractures Bleeding pelvic fractures Femur shaft fractures & hip fractures Acute nerve injuries / spinal cord injuries Surgical infections
Urgent-elective	< 2 weeks	 Cardiothoracic / cardiovascular procedures Cerebral aneurysm repair Vascular access devices Skin grafts / flaps / wound closures Scheduled C-section Closed fractures Spinal fractures & acetabular fractures
Elective (essential)	1–3 months	 Cancer surgery & biopsies Subacute cardiac valve procedures Hernia repair Hysterectomy Reconstructive surgery
Elective (discretionary)	> 3 months	 Cosmetic surgery Bariatric surgery Joint replacement Sports surgery Vasectomy / tubal ligation Infertility procedures

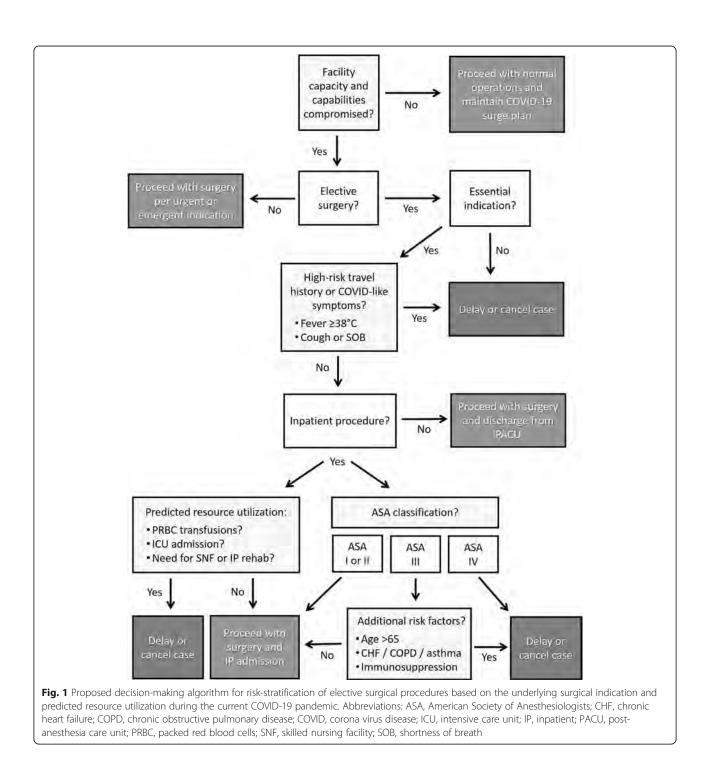
A recent publication from the Naval Medical University in Shanghai reported on the inherent risks of delaying surgery for colorectal cancer during the COVID-19 outbreak in China [13]. In addition, impressive anecdotal reports of individual patient stories illustrate the unintended consequences imposed by cancelling scheduled surgery, as exemplified by a woman who stated that she felt like there was a "time bomb" inside her after surgery for early stage cervical cancer had been cancelled and indefinitely postponed [14]. Unequivocally, many elective non-urgent surgeries will become urgent at some point in time, depending on how long the COVID-19 outbreak will prevail. Dr. David Hoyt, a trauma surgeon and executive director of the ACS, recently stated:" Right now, most people are planning for a time period of 4-6 weeks for the peak to hit, but nobody really knows. We're using our best judgment on the fly." [11].

In light of all the underlying assumptions and uncertainties, it appears imperative to design and implement clinically relevant and patient safety-driven algorithms to guide the decision-making for appropriate surgical care. Elective procedures can pragmatically be stratified into "essential", which implies that there is an increased risk of adverse outcomes by delaying surgical care for an undetermined period of time, versus "non-essential "or "discretionary", which alludes to purely elective procedures that are not time-sensitive for medical reasons. Table 1 provides a suggested stratification by urgency of surgical indications for considering appropriate elective case cancellation. Equivocal surgical cases - which do not fall into either "essential "or "non-essential "categories - appear to have shown an effective self-regulating mechanism in the early phase of the COVID-19 outbreak, driven by patients voluntarily cancelling their scheduled elective procedures and surgeons evaluating appropriate indications on a case-by-case basis [15].

In essence, during the current time of widespread anxiety around the COVID-19 pandemic [16], a pragmatic guide based on underlying risk stratification and resource utilization will help support our ethical duty of assuring access to timely and appropriate surgical care to our patients, while maintaining an unwavering stewardship for scarce resources and emergency preparedness. Figure 1 provides a tentative decision-making algorithm based on elective surgical indications and predicted perioperative utilization of critical resources,

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including the consideration for intra-/postoperative blood product transfusions, estimated postoperative hospital length of stay, and the expected requirement for prolonged ventilation and need for postoperative ICU admission.

Ultimately, if rationing of healthcare resources in terms of limiting access to surgical care in the United States will never be needed, then these ongoing crucial discussions will have served as an important exercise in nationwide disaster preparedness.

FDA clearance

Not applicable (Editorial).

Declaration

The author declares that the content of this editorial represents his exclusive personal opinion, and does not reflect the official position of any health care

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entity, including hospitals and associated facilities, health care systems, or professional societies and agencies.

Authors' contributions

P.F.S. designed and wrote this editorial. The author(s) read and approved the final manuscript.

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Exhibit 14

immunodeficiency virus and recommendations for postexposure prophylaxis. *Infect Control Hosp Epidemiol* 2013;34:875–892.

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Involving antimicrobial stewardship programs in COVID-19 response efforts: All hands on deck

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To the Editor—To our knowledge, no formal recommendations exist for the inclusion of antimicrobial stewardship programs (ASPs) in disaster planning or emergency response preparedness efforts.¹ A PubMed search utilizing the search terms "antimicrobial stewardship" AND "disaster planning" was performed on March 4, 2020, and yielded no results. ASPs are now ubiquitous. They often include pharmacists and physicians with advanced infectious diseases training, and they are a valuable part of hospital safety and quality programs. In some hospitals, compartmentalization of stewardship and epidemiology functions have developed over time to meet distinct institutional needs. However, domains should coalesce for purposes of emergency preparedness. The current SARS-CoV-2/COVID-19 outbreak highlights numerous opportunities where ASPs can support emerging pathogen response and planning efforts.

An informal Twitter poll was initiated on March 1, 2020, asking the infectious diseases and antimicrobial stewardship communities whether ASPs at their health systems had been involved in SARS-CoV-2/COVID-19 outbreak response or preparation. This yielded 254 responses: 30% noted direct involvement, 28% indicated indirect involvement, and 39% indicated no involvement in emergency response efforts or planning. Although formalized study is needed, real-time insights from the community provided valuable information. We identified multiple potential areas where ASPs can support emergency response efforts, and these are summarized in Figure 1.

ASPs that are integrated with hospital infection prevention programs have an advantage in response efforts to emerging pathogens in that (1) they are likely to have pre-existing infection prevention skills and experience, (2) they are likely to be involved in response efforts early, and (3) they will have access to and influence with key stakeholders. Because ASPs and infection prevention programs share similar technology infrastructure, data, and metrics, program integration has many advantages.² Response efforts to novel respiratory viruses like SARS-CoV-2/COVID-19 represent an opportunity for programs to formally integrate, to develop crosscoverage capabilities, and to create shared leadership opportunities.

ASPs can support SARS-CoV-2/COVID-19 response efforts in numerous ways within the context of their normal daily activities. A core component of antimicrobial stewardship includes postprescriptive review with feedback to providers.³ In this way, an ASP skill set can theoretically assist with early identification of potential cases. This approach may be especially useful in situations in which the definition of a person under investigation is fluid because traditional epidemiologic efforts usually focus on identifying patients at the point of entry into health systems. ASPs often coordinate with microbiology laboratories for real-time interpretation and action involving upper respiratory PCR test results. They can support SARS-CoV-2/COVID-19 evaluation efforts in this fashion as well. Novel respiratory virus outbreaks associated with secondary bacterial pneumonias and acute respiratory distress syndrome (ARDS) provide an opportunity for ASPs to monitor compliance with guideline-concordant therapy; severe COVID-19 cases have been treated with broad-spectrum antibiotics.⁴

Additionally, ASPs can help in the development of local treatment protocols involving repurposed antivirals; they can monitor and manage drug shortages due to supply chain interruptions⁵; and they can assist frontline providers with expanded access investigational new drug applications (eINDs) and local institutional review board procedures for investigational agents.

ASPs are now mandated in the United States and are often multidisciplinary. The Joint Commission accreditation standard for ASPs includes, when available, an infectious diseases physician, pharmacist, infection preventionist, and other practitioners.⁶ ASP physician and pharmacy leaders often have specialized infectious diseases training.³ Leveraging these resources for planning and response efforts for emerging pathogens is critical and can strengthen and sustain collaborative relationships.

We recommend that hospital epidemiology programs strongly consider integrating their ASP colleagues into disaster preparedness plans as well as identify a more formal role for stewards in their operations beyond the current COVID-19 outbreak.

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Fig. 1. Opportunities for antimicrobial stewardship programs to assist COVID-19 response preparation and planning efforts.

Conflicts of interest. All authors report no conflicts of interest relevant to this article.

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Protecting Chinese healthcare workers while combating the 2019 novel coronavirus

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To the Editor—Hospital-associated transmission is an important route of spreading the 2019 novel coronavirus SARS-CoV-2 and pneumonia (coronavirus disease 2019, COVID-19).¹ Healthcare workers (HCWs) are at high risk while combating COVID-19 at the very front line, and nosocomial outbreaks among HCWs are not unusual in similar settings. The 2003 severe acute respiratory syndrome (SARS) outbreak led to >966 HCW infections with

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1.4% deaths in mainland China.² As of February 11, 2020, 3,019 HCWs might have been infected with SARS-CoV-2 in China, and 1,716 HCW cases of COVID-19 have been confirmed by nucleic acid testing³ At least 6 HCWs have died, including the famous whistleblower Dr Li Wenliang. In view of this severe situation, we are recommending urgent interventions to help to protect HCWs.

A few aspects of COVID-19 have created a more severe situation than expected among HCWs. First, many infected individuals present with a typical symptoms, such as gastrointestinal symptoms and fatigue, or are asymptomatic.⁴ This situation may lead to a lack of recognition of the infection while patients are highly

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Exhibit 15

Check for updates

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Correspondence to: N Greenberg neil.greenberg@kcl.ac.uk Cite this as: *BMJ* 2020;368:m1211 http://dx.doi.org/10.1136/bmj.m1211 Managing mental health challenges faced by healthcare workers during covid-19 pandemic

Neil Greenberg, ¹ Mary Docherty, ² Sam Gnanapragasam, ² Simon Wessely¹

Neil Greenberg and colleagues set out measures that healthcare managers need to put in place to protect the mental health of healthcare staff having to make morally challenging decisions

The covid-19 pandemic is likely to put healthcare professionals across the world in an unprecedented situation, having to make impossible decisions and work under extreme pressures. These decisions may include how to allocate scant resources to equally needy patients, how to balance their own physical and mental healthcare needs with those of patients, how to align their desire and duty to patients with those to family and friends, and how to provide care for all severely unwell patients with constrained or inadequate resources. This may cause some to experience moral injury or mental health problems.

Moral injury

Moral injury, a term that originated in the military, can be defined as the psychological distress that results from actions, or the lack of them, which violate someone's moral or ethical code.¹ Unlike formal mental health conditions such as depression or post-traumatic stress disorder, moral injury is not a mental illness. But those who develop moral injuries are likely to experience negative thoughts about themselves or others (for example, "I am a terrible person" or "My bosses don't care about people's lives") as well as intense feelings of shame, guilt, or disgust. These symptoms can contribute to the development of mental health difficulties, including depression, post-traumatic stress disorder, and even suicidal ideation.² Equally, some people who have to contend with significant challenges, moral or traumatic, experience a degree of post-traumatic growth,³ a term

used to describe a bolstering of psychological resilience, esteem, outlook, and values after exposure to highly challenging situations. Whether someone develops a psychological injury or experiences psychological growth is likely to be influenced by the way that they are supported before, during, and after a challenging incident.

Moral injury has already been described in medical students, who report great difficulty coping with working in prehospital and emergency care,⁴ where they were exposed to trauma that they felt unprepared for. This may be similar to the unprecedented nature of the challenges healthcare staff are currently facing. In the UK, most NHS staff may have felt, with some justification, that with all its faults, the NHS gives the sickest people the greatest chance of recovery. As such, staff should and usually do feel that it is something to be proud of.

The huge current effort to ensure adequate staffing and resources may be successful, but it looks likely that during the covid-19 outbreak many healthcare workers will encounter situations where they cannot say to a grieving relative, "We did all we could" but only, "We did our best with the staff and resources available, but it wasn't enough." That is the seed of a moral injury. Not all staff members will be adversely affected by the challenges ahead (table 1) but no one is invulnerable, and some healthcare workers will hurt, perhaps for a long time, unless we begin now to prepare and support our staff.

Table 1 | Potential for moral injury: analogous examples of events or actions in military settings⁵ and the covid-19 pandemic

Military examples	Expected healthcare examples
Following orders that were illegal, immoral, or against the Rules of Engagement or Geneva Convention	Following clinical decisions by others that the individual believes were unethical, immoral, or against guidance from registered professional bodies
Failing to report knowledge of a sexual assault or rape committed against yourself, a fellow service member, or civilians	Failing to report serious clinical incidents, near misses, or bullying of yourself, colleagues, or patients
Change in belief about the necessity or justification for a conflict, during or after military service	Change in belief about the necessity or justification for treatment plans or protocols that have affected people's lives
Putting a colleague in serious danger because of own inexperience or indecision	Putting patients or colleagues in danger because of your inexperience, indecision, or working outside your normal competency
Returning home from deployment and hearing of the atrocities that occurred "on your watch"	Returning home from a shift and hearing of seriously worsening health outcomes in the facility in which you were working
Being told that you are unable to treat a seriously ill civilian (especially someone you perceive as vulnerable, such as a child) brought to the gates of your camp, who subsequently dies	Having to choose which of two equally sick patients is provided with specific care, one of whom does not survive, because of the non-availability of healthcare equipment
Giving orders during combat that result in the injury or death of a fellow service member or innocent civilians	Giving clinical orders or establishing protocols that result in the death of colleagues or patients
Using deadly force in combat and causing the harm or death of civilians, knowingly but without alternatives, or unintentionally	Responding acutely in medical emergency and causing the harm or death of patients, knowingly but without alternatives, or unintentionally
Feeling let down when the chain of command does not provide you with adequate reinforcements	Feeling let down because you are working with insufficient resources or staffing, especially when you perceive this was avoidable

Early support

Several potential mechanisms can help mitigate the negative moral effects of the current situation. All healthcare workers need to be prepared for the moral dilemmas they are going to face during the covid-19 pandemic. We know that properly preparing staff for the job and the associated challenges reduces the risk of mental health problems.⁶ They should not be given false reassurance but a full and frank assessment of what they will face, delivered without euphemisms and in plain English. To do anything else may add to the feelings of anger when reality bites.

As the situation progresses, team leaders should help staff make sense of the morally challenging decisions being made. This could be achieved by using discussions based on Schwarz rounds,⁷ which provide a forum for healthcare staff from all backgrounds to safely discuss the emotional and social challenges of caring for patients. The discussion should be led by team leaders and could be done remotely if needed.

Avoidance is a core symptom of trauma, so team leaders should reach out to staff who are just "too busy" or repeatedly "not available" to attend these discussions. Most people find that support from their colleagues and immediate line manager protects their mental health.⁸ Staff members who persistently avoid meetings or become overly distressed may require and welcome sensitive discussion and support from a suitably experienced person such as their team leader, trained peer supporter, or chaplain. If their distress is severe or persistent they should be actively supported or, for more serious cases, referred for professional mental health support. Single session psychological debriefing approaches should not be used as they may cause additional harm.⁹

Routine support processes (such as peer support programmes) available to healthcare staff should include a briefing on moral injuries, as well as an awareness of other causes of mental ill health and what to look out for. Even the most resilient team members may become overwhelmed by situations that have personal relevance, such as providing care for someone who reminds them of a relative or a friend. Even staff members experienced in breaking bad news to relatives may be overcome by having to do this many times a day for weeks on end, especially if they have genuine feelings of guilt. In such situations both moral injury and burnout may affect mental health.

Although there is a wealth of evidence that having a supportive supervisor protects your mental health,¹⁰ supervisors are human too. As such, more senior managers should keep an active eye on more junior ones and check how they are doing. If they show signs of presenteeism—that is, working less effectively because of poor mental health—this will directly affect the operational capability and health of all team members, and thus early identification and support are key.

After care

Once the crisis is over, supervisors should ensure that time is made to reflect on and learn from the extraordinarily difficult experiences to create a meaningful rather than traumatic narrative. The National Institute for Health and Care Excellence recommends "active monitoring" of staff to ensure that the minority who become unwell are identified and assisted to access evidence based care.¹¹ Clinicians who provide care for moral injuries and associated mental illness should also be aware of the potential to avoid speaking about guilt and shame and focus on other stressors during therapy. This therapeutic avoidance can lead to poorer outcomes.¹² These are extraordinary times. There is a pressing need to ensure that the tasks ahead do not cause long lasting damage to healthcare staff. They will be the heroes of the day, but we will need them for tomorrow. For hundreds of years, the military have recognised the critical role of junior leaders in maintaining the will and capability of troops to continue to fight even in the most arduous of conditions. Similarly, healthcare managers in supervisory positions must now acknowledge the challenge staff face and minimise the psychological risk inherent in dealing with difficult dilemmas, and those in charge of resources must provide them with the opportunity to do so.

Key messages

- Healthcare staff are at increased risk of moral injury and mental health problems when dealing with challenges of the covid-19 pandemic
- Healthcare managers need to proactively take steps to protect the mental wellbeing of staff
- Managers must be frank about the situations staff are likely to face
- Staff can be supported by reinforcing teams and providing regular contact to discuss decisions and check on wellbeing
- Once the crisis begins to recede, staff must be actively monitored, supported, and, where necessary, provided with evidence based treatments

Contributors and sources: This article is based on our collective professional experience and a review of published material. The authors have extensive experience of conducting research during and after major incidents, including the London bombings, Ebola, and infections such as swine flu. NG is a specialist in the understanding and management of psychological trauma, occupational mental ill health, and post-traumatic stress disorder and was president of the UK Psychological Trauma Society during 2014-17. MD is an expert clinical adviser to NHS England's adult mental health clinical policy and strategy group. SG has carried out research in disaster risk reduction with Public Health England colleagues and is currently undertaking clinical work in liaison psychiatry at King's College Hospital. SW is past president of the Royal College of Psychiatrists and president of the Royal Society of Medicine. He serves on numerous government committees for the Department of Health (Labinet Mact. The article was conceptualised by SW and NG. The original draft was led by NG. The manuscript was reviewed and edited by NG, SW, MD, and SG prior to submission. NG is the guarantor.

Competing interests: We have read and understood BMJ policy on declaration of interests and have the following interests to declare: NG runs a psychological health consultancy that provides resilience training for a wide range of organisations, including a few NHS teams. The work was supported by the National Institute for Health Research (NIHR) Health Protection Research Unit in Emergency Preparedness and Response at King's College London, in partnership with Public Health England and in collaboration with the University of East Anglia and Newcastle University. The views expressed are those of the authors and not necessarily those of the NHS, NIHR, Department of Health England.

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Exhibit 16



Policies and Guidelines for COVID-19 Preparedness: Experiences from the University of Washington

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Abstract

The Coronavirus Disease 2019 (COVID-19) pandemic initially presented in the United States in the greater Seattle area, and has rapidly progressed across the nation in the past 2 months, with the United States having the highest number of cases in the world. Radiology departments play a critical role in policy and guideline development both for the department and for the institutions, specifically in planning diagnostic screening, triage, and management of patients. In addition, radiology workflows, volumes and access must be optimized in preparation for the expected COVID-19 patient surges. This article discusses the processes that have been implemented at the University of Washington in managing the COVID-19 pandemic as well in preparing for patient surges, which may provide important guidance for other radiology departments who are in the early stages of preparation and management.

Essentials

- Radiology policy goals are to reduce COVID-19-related morbidity and mortality through early diagnosis, appropriate treatment and prevention of disease dissemination.
- Imaging currently is not routinely used to screen for COVID-19 unless access to RT-PCR results for COVID-19 is limited.
- Postponing elective imaging and procedures will preserve resources and hospital beds, while also limiting patient population exposures.
- Determination of time-sensitivity of procedures and imaging tests is by consensus with input from radiologists, patients, and/or ordering clinicians.
- Radiology departments must prepare for patient surges through streamlined approaches to imaging that will limit exposures to healthcare workers and patients.

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Since the initial report of the SARS-CoV-2 virus outbreak in Hubei province in China in late December 2019, the virus has spread across the world, infecting more than 858,000, and killing more than 42,000 individuals over the span of 3 months(1). Washington state reported the first known case of COVID-19 in the United States in February 2020, and subsequently became the site of the first major outbreak in the country. In the current pandemic, it is vital for radiology departments to partner with the emergency operations teams in the healthcare enterprise for planning and coordinating diagnostic algorithms, for patient management, treatment and disposition, and for management of patient surges.

Our healthcare system consists of our school of medicine, two academic, urban hospitals, 1 community hospital, a network of outpatient primary and urgent care clinics and an air transportation service. There are a total of 1,173 inpatient beds and 186 intensive care unit (ICU) beds between the 3 hospitals. Our hospital system is centered in King County, which currently accounts for 52% of all known COVID-19 cases in the state. Current forecasts indicate a potential need for 30% to 60% additional acute care and ICU hospital beds over current capacity across our healthcare system.

During the COVID-10 pandemic, the goal of our policies and preparedness has been to a) reduce patient morbidity and mortality related to infection through early diagnosis and appropriate treatment, and b) prevent disease dissemination to our employees, patients and the general community. We have also focused on preservation of healthcare resources, management of essential equipment such as personal protection equipment (PPE) and ventilators and preparation for patient surge.

In this communication, we highlight the University of Washington experience, programs and policies. Although guidelines are constantly changing as we learn more about this disease process, we hope our experiences will help other institutions as they prepare to deal with the COVID-19 pandemic.

Elective Imaging Exams

2

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To promote our efforts to protect our patients and employees from potential exposure, while performing critical and time-sensitive non-invasive diagnostic imaging studies, we are rescheduling elective examinations. This is being accomplished via automated patient texting services and direct calls to patients from radiology scheduling. We seek to reschedule elective examinations for patients with have flu-like symptoms (fever, new cough, dyspnea, weakness) and with pre-existing conditions making them vulnerable to infection. As of now, the postponement will extend to May 18, 2020.

Our plan for planned postponement of elective diagnostic imaging has been communicated to referring physicians. We also requested that all orders for outpatient imaging include information on examinations that are critical for patient care versus those that may be postponed (including the length of time for postponement). Each outpatient imaging requisition now includes in the indication section the dates between which the imaging should be performed. Screening mammography, lung cancer screening and dexa scans are considered to be elective and all of these examinations are postponed until late May.

Implementation of these processes resulted in a rapid decline in our imaging volumes. Across our medical system, radiology imaging volumes have declined 39-60%, with 55-70% decrease in outpatient imaging volume. The estimated total RVU loss during the 2-month time period of reduced outpatient scanning is 14,923.

Lab Testing

Our institutions virology program began working on a reverse transcription polymerase chain reaction (RT-PCR) test for COVID-19 in early January, when reports of the outbreak in China first surfaced(2). At present, we are fortunate to provide 3000 RT-PCR tests for COVID-19 per day with 10-24-hour turnaround time. Testing capacity and turnaround time is expected to improve in the coming weeks. In comparison with CDC and Department of Health comparator specimens, our RT-PCR test has near 100%

3

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sensitivity. However, in actual practice the sensitivity of testing is lower due to variation in swabbing technique and viral load of the specimen source (nasopharyngeal likely more sensitive than nasal and oropharyngeal in early stages, and sputum often more sensitive in late stages in the presence of pneumonia). Early studies suggest that sensitivity of RT-PCR ranges from 32-93%, depending on the source of the clinical specimen (3). In order to protect our health care workers, we screen all patients who are admitted as inpatients for COVID-19 with RT-PCR, regardless of the reason for admission.

Imaging of COVID-19 Positive or Suspected Patients

The decision to image patients who are COVID-19 positive or suspected is based on how the imaging will impact patient care. We do not routinely use imaging for COVID-19 screening, but imaging *is* performed in COVID-19 positive or suspected patients, to rule out other diagnoses that can be treated, including pulmonary embolism. In addition, emergent imaging may be necessary for evaluation of other urgent conditions, including stroke, trauma, infection and other disease conditions (**Figure 1**). Clinics and inpatient units are directed to call ahead regarding COVID-19 positive or suspected cases so that precautionary preparations to receive the patient can be made.

CT imaging and chest x-ray performance in COVID suspected or COVID positive patients is based on whether the imaging will change patient management. In approximately 5000 COVID-19 tested patients across our hospitals, we have performed 4700 chest imaging exams, including 1300 CT and 3400 x-ray examinations. These include screening exams, follow-up exams, and other exams including ICU films, CT chest as part of trauma protocols and CT pulmonary embolism protocols. Through communication, education and case discussion with our emergency department colleagues, COVID-19 screening imaging requests anecdotally have progressively decreased at our primary COVID-19 hospital from 6-7 CT chest without contrast and 5-6 chest radiographs requested per day for COVID-19 screenings at our primary

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COVID hospital, to few or no chest CT without contrast or radiograph exams ordered on most days. CT pulmonary embolism studies continue to be ordered at this hospital, typically 2 to 3 per day, when there is concern for COVID-19 and other disease processes.

Screening prior to imaging procedures. All patients are screened at the hospital entrances for COVID-19 symptoms, with a second layer of symptom screening at the radiology front desk. For elective imaging, if the patient did not reschedule their study, arrives at our department and is symptomatic per front door or front desk screening, the patient is provided with a surgical mask and placed in an isolation room.

Approaches to imaging. Portable radiography is the mainstay imaging tool for emergency department and inpatient settings. If imaging can be done using portable equipment (chest or abdominal x-ray), the technologist dons personal protective equipment (PPE) consistent with the potential exposure and performs the portable x-ray in the isolation room. For most imaging procedures, PPE consists of a gown, gloves, eye protection and a mask (standard/contact/droplet). Once x-ray is complete, the technologist doffs PPE gear, preferably with a trained observer monitoring removal, ensures that the patient continues to wear a mask, and will direct the patient out of the department. Similar measures are taken for patients imaged in non-portable x-ray, MRI, CT, ultrasound or nuclear medicine sections, except imaging is performed in the respective imaging suites.

We limit patient transfers in order to limit staff exposures and to conserve PPE. By employing a modified version of processes developed during the 2014 Ebola outbreak, we can obtain portable chest radiography either a) through the glass of an isolation room door or b) at a greater than usual distance (10-15 feet) across a semi-isolation antechamber into an isolation room. The patient is placed in a wheelchair or gurney inside the isolation room, facing the glass door or window. A nurse (who has already donned PPE) places a double-bagged x-ray cassette behind the patient. A radiology technologist outside of the closed room, indicates optimal positioning adjustments via speaker phone and/or hand

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gestures. After the exposure, the nurse disinfects the cassette outer bag and brings the cassette to the room door. The technologist pulls the inner bag containing the cassette from the outer bag, which stays in the room. The technologist disinfects the inner bag, removes the cassette and then processes the film. Afterward, the plastic bags are appropriately disposed. This technique has been highly successful when performed through clear and wire-reinforced glass windows as well as glass windows with opened metal venetian-type blinds (**Figure 2**) with few repeat exposures needed. Using this technique, staff exposure is reduced, PPE use is reduced and operational and conservation efficiencies are gained by decreased post-exam equipment cleaning.

Protection of Radiology Staff

An important consideration that radiology departments must weigh is taking appropriate precautions for imagers, staff and radiologists while conserving PPE by avoiding excessive precaution and resource utilization. We have two types of precautions for patients with COVID-19: a) less stringent standard/droplet/contact precautions and b) more resource-intensive standard/airborne/contact precautions. Standard/droplet/contact precautions apply to most patients, while standard/airborne/contact precautions apply to patients who are critically ill and intubated or are or could undergo aerosol-generating procedures while in the room(4) (**Figure 1**).

Airborne/contact precautions. These precautions require the use of N95 filtering facepiece respirators (FFR) or powered air-purifying respirators (PAPR) replacing the conventional surgical mask used for droplet protection. N95 FFRs and PAPRs protect health care workers from small infectious particles (> 5 micrometers) and are adequate in the setting of aerosolizing COVID-19. N95 FFRs require individual fitting (facial shape and size). Advantages of PAPRs include protection of head and neck (hood), use with facial hair and filtration of particles as small as 0.3 micrometers (equivalent to high-efficiency particulate (HEPA) filters) as well as those individuals who cannot be fit to an N95 FFR.

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Correct donning and doffing of protective measures is instrumental for the efficiency of PPE. At our hospitals, donning and doffing was practiced by each staff member in group sessions available during day and night shifts for all staff who are expected to come in contact with patients. Rapid N95 mask fit testing is offered concomitantly.

Airborne precautions. SARS-CoV-2 is believed to be primarily transmitted via droplets. Very small droplets (less than 4 micrometers) can be produced by virus-shedding patients through forceful coughing. As such, health care providers may become exposed to aerosols theoretically able to permeate N95 FFRs. Increasing air-exchange per hour (ACH) or HEPA filtration of room air represent potential supplemental mitigation measures(5). Air exchange rates varies between imaging suites, depending on ventilation, air circulation and room configuration. Infection control has reviewed our imaging suites to assess air circulation and the need for air exchange measures. For standard/airborne/contact precaution, we use HEPA filtration systems to increase air exchange, with the exception of MRI, as these units cannot be used in the MRI suite. Our MRI suites have better ventilation and hence better air exchange, so this is not thought to be an issue.

Room Cleaning

Imaging suites are sanitized using standard cleaning procedures between patients. Our standard cleaning procedure uses quaternary ammonium/alcohol impregnated wipes or other Environmental Protection Agency (EPA) -approved disinfectants(6). For patients requiring airborne/contact precautions, radiology technologists will perform room sanitizing after imaging while still wearing the same set of PPE as used during patient transfers. Although evidence about the effectiveness of air-exchange measures is limited, use of large stationary HEPA filters (except in MRI) in temporarily closed imaging suites can allow for sedimentation and removal of small aerosol particles. At our hospitals, imaging rooms are

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closed for 1 hour for airborne precautions in rooms with a minimum of 6 air exchanges per hour. We start the clock immediately after the patient leaves the imaging suite and cleaning time is included in the room closure downtime. Interventional radiology suites at one of our hospitals are closed for one hour after every COVID-19 positive or suspected patient (droplet or airborne precaution) due to limited air circulation, while at the other hospitals, the interventional suites are shut down for 1 hour only for airborne precaution.

Sick or Exposed Employees

In our healthcare system, COVID-19 exposed employees who are asymptomatic are required to return to work, to attest to their health daily and to self-monitor for symptoms twice per day. We do not require that employees wear masks following exposure to patients with COVID-19. This is because most exposures are unreported exposures occurring in the community. We do not perform RT-PCR tests on asymptomatic employees.

Employees who exhibit symptoms of acute respiratory infection are asked to undergo RT-PCR testing for COVID-19 at drive-through testing clinics and are instructed to stay home. If COVID positive, employees are required to stay in isolation for a minimum of 7 days from symptom onset and must be symptom-free for 72 hours before returning to work (7). For those that are COVID negative, they may return to work when symptom-free for 24 hours. In the radiology department, we have had one faculty member, two technologists and one transporter test positive, all presumed to be community acquired. We had a clinical fellow who had a false positive RT-PCR test, then on re-assessment of the sample by the state lab, was determined to be negative.

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Invasive Procedures in COVID-19 Patients

We use a 3-tiered approach for scheduling procedures under consideration (**Table 1**). Procedure requests are reviewed individually by subspecialty radiologists (interventional radiology, body imaging, musculoskeletal radiology and neuroradiology) and assigned a category in consensus with the ordering provider.

We perform critical procedures that would adversely impact patient care if not immediately scheduled. For all critical and time-sensitive procedures and imaging studies that involve anesthesia and may require intubation, a RT-PCR test for COVID-19 is performed prior to the procedure to ensure healthcare worker protection. To accomplish this, a rapid 75-minute RT-PCR test has been employed for these emergency procedures. For critical trauma cases, stroke interventions and active bleeding cases, the inhouse rapid COVID-19 RT-PCR test is not performed. For these patients, we employ airborne/contact precautions with assumption of COVID-19 infection.

Distribution of Patients for Imaging Procedures

In radiology, we direct patients with COVID-19 infection or suspected infection who have or suspected time-sensitive imaging away from hospital centers with a high-volume of critically ill patients (i.e., patients without COVID-19 infection) to outpatient imaging centers with lower patient volumes. A limitation of this approach is that patients may develop symptoms of infection between the time of infection and the date of the imaging examination.

Radiology Faculty and Staff Protections

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Our department has accelerated the process of providing home workstations for radiologists. We upgraded our PACS servers to support an increased volume of radiologists doing remote interpretation. For on-site radiologists, we established 21 single workstation reading room outposts across our various institutions to isolate radiologists. We have online sign-up sheets to reserve and use the above outpost rooms, and an automated dashboard that tracks home and outpost interpretations. Employees are now provided with daily standard 3-layer disposable earloop surgical masks for use during direct patient care. In addition, employees are permitted to wear these masks during non-patient care. If masks become soiled or if working with a COVID positive or suspected patient, the mask will be replaced with a new mask for use.

Due to the reduced imaging volumes and need for social distancing, we have restructured our shift coverage for faculty and trainees. We have 1 faculty radiologist, 1 imaging fellow and 1 resident in the reading room at any given time. Staff and trainees site at every other workstation to maximize their separation. Trainees have their own workstation and communication is achieved by conversation in the same room at a safe distance, or via screen control enabled video conference with trainee and staff sitting at different physical locations. On some services, such as nuclear medicine, we also created two rotating teams for in-person clinical daytime coverage, with each consisting of 1 faculty, 1 fellow and 1 resident that exclusively work together for service coverage for a week at a time, and rotate one week on and one week off. The off team provides remote support when needed. This limits cross-exposure between teams to limit transmission of disease that may negatively affect the team.

On-site radiology employees fill out mandatory daily online attestations to their health status when they arrive at work. For radiologists, these attestations pop up on PACS workstations every four hours. Answers get routed to supervisors to inform them of symptomatic team members.

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All meetings are encouraged to be held by video conference. We require that any meeting with more than 6 attendees be virtual or be cancelled. All faculty and trainee interviews are online, and our grand rounds and visiting professorships are held online as well.

Enterprise-wide Coordination and Communication

Early in the outbreak, our healthcare system created a command center to coordinate the system response to the myriad facility, staffing, safety and resource needs. A secure central repository was established for COVID-19 related policy and procedure documents and outbreak related resources, such as childcare and personal counseling (covid-19.uwmedicine.org). Daily command center briefings are available to all employees. Weekly enterprise huddles summarize recent actions, remunerate on-going initiatives and review regional and enterprise situation status.

At the department level, communication is facilitated through virtual daily huddles with department leadership and weekly faculty meetings. Daily huddles at each radiology site maintain safety and practice standards and provide an opportunity to answer questions.

Disaster Preparedness

Most models predict exponential increases in COVID-19 cases, hospitalizations and deaths over the next few weeks, with depletion of hospital resources, including hospital beds, specifically intensive care unit beds, ventilators and PPE. Hospital systems, and radiology departments need to prepare for a COVIDrelated patient surge.

UW Medicine hospitals are erecting triage tents outside the hospital to keep the non-critical COVID-19 patients and other patients with respiratory symptoms outside the hospital. Radiology is providing

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supporting imaging equipment, including portable chest x-ray equipment in adjacent spaces with imaging performed through glass doors or in adjoining triage tents. At HMC, access to MRI, CT and ultrasound equipment for those COVID patients that may require advanced imaging for other indications—including the evaluation for pulmonary embolism, brain or spine pathology—is available in adjacent HMC dedicated scanners. HMC has 2-1.5T and 1-3T MRI scanners, 3-128 slice, 1-dual energy and 1-SPECT-CT scanners, 7 ultrasound units, and 4 angiography suites. For potential surges, the plan is to dedicate the SPECT-CT scanner for COVID-19 CT imaging, with protocols developed for contrastenhanced imaging and an additional CT scanner if needed, as well as dedicating 1-2 x-ray imaging suites beyond the portable equipment deployed and an ultrasound unit. There has been planning of placement of a portable CT scanner in the triage tent at UWMC-ML. At UWMC-NW, the plan is to scan those patients that need CT to be scanned in the isolated SPECT/CT scanner in close proximity to the tent in order to limit in-hospital transit.

The hospital has prepared for the inpatient surge through rental of 180 patient beds and ventilators that are truck loaded. We have created scanner throughput plans, including designated CT scanners and imaging suites for COVID-19 positive patients. In addition, we have created imaging screening mitigation plans in case our lab testing algorithm gets overwhelmed.

The radiology department has submitted all able-bodied and non-vulnerable faculty into a general faculty pool that may be recruited for ED and inpatient direct patient care with support and guidance provided. There is a separate pool of residents and ACGME fellows.

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Category	Designation	Description	Evaluator
Category 1	Elective/Non-Urgent	If delayed, will not harm patients in the next 2-6 months. These procedures can be delayed until after postponement period	Radiologist in consensus with ordering clinician
Category 2	Time-Sensitive	Short delay is acceptable, within a certain time frame.	Radiologist in consensus with ordering clinician
Category 3	Critical	Cannot be delayed. Schedule these procedures right away.	Radiologist in consensus with ordering clinician

Table 1. Three-tiered Approach For Scheduling Procedures Under Consideration

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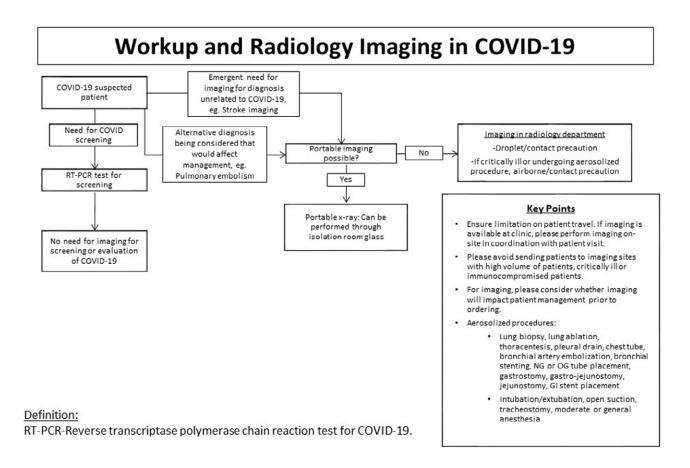


Figure 1. Workup and radiology imaging in COVID-19 suspected patients.

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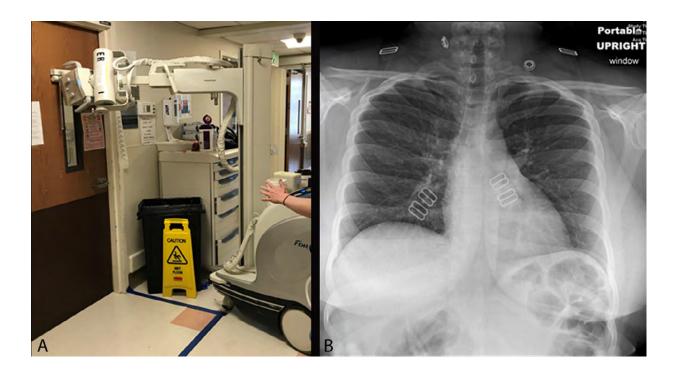
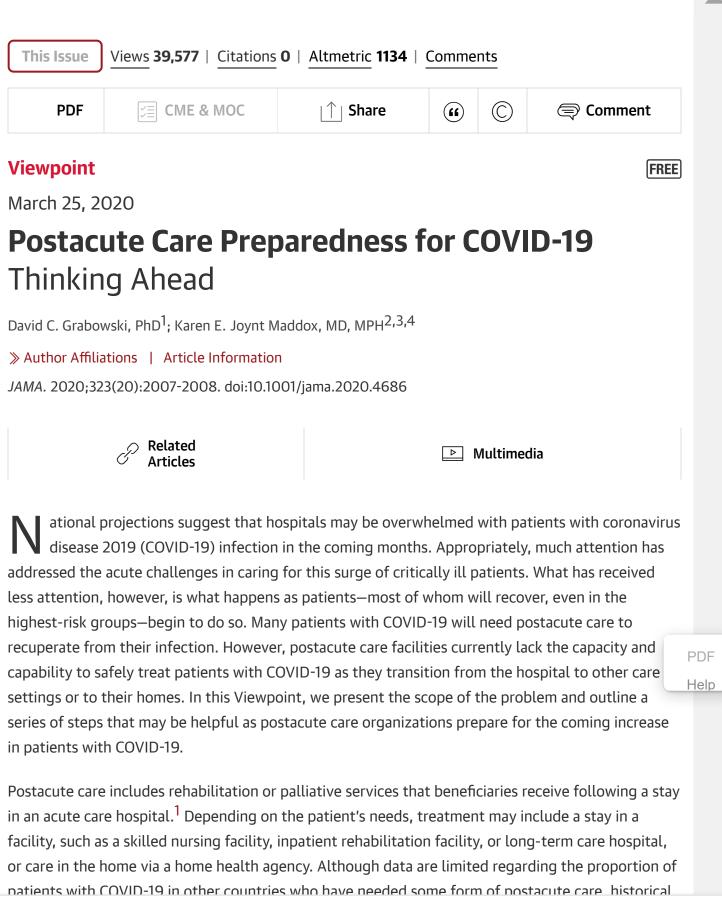


Figure 2. Chest radiography through glass. Technologists position the portable x-ray unit outside the patient room, with the tube peering through the wire-reinforced isolation room window (A). AP chest x-ray through obtained is of diagnostic quality (B).

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Exhibit 17



6/8/2020 Case 2:18-bk-20151-ER PreDecen4849 covided 06/09/20ad Entered 06/09/20/15:89:08NetwDesc Main Document Page 176-of 290 with inpatient mortality similar to that associated with COVID-19, require facility-based care and another 20% require home health care.³

Postacute care is also a "pop-off valve" for hospital capacity, in that moving patients to a such a setting once they recover from the most acute phase of their illness could free up hospital beds. Medicare has already loosened restrictions on criteria for transfers by relaxing the 3-day rule,⁴ which requires a Medicare beneficiary to spend 3 days in the hospital to qualify for the skilled nursing facility benefit. This will facilitate faster transfer for the least-sick patients.

Projections suggest a major surge in postacute care demand will occur following the hospital surge involving patients with COVID-19. Current skilled nursing facility supply varies nationwide (see the eFigure in the **Supplement**), and occupancy rates average 85%,¹ signaling that current capacity is inadequate for any surge. But the problems go beyond capacity alone. The discharge of patients with COVID-19 to skilled nursing facilities is complicated. The COVID-19 outbreak at Life Care Center in Kirkland, Washington, has already led to the death of 30 residents as of March 16, 2020, approximately one-quarter of its residents.⁵ The Centers for Medicare & Medicaid Services has instituted a series of rules in an attempt to prevent further outbreaks from occurring in these facilities, including no-visitor policies and no group activities or communal dining. In this context, it is not safe in some cases for hospitals to transfer patients with COVID-19 into the mainstream skilled nursing facility population because some patients may still be able to transmit disease.

Where will patients who have begun to recover from COVID-19 receive postacute care? What steps can policy makers and health care organizations take to ensure safe and appropriate postacute care services in the coming weeks and month?

As an important first principle, all patients need to be tested for COVID-19 when they are being discharged to a postacute care setting regardless of whether they were being treated for COVID-19 at the hospital. No individual who has COVID-19 should be discharged to a mainstream postacute care setting except for those rare instances in which the facility can safely and effectively isolate to patient from other residents. There is still uncertainty around how long patients remain contagious after clinical recovery, so testing guidelines may need to be revised as additional information becomes available.

Consequently, specialized postacute care environments will need to be developed to treat patients who are recovering from COVID-19 and cannot receive care at existing facilities while still potentially contagious. These specialized environments could potentially take several forms. One approach would be to dedicate certain postacute care facilities in each market to be "centers of excellence" specializing in—and exclusively assuming—the care of patients recovering from COVID-19. Because

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PDF Help 6/8/2020 Case 2:18-bk-20151-ER PreDocn4849 covided 06/09/20ad Entered 06/09/20Abs 89/08Net/Desc Main Document Page 177 of 290 care safely. Certain types of facilities such as long-term care hospitals and hospital-based skilled nursing facilities may be well-suited to adopt this specialized role initially because of their existing infrastructure for infection control and their generally higher capacity to care for complex patients.

In other local markets, temporary capacity will need to be built due to potential postacute care shortages. Rural hospitals, many of which have occupancy rates less than 50% and some of which have skilled nursing facility "swing bed" capacity, could be important sites to provide postacute care. New York Governor Andrew Cuomo proposed the idea of using the Army Corps of Engineers to retrofit unused buildings such as military bases and college dormitories as temporary hospitals. Similar approaches could be taken to establish temporary postacute care settings, which may be more appropriate for buildings in which the infrastructure is inadequate for hospital care but could plausibly meet the less intense needs of rehabilitative care.

Given the challenges with physical distancing in facility-based care, another important approach is treating patients who are recovering from COVID-19 in their homes when possible. Home health agencies are paid in 30-day episodes that typically consist of a mix of therapy, nursing, and home care aide visits. The current average level of care, however, will be insufficient to manage higher acuity patients with COVID-19 transitioning from the hospital. One potential solution is increased investment in hospital-at-home models,⁶ which provide institutional-level services in the home.

Regardless of which of these approaches is taken (and likely all will be needed), staffing will be key. The postacute care sector already faces issues in identifying high-quality staff willing to work in these settings.⁷ This issue will be magnified in the context of COVID-19. For this reason, the support of staff is essential. Staff must have the requisite training and personal protective equipment to treat patients recovering from COVID-19 safely. Staff will need to be tested regularly to ensure that they are not spreading the virus. And additional staff may need to be recruited to perform lower-skilled tasks that can be acquired relatively quickly, perhaps in part from industries that will experience major layoffs in the near term.

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Another important staffing issue is the lack of access to physicians and advanced practice providers, who may be in short supply given the increase in demand. Telemedicine might be one approach to increase access in both facility and home care settings,⁸ and in the context of COVID-19 has the added benefit of helping to prevent the spread of the disease by eliminating in-person contact. The recent announcement from Medicare indicating the provision of reimbursement for all telemedicine care, across video or voice platforms and with temporary Health Insurance Portability and Accountability Act (HIPAA) waivers,⁹ is a crucial step toward making this feasible.

Policy makers should consider several temporary policies to support preparedness for COVID-19. All

hospital care to encourage adoption of this model. The US has been playing catch-up in its COVID-19 response in terms of testing, physical distancing, and hospital capacity. Making changes in postacute care delivery and policy today could help contribute to having adequate capacity and capability in the coming weeks and months.

Advertisement

6/8/2020 Case 2:18-bk-20151-ER PreDocen4849 COVIDed 06/09/20ad | Enterced: 06/09/20Abs 89/08Net/Desc Main Document Page 178 of 290 rate should be implemented for providing care for patients with COVID-19 across all postacute care

incentivized to take on these cases and be given the resources to provide these patients with highquality care. Medicare should also reimburse hospital-at-home models at parity with institutional

settings. The treatment of these cases will mean added costs in terms of physical distancing, infection control, and staffing. Postacute care facilities and health care personnel should be

Article Information

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Exhibit 18

NEUROLOGY

DOI: 10.1212/WNL.000000000009519

Preparing a neurology department for SARS-CoV-2 (COVID-19): Early experiences at Columbia University Irving Medical Center and the New York Presbyterian Hospital in New York City

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Introduction

Beginning in December 2019, a novel coronavirus, SARS-CoV-2 (COVID-19), began spreading rapidly throughout China and now is a global pandemic with cases reported in over 192 countries and territories worldwide. Clinically, COVID-19 ranges from a mild, self-limiting respiratory illness to severe progressive pneumonia and multiorgan failure. The first COVID-19 case was reported at the beginning of March in New York City (NYC), and now just three weeks later, NYC and its suburbs have over 5% of global cases. Worldwide, there is a rapid increase in the number of cases daily, including the number of patients requiring hospitalization and intensive care support.

While our internal medicine, emergency room, pulmonary/critical care. and anesthesiology colleagues are at the frontlines, neurologists are playing a critical role in patient care. Here, we describe the initial steps our department has taken to prepare for the COVID-19 outbreak. We highlight some of the steps neurology departments should urgently consider to prepare for an increased volume of COVID-19 patients in their hospital system. This manuscript provides a comprehensive guide for other neurology departments in terms of preparation for an influx of COVID-19 positive patients into their hospital system.

General departmental initiatives

As a department, we began holding routine meetings to prepare for COVID-19 in mid-February. Multi-disciplinary meetings are held with key staff including nursing leadership, intensive care leadership, inpatient and outpatient neurology department leaders, and departmental administrative leadership (Table 1). At the beginning of March, we held webcasts to our department weekly given the restrictions for large in-person gatherings to provide updates

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on inpatient and outpatient clinical care activities, departmental research ramp-down, human resources issues, and updates on hospital and public health guidelines including key epidemiological information around COVID-19. There was an opportunity for departmental members including support staff to ask questions around work-related concerns.

Providing mental health support for the challenges we all face during this time due to social distancing and separation, child and elder care, financial, and clinical pressures was identified as an early critical component of our efforts. In addition to departmental neuropsychologists volunteering to provide free private counseling services, hospital-wide free tele-mental health support have also been made accessible to our department.

Inpatient neurology service preparation

Inpatient Neurology Services

During the early phase of our preparations, nursing leaders on our neurology units provided training for donning and doffing of personal protective equipment (PPE), nasopharyngeal sampling technique, review of protocols for patients who are persons under investigation (PUIs) and screening of our patients for possible COVID-19 symptoms. Hospitalbased guidelines are reviewed regularly. A checklist that the nurses completed is performed for all patients admitted to our units for possible COVID-19 symptoms. As community spread continued to rise, this checklist is now done daily on all our inpatients. A COVID-19 binder was created on each unit to compile COVID-19 related documents including clinical guidelines, hospital protocols, and policies as well as our daily operations. A daily nursing huddle occurs to share information on COVID-19 and discuss PUI and COVID-19 positive cases on the unit. All trainees and inpatient neurology team members were trained in the same manner regarding

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proper PPE use, protocols for PUIs and education around caring for COVID-19 patients routinely.

Inpatient leadership and our chief resident developed a schedule to scale down our inpatient services to necessary staff including resident trainees (Figure 1). Back-up schedules and defined skills for re-deployment (inpatient clinical, outpatient clinical, administrative, language skills) were done for trainees, neurohospitalists, and the neurocritical care team. Medical students and observers were removed from clinical services as was mandated by our hospital in early-March. All teams practice social distancing when rounding and teaching is occurring in workrooms and not at the bedside. We minimized the number of team members entering patients' rooms to the attending for PUIs or those who were COVID-19 positive. We are bundling orders and adjusting routine care (i.e. laboratory draws, the frequency of neurological checks, timing of medication administration) to the minimum to provide adequate care while being conscientious of nursing exposure time in PUI and COVID+ rooms.

All elective admissions for non-urgent purposes were cancelled in early March, and our epilepsy monitoring units (EMUs) were closed in both pediatrics and adult services. All urgent admissions and possible transfers were screened via phone for possible COVID-19 symptoms (including family members living in the same household) and accepted only if we could provide urgent management not available elsewhere. Re-screening for possible COVID-19 symptoms occurred when a patient arrived from an outside hospital or was directly admitted to our inpatient unit. If a patient was unable to answer questions regarding symptomology which is the case in many of neurological patients, we assumed these patients may have COVID-19 infection during ongoing community spread and considered them a PUI in consultation with our infection, prevention and control (IP&C) experts. All COVID-19 positive patients were centralized to

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designated hospital units as well as specialized COVID-19 teams as the pandemic in New York continues to rapidly evolve. Patients with primary neurological conditions who are COVID-19 positive or PUIs remain on our neurology services. Thus, training of PPE donning and doffing a well as PUI protocols were essential for our inpatient team members.

Neurology Consult services

On our neurology consult services, we transitioned to "curbside" consultations, reserving in-person consultations for urgent inpatient issues and ED consults (i.e. new brain hemorrhage, acute stroke consults, ongoing seizures). All electroencephalograms (EEGs) ordered by nonneurology teams for PUIs and COVID-19 positive patients were required to be approved by our neurology consult teams to avoid unnecessary studies in the context of limited PPE and to protect EEG technicians. We subsequently developed mechanisms to expand our inpatient teleneurology services to our emergency departments (EDs) and inpatient services.

Acute stroke care protocol in the ED, includes temperature check, oxygen saturation measurement and COVID-19 symptom screening before performing the National Institute of Health (NIH) stroke scale. If the patient cannot answer the screening questions, we assume the patient is COVID-19 positive requiring the use of PPE. The availability of PPE is an ongoing challenge in NY as well as many other regions of the country.

We changed our tissue plasminogen activator (tPA), thrombectomy, intracranial hemorrhage, and subarachnoid protocols across the hospital system enterprise to concentrate care allowing nursing care to focus on the COVID-19 surge of patients in the ED. Stroke care coordination across NYC centers has been essential with frequent citywide meetings involving

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neurointerventional radiologists, neurocritical care directors, stroke team leaders, and neurosurgery.

Neurocritical Care Unit (NICU)

Currently, approximately 20% of our inpatient COVID-19 positive patients require intensive care unit (ICU) support and thus a significant number of COVID-19 positive patients have been moved to the care in NICU. Our ICU director frequently coordinates with hospital ICU directors to optimize care the of critically ill COVID-19 patients. There has been rapid development of protocols around the safe management of critically ill COVID-19 patients (i.e. intubation and other aerosolizing procedures, cardiopulmonary resuscitation). In early March, our NICU director and NICU faculty provided routine education and preparation to staff and trainees around acute respiratory distress syndrome (ARDs) management, guidelines for noninvasive positive pressure ventilation and high flow nasal cannula oxygen for suspected or confirmed COVID-19 patients, as well as ongoing clinical trials on antimicrobial and immunomodulatory treatments. Neurocritical care fellows were now deployed to maximize the care for critically ill COVID patients throughout our hospital system. Our critical care rounding teams were split to include a COVID focused team led by our neuro-intensivists and a non-COVID-19 team focused on the COVID negative neurological critically ill-patients lead by our neurovascular team (Figure 1). Teams have been restructured to include essential personnel with some team members providing remote support (i.e. pharmacists).

All intubations are done by anesthesia for PUIs and COVID-19 positive patients. Early transfer of patients out of our NICU was prioritized with an emphasis on early tracheostomies and percutaneous endoscopic gastrostomy (PEG) tubes, as well as early shunts. Our role in the

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prognosis and assessment of brain death is essential as neurologists, and protocols are in place with regards to COVID-19 patients. Making an accurate and reliable prognostic decision will reduce ventilator usage, and conserve PPE resources. Guidelines from the American Heart Association (AHA) on neurologically related prognoses in COVID-19 patients after cardiac arrest are being developed. Some of the early steps we are taking include establishing a neurological examination by one intensivist, focusing on brainstem reflexes 48-72 hours after being off sedation, relying on spot EEGs rather than continuous EEG in select cases, and obtaining neuroimaging and somatosensory evoked potentials if feasible.

As with neurology patients in the ED, there was an early recognition that our NICU patients will not be able to provide the history to screen in which we have stressed to our institution the necessity of considering testing for COVID-19 in those circumstances in consultation with IP&C.

Ambulatory Neurology

In early March, ambulatory staff including call-center personnel and in-person patient greeters were trained to screen all patients and those accompanying the patient for possible COVID-19 symptoms. Patients were contacted to schedule their visit on a telecommunication platform and all patients were screened for symptoms. An ambulatory care protocol established by our hospital system was followed. Transition to tele-neurology visits began for our outpatient practices in early March with the complete transition by mid-March for all new and established patients. Plans were immediately implemented to provide laptops and technical support to enable all outpatient practitioners to practice remotely. Webinars and guides for both patients and providers were distributed rapidly to enable as many visits as possible to continue uninterrupted.

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The university-wide ramp down in non-essential research activities has enabled us to increase the availability of telehealth sessions by providers who had previously dedicated significant time effort to research. Each division in our department created guidelines on which clinical scenarios warrant an urgent in-person visit. Any in-person visit must be approved by the division head and departmental leadership. Home EEG testing has been expanded. Botulinum toxin treatment for migraine has been continued, after the appropriate screening, to prevent relapse and avoid emergency room visits. Neurology infusion center patients are delayed when appropriate, transitioned to home infusions or consolidated in the main hospital infusion center. Urgent post-discharge telemedicine appointment slots were established in all divisions to allow for expedited emergency room and inpatient discharge when appropriate.

All in-person visits in our resident clinic were also converted to telemedicine or, if patients do not have the technical capacity to participate in video visits, to a telephone visit. Residents performed telemedicine visits remotely and staff with an attending (also remote) by phone or by Zoom meeting. For the patients who needed to be seen urgently, or who came in person for an appointment (if we cannot contact them) we established a rotating call system whereby one resident and one attending were available to come in within 30 minutes if needed.

Research

To minimize the number of individuals in the Medical Center and to be able to re-deploy needed manpower, equipment and supplies, all non-critical clinical and basic researches were ramped down in under guidance from University. The implemented plan involved: (1) setting-up a 96-hour ramp down policy to complete all ongoing critical experiments, stopping all noncritical experiments and preventing all new experiments; (2) establishing a list of a small number of

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essential research personnel on-site at any given day to assure the proper functioning of large equipment such as freezers or incubators, maintenance of animal husbandry, and control the integrity of research spaces; (3) re-deploying research staff and post-docs, voluntarily and depending on skills, to assist teams working on critical tasks including COVID-19 research and testing; (4) pausing all clinical trials and observational studies that included patient contact which was not related to COVID-19 or did not have direct patient benefit per our institutional review board (IRB) policy and then eventually pausing all enrollment regardless of the potential for benefit. In addition, in discussion with the IRB and senior leadership concerning research administration, for patients already enrolled in clinical trials, potential or perceived risks of some protocol-specific events may outweigh the benefit and may be omitted, consistent with the Code of Federal Regulations. Once the ramp down plans were implemented, all research groups were encouraged to pursue all team activities and communications such as laboratory meetings, journal clubs, thesis committee meetings remotely via internet-based video conferencing technology.

Education

With regards to educational activities, all medical student clerkships- including neurology - were suspended in mid-March by the medical center and a virtual curriculum was created for the remaining weeks of their rotation. It was arranged with the National Board of Medical Examiners that the shelf exam is to be done remotely. For the residency and fellowships, conferences were continued via internet-based video conferencing technology.

Conclusions: Team involvement and cohesion, well-being, challenges and pathways ahead

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The importance of coordinated, multi-disciplinary efforts to prepare neurology departments for the COVID-19 outbreak is essential. We have worked cohesively within the department, the hospital, and university to implement strategies to minimize the risk of COVID-19 transmission and perform the best of care for our patients. This has required ongoing adjustments and flexibility in our department. The need for close communication has been essential to the functioning of the department during these incredibly challenging times. There are certainly challenges ahead (Table 2) during the unprecedented health crisis with further necessary adjustments and taking this pandemic seriously cannot be underemphasized for neurology departments across the country and world.

Acknowledgements

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Appendix 1: Authors

Genna Waldman MD	New Yerk Dreeks to start	
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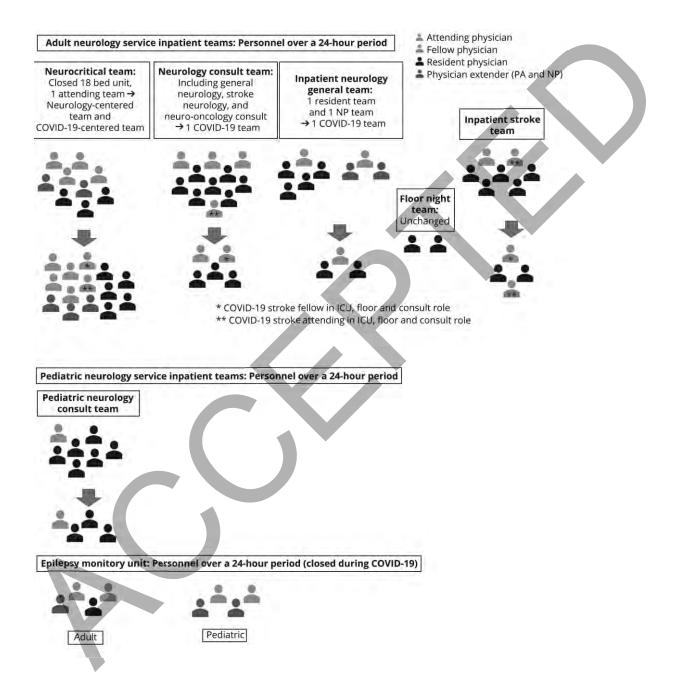
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	Medical Center, New York	content in paper , Revised
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	Medical Center, New York	_
	Neulai Center, New TOR	content in paper, drafted and
		revised the manuscript for
		intellectual content

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Figure Legend

Figure 1: Personnel changes on neurology inpatient services during the COVID-19 pandemic



Tables

Table 1: Interdisciplinary Meetings in the Neurology Department

Interdisciplinary Meetings and attendees	Select Topics of Discussion
Neurocritical Care	-alignment of hospital initiative of cohort
-Critical Care Attendings across departments	patients with COVID-19
-Neurology Inpatient Attending director	-align with hospital initiative of increasing
-Neuro-hospitalist Attendings	ICU beds
-ICU Nurse managers	-education on COVID-19 specific airway and
-Step Down Unit Coordinators	ventilator management and research
-Step Down Unit Nurse Managements	treatments
-Neurology Chief Resident	-screening protocol for the altered and aphasic
	patient
	-training on PPE donning and doffing
	-protocol for increasing step down unit care
	for non-intubated ICU patients
	-increase deployment of residents from
	neurology and neurosurgery departments to
	align with care for increasing volume and
	medical complexity
Consult Service	-addition of temperature and O2 saturation
-Inpatient Attending Director	measurement to the stroke code vitals
-Neuro-hospitalists Attendings	-screening protocol for the stroke responder
-Stroke Attendings	and consult resident in the Emergency
-Neurology Chief Resident	Department
-Pediatric Neurology Consult Attendings	-training on PPE donning and doffing
	-conversion to telephone consults
	-implementation of tele neurology
	consultations
	-minimize resident and attending staffing to
	essential personnel
Inpatient Meetings	-screening protocol implementation for the
-Inpatient Attending Director	outside hospital transfer and ED patient
-Neuro-hospitalists Attendings	-nurse training on daily screening checklist
-Stroke Attendings	-training on PPE donning and doffing
-Patient Care Directors	-minimize resident and attending staffing to
-Nurse Management	essential personnel
-Neurology Chief Resident	-limit personnel bedside, resident teaching
	done in workrooms
Ambulatory Neurology	-full conversion to tele medicine visits
-Outpatient Attending Directors	-a policy requiring Chairman review and
-Faculty Practice Administrative Director	approval for in-person outpatient visits
-Inpatient Attending Director	-screening protocol and education to staff and
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	in-person evaluation -defer non-emergent diagnostics tests -resident redeployment from outpatient clinical shifts to in patient essential clinical shifts
Inpatient to Outpatient Transition (Discharges) -Outpatient Attending Directors -Faculty Practice Administrative Director -Inpatient Attending Director -Neuro-hospitalists Attendings -Stroke Attendings -Neurology Chief Resident	-inpatient checklist of patient information to provide to the outpatient scheduler -implementation of rapid telemedicine visits for hospital discharges
Bi-Weekly Department Announcement -Neurology Chairman -Chief Financial Officer -Inpatient Attending Director -Faculty Practice Administrative Director	 -institution updates on hospital initiatives -education on symptoms and stay home policy if any symptoms present -work from home policy -telemedicine protocol updates -travel restrictions policy review -research updates

Table 2: Healthcare Worker (HCW) -related issues during COVID-19

HCW at risk: Preexisting conditions and age	-Recognizing pre-existing conditions in our HCW
of providers	-Deploy the HCW to low-risk clinical duties, such
	as telemedicine clinic, home consult call
Quarantine	-if any symptoms HCW is not to work
	-follow Institution guidelines and contact Work-
	Force Health and Safety for return to work
	guidance
Sick Call	-daily review of shift assignments, for the
	quarantined staff to identify those available for
	back up sick pull
Repurposed Staff	-follow institution policy for the redeployment of
	staff

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Exhibit 19

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Short Communication

Preventing Intra-hospital Infection and Transmission of Coronavirus Disease 2019 in Health-care Workers

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ABSTRACT

Coronavirus disease 2019 poses an occupational health risk to health-care workers. Several thousand health-care workers have already been infected, mainly in China. Preventing intra-hospital transmission of the communicable disease is therefore a priority. Based on the Systems Engineering Initiative for Patient Safety model, the strategies and measures to protect health-care workers in an acute tertiary hospital are described along the domains of work task, technologies and tools, work environmental factors, and organizational conditions. The principle of zero occupational infection remains an achievable goal that all health-care systems need to strive for in the face of a potential pandemic.

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1. Preventing Intra-hospital transmission of coronavirus disease 2019

The start of this new decade was dampened by reports of a cluster of novel viral pneumonia in Wuhan City, China. On 30 January 2020, the World Health Organization declared this emerging infectious disease, now known as coronavirus disease 2019 (COVID-19) as a Public Health Emergency of International Concern [1] and on 11 March 2020, declared COVID-19 a pandemic [2]. Merely 3 months from the time it has first reported, COVID-19 has spread rapidly from its epicenter in Wuhan City to 113 countries outside of mainland China. At the time of writing, there are more than 118,000 cases globally and almost 4300 fatalities [3].

Singapore reported its first case of COVID-19, diagnosed in a tourist from Wuhan City, on 23 January 2020. Even before the report of the first confirmed case, the Singapore Government had activated a Multi-Ministry Taskforce on 22 January 2020 to marshal a whole-of-government approach in containing the spread and impact of COVID-19 [4].

One of the containment strategies adopted by Singapore's Ministry of Health is to treat and manage all COVID-19 cases within hospitals, while concurrently undertaking rigorous contact tracing to identify, isolate and monitor all contacts with significant exposure to the index cases. Occupational exposure of health-care workers is therefore a real concern that needs to be addressed comprehensively and decisively.

Singapore has learned important lessons from the severe acute respiratory syndrome (SARS) in 2003. Forty-one % of 238 probable SARS cases in Singapore occurred in health-care workers [5]. Hospital-centric containment efforts were therefore implemented in a bid to curb intra-hospital transmission of SARS. These measures prevented the further unfettered nosocomial spread of SARS, but not before exacting a heavy toll on health-care workers caring for infected patients [6].

Similar to SARS, current evidence indicates that COVID-19 is primarily transmitted through respiratory droplets [7]. Infections in health-care workers have already been reported [8]. More than 3000 medical staff were reportedly infected in China by late February 2020 [9].

Singapore's systematic enhancement in capacity and capabilities for pandemic preparedness—from establishing a purposebuild National Centre for Infectious Diseases to stockpiling personal protective equipment (PPE) at the national level—seeks to limit the mortality and morbidity from the next communicable disease outbreak, such as COVID-19, while safeguarding the occupational health of its frontline health-care workers.

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The Systems Engineering Initiative for Patient Safety (SEIPS) is a human factors—based model used in health care to understand the impact of a work system and processes on outcomes [10]. The model is often used for root cause analyses of incidents involving patient safety, as well as to identify gaps for quality improvement in health care.

Based on the SEIPS model (Fig. 1), the work system describes how a worker performing tasks interfaces with the technologies and tools he or she uses to undertake those tasks, and the physical and organizational conditions he operates within. How well these work system components interact with one another will determine the quality of the outcomes, whether they pertain to job effectiveness or occupational health and safety.

The SEIPS model is a good framework to illustrate the ecosystem of measures taken to prevent the intra-hospital transmission of COVID-19 in an acute tertiary hospital in Singapore.

The health-care worker is at the center of the work system. All other system components, namely work tasks, technologies and tools, environmental factors, and organizational conditions, serve to enable the health-care worker to perform his or her role safely and effectively. Therefore, any measures to strengthen these system components must be worker-centric to facilitate acceptance and implementation.

First, work tasks must be delineated by segregating health-care teams caring for suspect and confirmed cases of COVID-19 from teams managing other patients. This minimizes the risk of cross-infection of patients and health-care workers.

Work tasks also interface with another component of the work system, namely tools. Tasks should be risk-stratified to determine the appropriate tool (PPE) for the health-care worker. The highest risk tasks are aerosol-generating procedures such as airway suctioning, intubation, and bronchoscopy. These warrant the donning of full PPE, including eye protection, disposable gown, gloves, and either an N95 mask or a powered air purifying respirator. Medium risk tasks, such as triaging Emergency Department patients at first presentation for fever and/or respiratory symptoms, require a lower level of PPE. Calibrating the PPE requirements to the occupational exposure risk level, coupled with stepped up audits, improve compliance to the use of PPE where they are most essential.

Second, technologies and tools have a force-multiplying effect on work, while keeping the environment safe for the worker.

Respiratory swab for COVID-19 PCR test is available at the "frontline", namely the Emergency Department and the hospital's designated clinic to see unwell health-care workers. While not as rapid as point-of-care testing, the turnaround time of 3-4 hours ensures that at-risk patients are identified early and segregated. As part of hospital contamination strategies, these patients are treated in negative pressure isolation rooms, which prevent the spread of the infectious pathogen to the rest of the ward environment.

Twice daily temperature monitoring of all health-care workers is made mandatory to identify those who are unwell and prevent intra-hospital propagation of disease. Utilizing a governmentdeveloped IT platform (form.gov.sg), health-care workers are able to log their personal particulars and temperature recordings remotely and securely even when not at work. Health-care workers whose logged temperature readings are higher than 37.5 degree Celsius will be flagged up to the hospital's clinical epidemiology team for further evaluation. This convenience improves compliance, allowing data to be consolidated and analyzed for epidemiological trends.

Third, physical and environmental factors must be reinforced to limit the impact of any hospital transmission of COVID-19 on healthcare delivery.

To minimize the risk of occupational exposure, care teams are segregated in 2 dimensions. Cross-institution coverage by doctors is suspended, and medical staff members are limited to practise in 1 primary institution. Care teams are also kept small to reduce the impact of any inadvertent occupational exposure on personnel downtime owing to the need to quarantine contacts. Meal times for health-care workers are staggered. Didactic teaching and departmental meetings are conducted using video conferencing. Medical students are withdrawn from clinical attachments. These measures, while inconvenient and sometimes painful, are necessary as part of risk mitigation and to sustain a hospital's business continuity should there be cross-infection of and among health-care workers.

Fourth, organizational conditions play a pivotal and influencing role on all other components of the work system.

The most tangible organizational measure is to avail manpower and PPE resources to frontline health-care workers. In a public health crisis, there is global demand for PPE resources but often insufficient supplies, as is the case for COVID-19 [11]. Learning from SARS, one of Singapore's national strategies for pandemic preparedness is the stockpiling of PPE, which has been progressively released to public health-care institutions because the upgrading of the COVID-19 risk assessment level. Within the hospital, demand projection and proactive replenishment of supplies builds resilience within the ecosystem.

The evolving case definitions of COVID-19 makes it challenging for contact tracing, triaging and risk stratification of patients by health-care workers. Policies and infrastructure to support clear and timely communications will facilitate effective cascading of information to frontline staff members, enabling their work and facilitating their interactions with the public [12]. Daily routine instructions disseminated through emails and the use of institution-based social media platforms, such as Workplace from Facebook, are a few of the communications channels being used, allowing access on-the-go and reducing the lag time to important information updates.

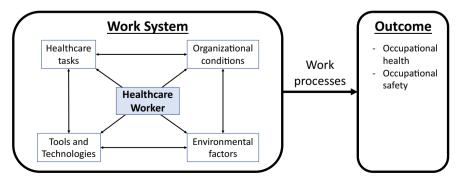


Fig. 1. Systems Engineering Initiative for Patient Safety (SEIPS) Model.

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The SEIPS model provides a good framework for a health-care system to critically evaluate the armamentarium of measures to minimize the risk of intra-hospital spread, and protect its frontline health-care workers against occupational COVID-19 infection. However, there are limitations that must be highlighted.

The model focusses on the worker as the nexus of interventions. Although extrinsic organizational, infrastructural and procedural conditions are enablers that can be put in place, the intrinsic state and well-being of the health-care worker must also be addressed in order for him or her not to be the weakest link.

In a public health crisis, health-care workers not only have to work harder and longer hours, they often do so in a context where the knowledge and understanding of the novel pathogen is still suboptimal. The regular donning and doffing of full PPE add to physical fatigue and psychological stress.

At this time, it is important for them to be and to feel supported. Clear directions from leadership and a collaborative team spirit will create conducive work conditions and reduce tensions. Peer support programs form part of an organization's crisis management framework. By facilitating more senior medical workers reaching out to provide encouragement, self-care tips and psychological first aid to those in need, these interventions at the personal level strengthen the resilience in our frontline staff.

Another watch area in the use of the SEIPS model is to be mindful of the context of "environment". Community spread of COVID-19 infections has already been reported [13]. Hence, the environmental ecosystem for prevention of intra-hospital transmission should not be restricted to the hospital alone, nor only inter-healthcare worker and health-care worker—patient interactions.

Visitors and outpatients are potential carriers of infectious pathogens into the hospital environment. To minimize this risk, all visitors and outpatients undergo a questionnaire survey of travel and contact history, as well as thermal scanning for fever before they are allowed into the hospital premises. Each inpatient is restricted to only 2 specified visitors through the period of hospitalization. Similarly, each outpatient is only allowed 1 accompanying person when attending the specialist outpatient clinic. These measures serve to reduce the likelihood of introducing COVID-19 from the community into the hospital environment and complements all other preventive measures put in place at the hospital-level.

At this point, it is still too early to gauge the success in achieving the desired outcome of zero occupational infection of COVID-19 in the acute hospital's health-care workers. However, unlike SARS, where 7 of the first 13 SARS cases in Singapore were health-care workers, the country's health-care system is in a more robust, resilient, and safer position today. The principle of zero occupational infection remains an achievable goal that all health-care systems need to strive for, as the world continues its battle against the newest novel infectious disease that has already claimed lives and disrupted normal living at the turn of the decade.

Conflicts of interest

The authors do not have any conflict of interest to declare.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.shaw.2020.03.001.

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Exhibit 20

Case 2:18-bk-20151-ER Clinical Infectious Diseases

BRIEF REPORT

Protecting Healthcare Workers During the Coronavirus Disease 2019 (COVID-19) Outbreak: Lessons From Taiwan's Severe Acute Respiratory Syndrome Response

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During major epidemic outbreaks, demand for healthcare workers (HCWs) grows even as the extreme pressures they face cause declining availability. We draw on Taiwan's severe acute respiratory syndrome (SARS) experience to argue that a modified form of traffic control bundling (TCB) protects HCW safety and by extension strengthens overall coronavirus disease 2019 (COVID-19) epidemic control.

Keywords. traffic control bundling; healthcare workers; COVID-19; protection.

We are daily learning of new developments in prevention and control efforts taken by the Chinese government in response to the COVID-19 outbreak. Particularly notable is the unprecedented scope of several extreme public health containment efforts initiated by the Chinese government to counter the coronavirus's spread. These actions include regional lockdowns of > 53 million people, severe travel restrictions, and forced quarantines, aimed at least in part at containing the disease during the peak Chinese Lunar New Year travel period.

While the outbreak has had many impacts, here we focus in particular on the impact COVID-19 is having on HCW safety and, by extension, their willingness to continue to work. Through 25 February 2020, China reported 3387 infected HCWs in Hubei alone, at least 18 of whom died, causing growing concern among HCWs [1]. While there are many unknowns regarding COVID-19, several lessons from past outbreaks of similar coronaviruses (eg, SARS-CoV) can be usefully applied to efforts to protect HCWs [2, 3]. We draw primarily on

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Taiwan's SARS experiences, but also on lessons learned from the current COVID-19 outbreak to offer recommendations specific to in-hospital preparedness and response with the goal of protecting the front-line HCWs striving to contain the outbreak.

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During an outbreak, HCWs are expected to work long hours under significant pressure with often inadequate resources, while accepting the dangers inherent in close interaction with ill patients. HCWs, like everyone else, are vulnerable both to the disease itself and to rumors and incorrect information that necessarily increase their anxiety levels. In our study of the 2003 SARS outbreak, we found that, to varying degrees in both China and Taiwan, HCW anxiety levels rose in reaction to cases of HCWs falling ill or dying. As a result, HCWs became increasingly reluctant to work. HCW anxiety was further impacted by growing stigmatization and loss of trust by their own communities [4, 5]. In short, even as demand for HCWs rapidly rises during an outbreak, so too does HCW anxiety and reluctance to work.

As noted, a key source of concern among HCWs is the danger of contracting the disease. In Taiwan, we found that once patients were admitted to hospital, nosocomial SARS outbreaks occurred with transmission via fomites (as occurred during the South Korean Middle East respiratory syndrome outbreak) [2, 3]. Indeed, in Taipei Hoping Hospital, 17 HCWs contracted SARS despite working in separate areas of the hospital with no direct contact with the index patient. Within 2 weeks, the hospital had suffered 150 SARS cases. A post facto study at a separate Taipei hospital found SARS-CoV RNA nucleic acid on water fountains in the triage and observation units, in designated SARS areas, and in supposedly "clean" areas [6]. Though descriptions of viable viral transmission are rare in the literature, detection of RNA nucleic acid in the environment indicates the fingerprint of existing, viable virus in the environment [7]. And, while no firm evidence was found of airborne transmission, SARS-CoV proved able to survive in fomite form in the environment for up to 3 days. Indications are that HCWs were unwittingly spreading SARS and infecting patients and HCWs throughout the hospital via fomites [2, 3].

These worsening conditions caused heightened anxiety and distrust of government among HCWs who in some cases refused to work [2, 4]. Today's hyperconnected society makes information control more challenging, with the result that often exaggerated or misleading information exacerbates already extant anxieties among HCWs.[5]

Further contributing to anxiety during the current COVID-19 outbreak is the discovery of increased human-to-human infection via droplet, contact, and fomite transmission [8] and, in particular, the existence of asymptomatic people who

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are nonetheless ill with SARS-CoV-2 [9, 10]. For example, in Wuhan, 14 HCWs were infected by 1 super-spreader with an atypical presentation, including 1 physician who died as a result [11]. These factors may once again drive a shortage of HCWs, potentially initiating a cycle of substandard infection control procedures leading to hospital cross-transmission and further disease transmission into and within the community. Ultimately, this cycle may contribute to a cascading effect resulting in regional epidemic saturation.

To counteract the potential decline in HCW availability due to fear and anxiety, and to curtail the potential rise of nosocomial infection, it is critical to strengthen HCW safety and trust in the system within which they work. To this end, we recommend implementing TCB—a tool that proved effective in dramatically reducing infection rates among HCWs in Taiwan during the SARS outbreak. The essence of TCB involves triage outside of hospitals (in tents or other shelters); ensuring patients are triaged in outdoor screening stations to ensure ill patients are directed to a contamination zone; and zones of risk—clearly delineating separate zones, including a contamination, transition, and clean zone, each separated by checkpoints. We slightly modify the TCB model applied during SARS to address differences between SARS and COVID-19.

TCB adjusted for COVID-19 begins with outdoor triage. Patients testing positive for COVID-19 are directed to an isolation ward (hot zone) where they are placed in individual isolation rooms for further care. Patients exhibiting atypical symptoms or whose tests remain inconclusive are directed to a quarantine ward (intermediate zone) where they remain for the extent of the incubation period. Patients directed to the isolation or quarantine wards travel via a designated route that avoids contact with the clean zone. Thus, patients move along routes other than those taken by HCWs (here we include nurses, physicians, janitorial staff, and other hospital staff).

As described in Figure 1, before moving from the clean zone to the intermediate or hot zones, HCWs must gown up and use

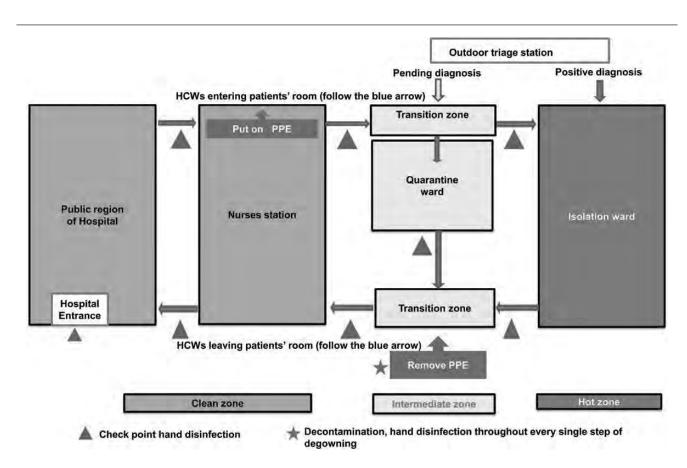


Figure 1. Conceptual scheme of traffic control bundling. When first arriving, all patients undergo triage outside the hospital. Those diagnosed with coronavirus disease 2019 (COVID-19) are directed to an isolation ward where they are placed in separate rooms. Those exhibiting atypical symptoms or awaiting confirmed diagnosis are directed to a quarantine ward for the maximum incubation period. In both cases, patients follow a designated route to the relevant ward that avoids the clean zone. Hospital staff transitioning through the zones utilize 75% alcohol dispensers for gloves-on hand sanitation at checkpoints positioned between each zone. Hospital staff don personal protective equipment (PPE) and, as needed, additional equipment such as eye protection and respirators before entering the intermediate or hot zone. When exiting the intermediate or hot zone, hospital staff disinfect their hands, gloved or not, to avoid accidental contact by skin/mucosa with the virus. To adjust for the asymptomatic nature of some cases, all visitors to the hospital must don masks and use 75% alcohol hand sanitizer prior to entry. Abbreviations: HCW, healthcare worker; PPE, personal protective equipment.

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gloves, eye protection, and N95 masks. If indicated, they will add additional protective equipment. When returning to the clean zone, HCWs pass through a transition zone where they de-gown and remove all additional protective equipment.

As they transition between zones, HCWs at each step engage in hand disinfection with 75% alcohol. [2] Each transition point is clearly delineated with signage, doors, and in many cases, with lines painted on the floors (green for clean zones, yellow for intermediate zones, and red for hot zones). To emphasize the importance of adhering to TCB protocols, each transition zone includes prominently posted descriptions of the steps to be taken in that location.

Prior to implementing TCB, HCWs are thoroughly trained in TCB protocols, including proper gowning and de-gowning practices, correct use of all appropriate personal safety equipment (eg, respirators and eye protection), and how to safely move among the zones. Patients too receive explanations about the various zones and why they are required to remain in their designated zone.

Finally, we recommend routine daily environmental cleaning and disinfection in the clean and transition zones. To avoid increased danger of HCW infection, cleaning and disinfection in the hot zone is limited, and only required in the case of visible contamination with bodily fluids. We also recommend establishing checkpoints at hospital entrances where visitors disinfect their hands and don masks as a way to further mitigate the risk of droplet/contact and fomite transmission in clean zones.

In its assessment of Taiwan's SARS response, the Taiwan Centers for Disease Control found that TCB dramatically reduced HCW and patient infections. In the 18 hospitals implementing TCB, zero HCWs and only 2 patients developed nosocomial SARS infection. By contrast, in the 33 control hospitals, 115 HCWs and 203 patients developed SARS [2].

To conclude, COVID-19 represents a fast-moving threat that has sparked unprecedented actions by China. However, overworked and underresourced HCWs facing the real possibility of infection, and reliant on potentially misleading information about a rapidly developing epidemic, may refuse or be unable to work. The result can be critical HCW shortages. A proven model of coronavirus containment and HCW protection will do much to ease concerns both for HCWs and the patients they serve. Furthermore, it can contribute to breaking the cycle of community–hospital–community infection. We therefore urge public health authorities to implement modified TCB so that protection for HCWs and patients is improved and HCW shortages can be mitigated.

Notes

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Potential conflicts of interest. The authors: No potential conflicts of interest. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest.

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Exhibit 21

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Exploring the reasons for healthcare workers infected with novel coronavirus disease 2019 (COVID-19) in China

Jiancong Wang, Mouqing Zhou, Fangfei Liu

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Journal Pre-proof

Exploring the reasons for healthcare workers infected with novel coronavirus disease 2019 (COVID-19) in China

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Sir:

The outbreak of novel coronavirus disease 2019 (COVID-19) in Mainland China has been declared as a Public Health Emergency (PHE) by World Health Organization (WHO) [1]. Globally, until 28th February 2020 there have been reported 83,774 confirmed cases and 2,867 deaths [2]. During the periods of outbreak of COVID-19 or other infectious diseases, implementations of infection prevention and control (IPC) becomes a great importance in healthcare settings [3], particularly the great importance of personal protection of healthcare workers [4]. In order to contain the outbreak of COVID-19 in Mainland China, National Health Commission of the People's Republic of China (NHCPRC) have so far dispatched medical support teams (41,600 healthcare workers from 30 provinces and municipalities) to support the medical treatment in Wuhan and Hubei province [5]. A survey by Health Commission of Guangdong Province released information on the distribution of 2,431 healthcare workers in Guangdong medical support teams [6]. Nurses (around 60%) were the predominant healthcare workers in the teams, followed by clinicians (around 30%). Half of clinicians with job titles were deputy chief physician; and 25% specialized at the respiratory and critical medicine [6]. It is worth mentioning that 5.8% (140/2431) healthcare workers have worked on the outbreak of severe acute respiratory syndrome in 2003 [6].

Recently, Wu and colleagues [7] have reported the problems of COVID-19 IPC in healthcare settings, particularly highlighting the problems of personal protection of healthcare workers. However, sadly, until 24th February, NHCPRC reported in press conference of WHO-China Joint Mission on COVID-19 [8] that 3,387 healthcare workers have confirmed infected COVID-19, with 22 (0.6%) deaths. More than 90% of infected healthcare workers were from Hubei province. Therefore, the director of

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National Hospital Infection Management and Quality Control Centre summarized some reasons for such high number of infected healthcare workers during emergency outbreak [9]. First, inadequate personal protection of healthcare workers at the beginning of the epidemic was a great issue. In fact, they did not understand the pathogen well; and their awareness of personal protection were not strong enough. Therefore, the front-line healthcare workers did not implement the effective personal protection before conducting the treatment. Second, long-time exposure to large-scale of infected patients directly increased the risk of infection for healthcare workers. Also, pressure of treatment, work intensity, and lacking of rest indirectly increased the probability of infection for healthcare workers. Third, shortage of personal protective equipment (PPE) was also a serious problem. First-level emergency responses have been initiated in various parts of the country, which has led to a rapid increase in the demand for PPE. This circumstance increased the risk of infection for healthcare workers due to lacking of sufficient PPE. Fourth, the front-line healthcare workers (except infectious disease physicians) received inadequate training for IPC, particularly lacking of the knowledge of IPC for respiratory-borne infectious diseases. After initiation of emergency responses, healthcare workers have not had enough time for systematic training and practices. Professional supervision and guidance, as well as monitoring mechanism were lacking. This situation further amplified the risk of infection for healthcare workers.

Finally, international communities, particularly for other low-and-middle income countries with potential COVID-19 outbreak, should early learn how to protect the healthcare workers. Furthermore, the COVID-19 confirmed cases have been reported to surged in South Korea, Japan, Italy, and Iran in the past few days [2]. The increase of awareness of personal protection, sufficient PPE, and proper preparedness and response would play an important role in lowering the risk of infection for healthcare workers.

Conflict of interest None

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Exhibit 22



Innovations in Care Delivery



Reassessing Covid-19 Needs: How Providers Can Reexamine Their Surge Capacity, Supply Availability, Workforce Readiness, and Financial Resiliency

As the coronavirus pandemic continues to create unprecedented challenges for health care providers, it is especially important to create and, as needed, revise plans to mitigate disruption to the degree possible. The authors share detailed guidance to help leaders stay focused on the most pressing issues.

By Pooja Kumar, MD, Omar Kattan, MD, Bede Broome, MD, PhD & Shubham Singhal, MBA

May 7, 2020

Summary

Health care providers across the world have been launching multifaceted efforts to respond to the rapid spread of Covid-19. We face different phases of urgency — some providers have had relatively little increased demand (patient volume), while others are actively experiencing overwhelming demand and depleted resources. Across these levels of urgency, there are five action areas providers should stay focused on: surge capacity, supply availability, workforce readiness, clinical operations processes, and Covid-19 governance structure and financial resiliency. The authors have developed a set of checklists for providers to leverage in both planning and active response to Covid-19 across each of these action areas.

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6/8/2020 Case 2:548-bly 2015 1:4ER HoDoov/4848 in Feiled 0:00/09/20e CEntered 0:00/09/20, 15:69:08-ad Dessend Finan... Main Document Page 215 of 290 Throughout the world, multifaceted efforts to address Covid-19 have included response and recovery that support affected patients, families, and communities, as well as accelerated efforts to develop a vaccine and therapeutics. To address this ongoing crisis, health care leaders across the board will need to respond in an evidence-informed manner. For health care providers in particular, this will require leveraging public health infrastructure and broader federal/regional collaborative efforts in parallel with significant internal response efforts, rooted in thoughtful planning that anticipates needs while also providing flexibility to pivot.

Worldwide, we have seen a similar trajectory early in the epidemic, but curves diverge based on measures taken by policy makers and individuals.¹⁻⁵ With ranges of up to 20% of cases estimated to be severe/critical, significant health system capacity for testing and critical care infrastructure is required,^{6,7} while maintaining the ability to treat patients who require urgent care for other non-Covid conditions. Around the globe, providers are facing different phases of increased demand, with some still preparing for a wave of patients and some engaged in active but reasonable management. In areas such as New York City, providers have been experiencing massive overload of baseline resources.

Across these levels of urgency, there is a range of actions health systems should consider in response to Covid-19. Five imperatives for all providers to consider are: surge capacity, supply availability, workforce readiness, clinical operations processes, and governance and financial resiliency. We describe a set of best practices for these areas and have prepared accompanying checklists that may serve as tools for health care leaders (see Appendix). Given rapid changes and evolving behavior of the virus, providers are often facing the need to make decisions they have not prepared for and these checklists can serve as tools to ensure readiness across priority areas. Checklists were prepared by the authors based on expertise and experience serving health care stakeholders across the value chain through the Covid-19 crisis, previous pandemics, and relevant topics.

Surge Capacity

With the shortage of hospital beds accompanying the Covid-19 pandemic, hospitals should consider options to expand capacity. To rapidly increase bed capacity to treat Covid-19– positive patients, providers are (a) cancelling nonurgent procedures through the development of detailed procedural priority levels detailed at service-line levels (e.g.,

6/8/2020 Case 2:348-bk 2015 1:4 R HoDoov 4840an Feiledi 06/09/20e CEntered 06/09/20, 15:39:08-ad Dessend Finan... Main Document Page 216 of 290 orthopedics, cardiovascular); (b) moving care of non-Covid-19 patients to telemedicine whenever possible; (c) encouraging and supporting Covid-19 patients with mild symptoms to stay home (and leverage remote care); (d) preparing to increase bed capacity for treating patients who need hospitalization by developing tiered surge plans or utilizing recently developed tools⁸ that guide decision-making with bed capacity thresholds as activation triggers; and (e) preparing to efficiently discharge patients once appropriate as they recover.

"

Five imperatives for all providers to consider are: surge capacity, supply availability, workforce readiness, clinical operations processes, and governance and financial resiliency."

Options for increasing capacity include deploying mobile hospitals, bringing online decommissioned beds, increasing beds per room, exploring additional areas within facilities (e.g., physical therapy treatment areas), using attached specialty hospitals, converting existing post-acute care facilities, partnering with outpatient clinics, using nonhealth care facilities (e.g., college dorms or hotels), and partnering with other types of local hospitals (Figure 1 and Appendix). Providers should be selecting alternative care sites through a systematic process asking critical questions around location (e.g., assessing nearby existing real estate structures and availability for modular additions) and labor and supplies (e.g., associated workforce and labor needed driven by level of care required). For example, the Cleveland Clinic has converted a nearby health education building to house more than 300 beds to handle the surge of anticipated Covid-19 patients. The building does not have ventilators but is equipped to care for low-acuity patients and has room for roughly an additional 700 hospital beds if the need arises.²

Figure 1.

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Detailed Provider Checklist for Surge Capacity

Surge (care) capacity

Inventory bed count across ICU, Med Surg, and ED to estimate the maximum capacity for admissions based on availability of beds, clinical workforce, and adaptability of facility space
Identify potential care areas for patient overflow for diagnostic holding or potential Covid-19 ward (e.g., auditorium, gym, PT treatment space, lobby, space for outdoor tents, parking lot)
Establish protocols for utilizing alternative sites for patient evaluation/treatment:
Activation triggers for establishing alternate sites (e.g., based on bed capacity levels)
Outsourcing care of non-critical patients to appropriate alternative treatment sites (e.g., adapt outpatient departments for inpatient use, home care for low-severity illness, connecting patients with social needs to community-based services organizations, hoteling)
Consideration to segregation of Covid-19 and non-Covid–19 patients to separate sites to prevent disease spread should be given. This has implications on workforce and supplies needed, depending on site designation
Establishing a contingency plan for inter-facility patient transfer; verify availability and resources required for patient transportation
Coordinate with other area hospitals on referral protocols and clarify your facility's position within broader geographic network
In coordination with public health authorities and other area health systems, identify additional sites that can be converted to patient care units (e.g., hotels, schools, community centers, gyms); develop operational plans (staffing, equipment, supplies, etc.)
Coordinate with health authorities, neighboring hospitals, and private practitioners to define roles and responsibilities for each member of the local health care network to ensure continuous provision of essential medical services throughout the community
 Develop activation trigger and plan for initiating facility lock-down and/or limited access and entry
Source: The authors
NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

Supply Availability

Most providers have or will be facing significant challenges related to supplying critical protective and treatment items. As Covid-19 cases increase, these pressures will increase. Even as some regions see a leveling or decline of infections, the potential for additional waves of resurgence remains. Protocols, visibility, and collaboration are instrumental in mitigating supply chain risk. Centralizing buying, inventory balancing, and distribution at a system/regional level with a rapid response team will help ensure supplies reach areas of greatest need. Promoting supply conservation and establishing alternative clinical scenario plans are becoming realities.

6/8/2020 Case-2::48-bly/c20151/ER HoDpo/4848 in Feiledi/06/09/20e CEntered/06/08/20, 15:09:08eadDessend Finan... Main Document Page 218 of 290 Providers are developing tiered scenarios for each of the clinical supplies (e.g., alternative usage protocols based on certain threshold levels), and communicating plans to clinical site leaders. Some providers are utilizing a <u>PPE (personal protective equipment) calculator</u> provided by the Centers for Disease Control and Prevention (CDC) to help facilities determine their PPE consumption rate and future needs. Some of these plans include alternate sourcing and product use, and conservation strategies when possible. For example, the University of Alabama at Birmingham Hospital has begun to decontaminate and reuse their N95 masks, a practice increasingly being used.¹⁰

The largest determinant of collective success will be collaboration between providers, suppliers, manufacturers, and public agencies. For example, health systems with multiple facilities within a region have explored a Center of Excellence model, with facilities designated as Covid-19 sites while others attempt to treat other emergent volume, with appropriate PPE policies at each site. Another example of collaboration is the development of supply-demand aggregation platforms by many organizations: <u>Project N95</u> is one of many that was created to serve as a national clearinghouse to connect health care providers with critical equipment (see Appendix).

Workforce Readiness

Hospitals likely will need to plan appropriate staffing levels based on a complex set of dynamics. These may include fewer available workers due to known or suspected Covid-19 infection, or those who are less available due to burnout or increased caregiving needs due to lack of child/elder care. Simultaneously, there may be a need for increased hours from the workforce resulting from rising patient burden — though potentially offset by more staff available due to cancelled elective procedures.

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Even as some regions see a leveling or decline of infections, the potential for additional waves of resurgence remains. Protocols, visibility, and collaboration are instrumental in mitigating supply chain risk."

6/8/2020 Case-2:48-bkc20151. ER: HoDoov4848an REiledil@6/09/20e cEntored:06/08/20, 15:89:08eadDessend Finan... Main Document Page 219 of 290 Our volume-based estimates indicate that workforce needs could increase anywhere from around 40% to 120% at the peak of the epidemic, with wide variation predicated on the *attack rate* of the virus in specific regions, workforce callout and infection rate in a particular region, and the actions taken in response. Additionally, health care providers and states may struggle with providing training required to rapidly upskill staff, including training nurses to provide care to ventilated patients.

We anticipate escalating challenges with absenteeism, with 10% to 20% of staff calling off shifts due to illness, dependent care needs, quarantine, or other reasons. Given the rate of school cancellations, absenteeism will likely increase due to a lack of childcare alternatives. Some providers have been able to address this by establishing programs to provide childcare for the clinical workforce such as with Ohio State University's Wexner Medical Center.¹¹

Providers are also facing challenges when pursuing the usual solutions, such as agency or travel nurses. Attempts to increase workforce availability, including medical schools allowing their fourth-year medical students to graduate early or sending nurses across state lines, have been met with logistical challenges. These include having plans approved by state education and medical-licensing boards, and working with regulatory bodies to secure temporary licenses for doctors who were not planning to be in hospitals until July.¹² Providers also should develop plans to address burnout and the mental health needs of their workforce, including anxiety and depression stemming from long hours and difficult work treating Covid-19 patients. For example, UCHealth offers employees behavioral health counseling, a 24-hour crisis hotline, and an employee leave program for times of hardship. Since Covid-19, it launched additional training to help health care workers deal with the mental toll of the outbreak¹³ (see Appendix).

Clinical Operations Processes

Given limited inpatient resources, providers have expanded their strategies to include preventing unnecessary visits to acute care sites by both persons under investigation, and those with mild confirmed Covid-19. To support this effort, providers are making significant investments in ambulatory care, telehealth, testing, and home health services. In addition, to support keeping Covid-19–negative patients uninfected, keeping the workforce healthy, treating sick patients efficiently and effectively, and protecting their 6/8/2020 Case 2sides bk 2015 LER: Holder vi4840an Filedi 06/09/20e c Entered 06/09/20, 15:89:08ead Besond Finan... Main Document Page 220 of 290 financial position/ability to serve patients as much as possible during the peak of this pandemic, providers are making adjustments to their clinical operations (see Appendix).

A significant challenge in executing against all these efforts is the availability of tests and testing capacity. As a result of limited testing capacity and supplies as well as turnaround times, health systems in concert with public health and other government officials are addressing challenges through multiple considerations, including: modeling potential capacity based on available equipment and systems, workforce/staffing, etc.; determining bottlenecks; and adjusting workflow and resourcing in order to optimize testing capacity.

Governance and Coordination

All actions described here and in the Appendix will require coordination. We advise preparing a specific Covid-19 management strategy and establishing an Emergency Operations Nerve Center/Team. The Nerve Center should be organized to monitor development of the crisis and coordinate a response. It should act as the single source of truth, maintaining the organization's perspective on pandemic progression, as well as a single point of aggregation of key operational metrics to track the organization's ability to respond to the crisis. We recommend identifying a designated Covid-19 emergency response program lead with backups in case of burnout and/or clinical need.

"

The largest determinant of collective success will be collaboration between providers, suppliers, manufacturers, and public agencies."

Several systems have shared that their analytics capabilities were unable to support the real-time decisions required during the crisis. Thus, we also recommend deploying a data lead and team to develop a comprehensive dashboard to prioritize continuous monitoring of key operational (e.g., beds, volumes), supply (e.g., ventilators, masks, advance purchasing), and financial (e.g., days cash on hand, supply cost variability, elective volume declines) metrics. The Nerve Center should provide the ability to look forward by tracking leading indicators to warn leadership of likely developments or operational shortfalls — while much of the organization is forced to focus on the present. It should act as a channel for interventions, serving as the single point of escalation for decision-making and

6/8/2020 Case 2:3 Selbk 2015 LER: HoDoovid840an Feiledin06/09/20e CEntered 06/09/20, 15:89:08eadiDes and Finan... Main Document Page 221 of 290 deployment of top-down resources to unblock operational challenges (e.g., flexing surge capacity). For your top management team, quickly clarify new responsibilities and responsibilities that are paused given the context of this pandemic (see Appendix).

Looking Ahead

As providers face Covid-19, there are many known unknowns. This includes the trajectory of continued infection rates, effectiveness of society-wide physical distancing, the length of the crisis, when the peak will hit, if and when subsequent waves of infection may hit, and which members of society will be hit the hardest. In addition, since the pandemic began, a few unknowns have come to light. These include protests demanding governors reopen the economy, the 38% decrease of STEMI events in high-volume cardiac labs,¹⁴ and the higher rates of black Americans contracting Covid-19 while also being less able to access testing.¹⁵ Tactical and coordinated action can mitigate the most devastating scenarios and should be an immediate and ongoing priority for health systems.

Given the financial risk due to the Covid-19–related demand shock and economic downturn, providers are beginning to develop resiliency plans to be able to serve their patients and communities in the medium term. To better understand risk, we suggest providers build stress-test scenario models to help forecast and prepare for changes in cash flow as a result of the drop in elective cases, rise in lower-margin ED/ICU cases, shift in payer mix, increased workforce/external spend costs, delayed payments, etc. Providers should also identify potential near-term and long-term impacts of financial losses (e.g., investment income, near-term liquidity/solvency, and long-term losses due to potential economic downturn). Lastly, they should develop a comprehensive road map to meet non-emergent needs that had been deferred (referral/physician pipeline management, capacity planning for recovering demand for non-emergent procedures).

The next normal is on the horizon. Each day offers an opportunity for providers to build strategies where we hope for the best, but prepare for the worst.

Pooja Kumar, MD

Partner, McKinsey & Co.

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Omar Kattan, MD

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Shubham Singhal, MBA

Senior Partner, McKinsey & Co.

Appendix

Checklist Exhibits 1-6.

Disclosures

References (15)

Topics

Clinician Burnout and Resilience

Care Management

Patient Safety

Disruption and Innovation

Digital Health

Specialty Care

Primary Care



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ARTICLE | JUN 08, 2020

Re-envisioning Discharge Planning and Expanding Post-Acute Care Capacity During a Pandemic

By Amelia Shapiro, Nancy O'Toole, Donna Tinling-Solages, Timothy McGarvey, Michael Tretola & Paul Dunphey

Much attention to Covid-19–related care, appropriately, is focused on establishing community-based infection-prevention tactics and addressing hospital-based intensive care needs for patients. At NewYork-Presbyterian, leadership also developed and

6/8/2020 Case 2:18:bk 20151 ER: Holder vi4840an Feiledi 06/09/20e cEntered 06/09/20, 15:89:08eadi Desend Finan... Main Document Page 224 of 290. implemented a multipronged approach to deal with the post-discharge care for its coronavirus patients through planning and collaboration.

ARTICLE | JUN 04, 2020

Adapting Hematology and Medical Oncology Clinical Care in the Epicenter of the Covid-19 Pandemic

By Manish A. Shah, Mary Frances F. Emlen, Sebastian Mayer, Paula Goldstein, Lara Scrimenti & Manuel Hidalgo

Taking care of cancer patients during the Covid-19 pandemic requires major restructuring of specialty services. A large teaching hospital addresses patients' needs with a dramatic expansion of telemedicine, an allocation of space specifically for Covid-positive cancer patients, and a flexible redeployment of a leaner staff.

ARTICLE | MAY 29, 2020

A Paradigm for the Pandemic: A Covid-19 Recovery Unit

By Renuka Gupta, Alka Gupta, Arnab K. Ghosh, Joel Stein, Leroy Lindsay, Akinpelumi Beckley, Angelena M. Labella, Rudy Tassy, Lisa Rivera, German Rodriguez, Melissa D. Katz, Lauren Hartstein Howard, Amelia Shapiro, Emme L. Deland & Katherine L. Heilpern

A dedicated multidisciplinary post-ICU recovery unit for Covid-19 patients addresses their unique complexities and lets them begin rehabilitation earlier than they would with a normal progression from ICU to medical-surgical unit to rehab unit.

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Exhibit 23

Essays

Responding to Covid-19: *How to Navigate a Public Health Emergency Legally and Ethically*

by LAWRENCE O. GOSTIN, ERIC A. FRIEDMAN, and SARAH A. WETTER

Few novel or emerging infectious diseases have posed such vital ethical challenges so quickly and dramatically as the novel coronavirus SARS-CoV-2, which causes Covid-19. SARS-CoV-2 is thought to have originated in a wet market in Wuhan, China, in early December, making a zoonotic leap from a bat (through an animal intermediary) to a human. It rapidly spread throughout China with highly efficient humanto-human transmission and has now circumnavigated the globe, with a foothold in every continent except Antarctica. The World Health Organization declared a public health emergency of international concern and recently classified Covid-19 as a worldwide pandemic.

As of this writing, the epidemic peak has not yet been reached in the United States, but community transmission is widespread. President Trump declared a national emergency as fifty governors declared state emergencies¹—a situation unprecedented in modern America. In the coming weeks, hospitals will become overrun, stretched to their capacities.

Widespread social separation is rapidly becoming the norm, with closures of schools and universities, telecommuting, bans on large gatherings, and millions of people isolated in their homes or makeshift facilities. Bans on international travel are already pervasive. Domestic travel restrictions are exceedingly rare but now within the realm of possibility. Officials are even ordering cordon sanitaires (guarded areas where people may not enter or leave), popularly described as "lockdowns" or mass quarantines. For example, San Francisco recently ordered a lockdown, with other cities and states closing gathering places (such as bars, restaurants, and movie theaters) and advising residents to shelter in place.

When the health system becomes stretched beyond capacity, how can we ethically allocate scarce health goods and services? How can we ensure that marginalized populations can access the care they need? What ethical duties do we owe to vulnerable people separated from their families and communities? And how do we ethically and legally balance public health with civil liberties?

A Strained Health System: Surge Response, Triage, Ethical Allocation

A surge of individuals exhibiting flu-like symptoms, along with the "worried well," will undoubtedly stress the health system. Health facilities do not have the capacity to cope with the expected patient numbers: they lack enough critical care beds, ventilators, essential medicines, and personal protective equipment for health workers. N95 masks, a key tool to prevent respiratory infections, are in short supply. Scarcity of health resources not only places Covid-19 patients at risk but will also delay care for patients with urgent needs such as for cancer, diabetes, and heart disease—and even affect safe delivery for pregnant women. Disruptions to the health system will likely cause more deaths of persons with a variety of urgent health needs than of patients diagnosed with Covid-19.²

In times of crisis and with health systems facing scarcity, hospitals, with guidance from public authorities and professional bodies, must make hard decisions to best ensure optimal health outcomes and fair distribution.

How can we avoid the scarcity dilemma? Where possible, every effort should be made to avoid the scar-

Lawrence O. Gostin, Eric A. Friedman, and Sarah A. Wetter, "Responding to Covid-19: How to Navigate a Public Health Emergency Legally and Ethically," *Hastings Center Report* 50, no. 2 (2020): 8-12. DOI: 10.1002/hast.1090

We are all only as safe as the most vulnerable among us—both in the United States and globally. Equity and public health go hand in hand.

city dilemma altogether. We are already trying to do that through strict physical distancing, which could flatten the epidemic curve and moderate demand on the health system. But since the United States is so late in its mitigation efforts, scarcity is likely to become a reality. What should we do? A World War II-type mobilization could ramp up the production of personal protective equipment, ventilators, and other essential supplies and equipment that could become scarce. The president should exercise his full authority under the Defense Production Act to mobilize industry to provide urgently needed resources. Regions experiencing limited levels of Covid-19 could lend equipment, and deploy first responders, to regions where health system capacity is strained. Retired health workers or trained health workers not presently practicing could return to service. With ample funding, leadership, and coordination, scarcity can be, if not entirely avoided, then at least mitigated. The president or governors could also call in the military, National Guard, or Army Corps of Engineers for assistance with logistics, supply chains, and even building clinics.

How can we ethically balance physicians' duties to patients and to the wider community? Standards of care ordinarily require physicians to meet the specific medical needs of their patients. But in a crisis, we may have to shift the standard of care to emphasize the needs of the community,³ while still providing the best possible individual-level care. This concept was encapsulated by the National Academy of Medicine as "crisis standards of care," defined as the "optimal level of care that can be delivered during a catastrophic event, requiring substantial change in usual health care operations."⁴

In jurisdictions with declared public health emergencies,⁵ crisis standards of care provide a mechanism for reallocating staff, facilities, and supplies to meet population needs. To free up scarce medical resources, for example, hospitals could postpone nonemergency tests and procedures. In the areas hardest hit so far, like Seattle and New York, hospital administrators have been canceling or postponing elective and even some more serious⁶—surgeries.

To avoid harm, health agencies and organizations must plan now to implement crisis standards of care; they should not wait until the disease is widely detected in the community. Implementing crisis standards must be part of a systemwide approach in which all stakeholders, including health professionals and the public, participate in transparent decision-making.⁷

How can we ethically allocate scarce resources? Even with increased production and measures like postponing nonur-

gent medical procedures, there might still be too few health workers and critical care beds and not enough supplies and equipment. These resources must be allocated ethically. First and foremost is the need to protect health workers delivering care in the midst of the crisis, for without them and their extraordinary efforts, the entire health system would collapse. Along with ensuring that health workers are adequately trained in infection control, supplied with protective equipment, and provided vaccines once available, the health system should designate health workers a top priority for receiving scarce resources that are vital for their own protection, care, and treatment.

Second, beyond health workers, decisions about who is tested or who receives treatment must center on prevention of SARS-CoV-2 transmission (public health), protection of individuals at highest risk, meeting societal needs, and promoting social justice. Protecting public health may mean prioritizing resources for people in confined settings (such as homeless shelters, prisons, and nursing homes), where the virus can spread rapidly from person to person. Resources may need to be targeted to areas experiencing localized outbreaks to curb transmission and prevent hospitalizations. Groups at highest risks, such as older adults, people with compromised immune systems, and people with underlying conditions (such as heart or lung disease or diabetes) are another priority, as they are most likely to become seriously ill and die. Meeting societal necessity means protecting critical services, like public safety, fire protection, and sanitation, as well as producers and suppliers of essential goods and services, like food and medicine, as well as people who carry out critical public health functions. Even with mass closures during Covid-19, these services must continue, and people working in these areas should be priorities as well. Finally, social justice demands that needed supplies and countermeasures are distributed equitably, with steps to ensure that poorer and marginalized populations-segments of the population traditionally left behind, like people with disabilities and people of color-receive a fair distribution of scarce resources.

In addition to identifying specific groups that need special care, ethical distribution requires a fair process in deciding. To the extent possible, decision-making about the allocation of scarce resources in response to Covid-19 should include the public and be made in advance, and it must be transparent and based on clearly explained rationales that are grounded in scientific evidence related to transmission of the virus, morbidity and mortality, and other relevant considerations, such as those delineated above.

Fair distribution is not only a national issue. Globally, lower-income countries will face much more scarcity than wealthier states and, if Covid-19 takes hold, a higher burden of disease. The United States is ethically obligated to assist-even if this means reducing American stockpilesto maximally protect and equally value all human life.⁸ Vitally needed supplies like personal protective equipment and, when available, vaccines and treatments, must not be hoarded by wealthier countries or the countries where they happen to be manufactured. This is a matter not only of ethics but also of ensuring Americans' health. Even if we get Covid-19 well under control in the United States, new outbreaks here will be all but inevitable unless other countries do so as well. Imagine the global political fallout if millions of people died in sub-Saharan Africa, while availability of an effective vaccine saved those living in North America and Europe.

Access to the Health System: Protecting the Most Vulnerable

H igh costs, fear of discrimination, and fear of deportation can make Covid-19 testing and treatment inaccessible for vulnerable populations, including under- and uninsured persons and immigrants,⁹ and this lack of access implicates both health and justice concerns. Governments must assure that Covid-19 testing and care, and vaccines and treatment once available, are free so that cost does not cause anyone to delay or avoid care. Health facilities should be enforcementfree zones for undocumented immigrants, spaces where they will not face any risk of being detained or deported. Further, hospitals and health departments must have staff members trained in and responsible for communicating with people who do not speak English or are members of vulnerable populations, like refugees and undocumented immigrants and those with impaired hearing or vision.

Special measures may be necessary to ensure that vulnerable populations have access to health care and can practice good hygiene. For example, public health agencies should provide supplies of hand sanitizer or hygiene kits to shelters and outreach workers to distribute to people who are homeless for use throughout the day.¹⁰ And authorities could direct or incentivize businesses to permit people who are homeless to use their toilets and washing facilities.

Ethical Physical Distancing: Gaining the Public's Cooperation

A mple evidence shows extreme Covid-19 risk in congregate settings such as cruise ships, nursing homes, prisons, churches, shelters, and dorms. In Washington state, at least twenty-seven Covid-19 deaths are linked to a single nursing home.¹¹ Physical distancing measures, including closing public spaces (schools, childcare, workplaces, mass transit) and canceling public events (holiday celebrations, religious ceremonies, sports events, political rallies), are becoming widespread and could help reduce viral spread if they are implemented smartly, scientifically, and ethically.

In this unprecedented period of social separation, loneliness, emotional detachment, and disruptions to social and economic life will produce profound harms. Vital cultural practices such as faith-based services, family bonding, and social connectedness are vanishing from public life. We are also witnessing something all too common in disease epidemics—blaming "the other." Racial and ethnic discrimination, in this case against people of Asian, and especially Chinese, descent, may result from the spread of misinformation or sheer ignorance. Governments must be prepared to address these harms.

Protecting the most vulnerable among us. Sacrifice is necessary, but it must be part of a fair social compact: people should adhere to advice or even mandates for physical distancing, but governments, in turn, must ensure that their needs are met. For the well-off, with well-stocked pantries and generous telework or paid leave, staying home may be feasible. But for poorer families and individuals, physical distancing can be harmful if they are cut off from sources of income, assistance, and support. Once out of work, individuals may not be able to afford necessities like food, housing, and medicine. With many schools closed across the United States, parents without paid family leave will struggle to find childcare and to provide meals that children would normally receive at school. For people who are elderly or with physical or mental disabilities, ordering food online or going to the grocery store can be difficult or impossible.

Where compliance with physical distancing is directly at odds with meeting basic needs, societal harms are inevitable and must be mitigated. Governments must provide wraparound medical care for the under- and uninsured and meet essential needs like medication, food, and water. If schools are closed, leaving low-income children without school breakfasts and lunch, authorities should arrange for children and families to receive food at home.12 Paid sick leave should be afforded to people temporarily out of work due to quarantines, isolation, business closures, or lack of childcare.13 People with disabilities and their caregivers should receive funding to ensure that their needs are met and to cover extra costs, such as for home delivery of food and other necessities.¹⁴ If Americans are doing their part to stay home and prevent Covid-19 transmission, government must do its part, too. That is an essential part of the social bargain.

Further, physical distancing may be very difficult in some places, such as in prisons, detention centers, homeless shelters, and nursing homes. We must protect against disease outbreaks at these sites, including ensuring good medical care, sanitary facilities, and good hygiene (such as ample supplies of soap and hand sanitizer). Large-scale and immediate use of compassionate release programs can protect nonviolent prisoners, especially if they are elderly or vulnerable, without compromising public safety.¹⁵ Other action will be needed, too, to prevent prisons and jails from becoming hotbeds of infection. Such actions might include releasing people with electronic monitoring (allowing for freedom of movement),¹⁶ releasing people who are jailed simply because they cannot pay bail, and reducing arrests and delaying sentencing.¹⁷ Those who have underlying medical conditions might be particularly good candidates for these measures. Some, like people who are at low risk of reoffending, might simply be released. And the government should enable people who are homeless and currently unsheltered to have safe shelter, whether procuring hotel rooms or developing emergency shelters designed to enable physical distancing.

Informed and trusted communication. Physical distancing policy must go hand in hand with informed and transparent public communication strategies. A trusted source of information must inform the public about known risks, unknown risks, and what steps are being taken to learn more. The public must be assured that their basic needs will be met and that strategies to mitigate harms, such as online instruction for elementary and secondary schools and broadcasting religious services, will be available. The public must be properly informed about good hygiene practices that can help prevent Covid-19's spread—and about how they can access hygiene products.

Isolation, Quarantine, Cordon Sanitaire, and Physical Distancing

Governments seeking to limit the spread of Covid-19 may isolate sick individuals, quarantine exposed individuals, and institute cordon sanitaire.¹⁸ Isolation and quarantine were widely used in Asia and Canada during the SARS outbreak, but their effectiveness depends heavily on outbreak stage and viral transmission characteristics, which are not yet fully understood for SARS-CoV-2. These measures, where known or expected to be effective in reducing viral transmission, can be lawful, but infringements on individual privacy and liberties must be carefully considered.

Balancing public health and civil liberties. Quarantine, isolation, and cordon sanitaire are extreme measures that entail stringent restrictions on freedom of movement, association, and travel and can cause massive economic and social disruption. When balanced against public health interests, a basic rule is that governments should employ the least restrictive means necessary to protect public health. Meeting this standard requires that any Covid-19 isolation, quarantine, and cordon sanitaire must be based on rigorous scientific assessment of risk and effectiveness. Quarantine and isolation for Covid-19 should be ordered only if the person is known or highly suspected to have been exposed to the disease, and only for the maximum duration of incubation (fourteen days for Covid-19). Procedural due process requires that a person has proper notice and an opportunity to challenge a containment order, where feasible.

Further, individuals subject to isolation, quarantine, or cordon sanitaire orders must be assured a safe and habitable environment. Especially in large-scale quarantines, there could be challenges to ensuring safe and hygienic locations, medical and nursing care, necessities like food, water, and clothing, and communications. Vulnerable populations must be protected; authorities should identify in advance those who may need extra assistance (such as older people and people with disabilities) and develop plans to meet their needs. Above all, containment measures must not be a subterfuge for discrimination.

Deciding how far governments should go. Compulsory orders for quarantine, isolation, and cordon sanitaire bring enormous legal, ethical, and logistical challenges and should be used only as a last resort. Self-isolation or self-quarantine are preferable and generally effective. When properly informed, most people will follow their instincts to stay safe and will shelter in place at home. Self-isolation has another benefit besides limiting infringement on people's civil liberties: if hospitals become overwhelmed, as in South Korea and Italy, self-isolation for people with mild symptoms can help make more hospital beds available for sicker patients.

Where voluntary compliance is not an option, governments may need to enforce containment orders in the interest of public health, but how far should they go? It may be relatively easy to enforce isolation and quarantine orders against individuals who pose a known danger. Yet we are witnessing large-scale quarantines imposed without any individualized risk assessment. Elderly persons, for example, face such a high risk of death if they contract Covid-19 that many nursing homes have gone on "lockdown" mode, forbidding residents to leave or visitors to enter the facility. As described above, these orders must follow rigorous safeguards, including opting for the least restrictive alternative, depending on scientific assessment of risk and effectiveness, ensuring procedural due process, and providing a safe and habitable environment. Difficult questions will still arise, though. For example, are complete lockdowns necessary, or may an eighty-year-old without underlying conditions go for a short walk outside while practicing physical distancing?

Further, monitoring and enforcement through surveillance modes, including thermal scanners, electronic bracelets, and web cameras such as those used during the SARS outbreak,¹⁹ implicate privacy interests. Enlisting armed police and citizen informers to control large populations in cities like New York or Chicago seems so contrary to American values and the rule of law that it is difficult to conceive opting for that route in the days and weeks ahead. But San Francisco has already ordered its population to shelter in place for three weeks, with people directed to stay inside and avoid contact with others, though with numerous exceptions. People can leave their homes without government permission, but law enforcement has been asked to ensure compliance.

At a time of vast inequities, we are all only as safe as the most vulnerable among us—both in the United States and globally. If poor or disadvantaged members of our community cannot practice physical distancing or access health services, then we will all be at greater risk. Conversely, those who are better off should take measures to protect themselves from infection, both for their own health and in order to protect everybody else. Equity and public health go hand in hand. We are in uncharted territory, where vital human connections and economic activity are disrupted in ways not seen in generations. If we want to safeguard the public's health while being faithful to our most fundamental values, then we must ensure that our response is effective, ethical, and equitable.

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Exhibit 24

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Responding to COVID-19: The UW Medicine Information Technology Services Experience

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Abstract

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Background UW Medicine was one of the first health systems to encounter and treat COVID-19 patients in the United States, starting in late February 2020.

Objective Here we describe the rapid rollout of capabilities by UW Medicine Information Technology Services (ITS) to support our clinical response to the COVID-19 pandemic and provide recommendations for health systems to urgently consider, as they plan their own response to this and potentially other future pandemics.

Methods Our recommendations include establishing a hospital incident command structure that includes tight integration with IT, creating automated dashboards for incident command, optimizing emergency communication to staff and patients, and preparing human resources, security, other policies, and equipment to support the transition of all nonessential staff to telework.

We describe how UW Medicine quickly expanded telemedicine capabilities to include most primary care providers and increasing numbers of specialty providers. We look at how we managed expedited change control processes to quickly update electronic health records (EHR) with new COVID-19 laboratory and clinical workflows. We also examine the integration of new technology such as tele–intensive care (ICU) equipment and improved integration with teleconferencing software into our EHR. To support the rapid preparation for COVID-19 at other health systems, we include samples of the UW Medicine's COVID-19 order set, COVID-19 documentation

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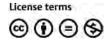
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template, dashboard metric categories, and a list of the top 10 things your health care IT organization can do now to prepare.

Conclusion The COVID-19 response requires new and expedited ways of approaching ITS support to clinical needs. UW Medicine ITS leadership hope that by quickly sharing our nimble response to clinical and operational requests, we can help other systems prepare to respond to this public health emergency.

Background and Significance

The novel coronavirus (COVID-19), which originated in late 2019, presents an unprecedented challenge to health systems. The potential for asymptomatic rapid spread and the high mortality rate for vulnerable elderly and immunocompromised populations make rapid identification and containment of positive patients essential.¹ Within the United States, the first COVID-19 patient was identified in Washington State in January, 2020² and Washington was the early epicenter of the U.S. outbreak.³

UW Medicine is a large health care organization in the Pacific Northwest with nearly 30,000 personnel. Our organization includes four hospitals, 15 neighborhood clinics, the University of Washington School of Medicine, an air ambulance service, and a wide network of practitioners. Combined, UW Medicine has 64,220 hospital admissions, 1,675,442 clinic visits, 204,634 emergency department visits each year, and 1,544 licensed beds. Information technology services (ITS) consist of 528 employees responsible for the IT infrastructure and clinical applications of UW Medicine.

UW Medicine acted quickly to establish structures and systems to respond to COVID-19. A task force was established on February 29, 2020, to monitor COVID-19 issues. We created a new governance to enable a more rapid response to COVID-19 issues, as they arose and focused on ways that IT could support the ongoing clinical needs of the organization. Through this governance, we created new communication systems, accelerated efforts to support our workforce, and worked to identify and mitigate new security concerns. In this manuscript, we seek to characterize the health information technology challenges we faced, to share our newly acquired knowledge more broadly with the informatics community, and to facilitate the rapid adaptation of other health systems to the public health threat of COVID-19 and other potential future emergencies of this type.

New Structures to Accelerate Response

Hospital Incident Command and ITS Emergency Management

Hospital incident command is an approach to systemic organization during exceptional events.^{4,5} UW Medicine utilizes an enterprise-wide Hospital Incident Command System (HICS) approach to manage major incidents. Eight site-based incident command centers (SICCs) are established and are linked to the enterprise HICS through shared planning, logistics, and operational groups (**-Fig. 1**). The enter-

prise HICS addresses system-wide concerns and provides overall coordination. UW HICS partnered with King County Public Health, Washington State Department of Health, the Northwest Healthcare Response Network, the U.S. Centers for Disease Control and Prevention, and other local, regional, and national organizations.

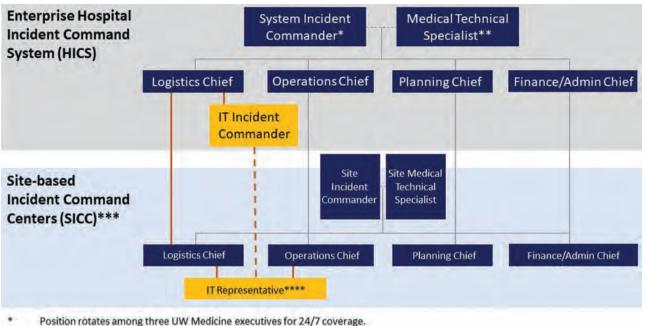
IT integration into the HICS is managed via the ITS Business Continuity and Disaster Recovery program, which coordinates and leads our ITS emergency management activities. The IT incident commander (IT IC) represents ITS and reports to the HICS logistics' chief. Both the ITS chief information officer and IT IC participated in twice daily phone briefings with HICS. The IT IC cascades information to the ITS executive team through a daily 07:00 meeting of ITS executives concerning COVID-19, where the IT IC shares guidance from the HICS and gathers feedback to report back up. The IT IC also disseminates an e-mail update to executives every other day. The ITS workforce receives updates on a daily to twice weekly e-mail schedule.

ITS clinical informaticians are seated in individual SICCs; and the IC coordinates, three IT focus threads are people, electronic health record (EHR)/clinical, and technology; each of which has an internal IT leader responsible for assigning resources and tracking work to completion. As the pandemic progressed and demand for ITS increased to round-the-clock, additional IT program managers (PM) were reassigned to support the IT IC with COVID-19. For example, one PM was put in charge of COVID-19 project intake to help clarify incoming requests for equipment and new capabilities.

Enterprise and site-based command center staff were expected to be available during core hours of 07:30 to 16:30, with tasks completed by personnel working through the night if needed. We rotated responsibility for the key position of IT IC, enabling ITS to switch from sprints to marathon support. This is very different than historical disaster-related responses that are usually linked to short-lived span, though highly impactful events such as mass shootings and earthquakes.

New Governance to Accelerate Response

The ability to adapt quickly while maintaining system stability is critical. ITS typically uses a mixture of methodologies that include waterfall and elements of iterative development. The COVID-19 ITS response included many small projects and some much bigger. We are moving to more iterative implementations in some areas that would have been pure waterfall otherwise. For example, COVID-19 related change requests to the EHR were automatically classified as emergency change requests. The change control process for larger, more complex



** Medical Technical Specialist is a physician who shares accountability with the System Incident Commander.

*** UW Medicine has eight site-based Incident Command Centers: Airlift Northwest, Harborview Medical Center, UW Medical Center, UW Medical Center – Northwest, UW Neighborhood Clinics, UW Physicians, UW School of Medicine, and UW Medicine Valley Medical Center. Some SICCs, such as those at the hospitals, have more robust structures that include more elements, such as IT representatives.

**** Reporting chain for the IT Representative varied by site for IT representatives into the site-based Incident Command Centers.

Fig. 1 IT Services integration into hospital incident command system structure.

changes is usually on the order of weeks. We developed a modified change control process for COVID-19–related items. Changes were evaluated and implemented within hours, while still maintaining internal change control and consistent IT practices.

Early EHR change requirements included creating an order set for home visits by a newly created home assessment team,⁶ precautions for blood processing, orders, standard documentation phrasing, and alerts. COVID-19 related requests were being made at all hours of the day. Our IT IC allowed us to quickly operationalize new guidance by incorporating it into EHRs. We monitored our EHR vendor sites for emergent system updates and have designated IT employees staffed around the clock to evaluate and implement change requests.

New Supportive Dashboards

Enterprise IC needed visibility of events, actions, and changes happening across the enterprise to support decision making in the HICS. They provided metric requirements, and ITS created a real-time dashboard (**~Fig. 2**) of critical metrics including the number of tests by result and facility per day, laboratory turnaround time, current admitted patient counts, counts of personal protective equipment on hand by facility, and telehealth visits per day related to COVID-19. More recently, we tracked patients in intensive care unit (ICU), as well as the number, and percentage of COVID-19 positive patients. We are using this information to project COVID-19–related care demand. A full list of the metrics collected by incident command is collated in **~Table 1**. In addition to the enterprise IC dashboard, we created specialized reports including a dashboard for the laboratory and supply chain, operational reports, and patient lists. Laboratory dashboards identify tested patients, turnaround times, and specimen source location information. These reports are automated where possible, allowing decision makers to analyze data in a self-service manner, and to ensure their continuous availability.

Optimize Communication to Support New Needs

A rapidly evolving pandemic situation requires real-time internal and external communication. ITS created a variety of push and pull platforms to support the UW Medicine workforce, and our wider community, including patients.

In addition to the executive communications described previously, UW Medicine sought to communicate regular updates to staff across the enterprise. Daily updates were initially sent (1) as e-mails to senior leaders, who were tasked with forwarding as indicated or (2) via "The Huddle," a daily newsletter to all UW Medicine staffs. The lack of centralized communication capability (stemming from the fact that facilities within the enterprise typically manage their own staff communication) resulted in a flood of e-mails that were difficult to process and prioritize by end users. In response, ITS and UW Medicine internal communications collaborated with human resources (HR) and local sites to create more complete distribution lists, including sublists targeting specific stakeholder groups for COVID-19 outreach. As these efforts



Fig. 2 COVID-19 incident command dashboard. UW Medicine IT services created a dashboard for our COVID-19 hospital incident command. A list of metrics collected can be found in **Table 1**.

Table 1 COVID-19 dashboard metrics

The following metrics are collected by UW Medicine COVID-19 Incident Command
No. of tests by result and by facility per day
Laboratory turnaround time
• No. of patients currently in ICUs as well as the no. and % of those patients who are COVID-19 positive
No. of current positive and pending tests among inpatients
Current location of patients with positive or pending tests
On hand supply counts of personal protective equipment at each facility
No. of outpatient visits per day
• No. of outpatient no shows per day
No. of outpatient cancellations per day (separated by COVID-19-related or not)
No. of ED visits per day
• ED Length of stay
• List of test results for patients tested who presented at the ED
Telehealth visits per day for COVID-19-related symptoms
COVID-19 info line calls per day (by nurse triage needed or not)
• % of calls abandoned and average call speed for calls into COVID-19 info line

Abbreviations: COVID-19, novel coronavirus; ED, emergency department; ICU, intensive care unit.

progressed, UW Medicine was able to reduce its reliance on cascading e-mails and reduced redundant e-mails. Communications became more focused and tightly organized.

Communicating EHR changes is critical to ensure that clinical staff are aware of the latest COVID-19 tools. ITS sent e-mail concerning special updates to users (overriding previous unsubscribe requests) and repeated news in four enduser newsletters. ITS physicians also sent change information to expert users, and hospital/physician leadership. Communication to the community is more complex than communicating with staff given the variety of public outreach mechanisms, ranging from multiple UW Medicine web sites, automated patient e-mail and text patient notifications (e.g., appointment reminders), and hold messages when calling the UW Medicine Contact Center. The IT IC worked with the owners of these groups to align external messaging to enterprise COVID-19 updates regarding selfscreening and testing guidance, transition from in-person to telehealth visits, and discontinuation of online selfscheduled appointments.

To ensure consistency, ITS created an intranet and an extranet page to house COVID-19 resources. The internal webpage included screening and testing algorithms, policies and procedures, and signs and posters for clinics. The internal webpage clearly describes what content is UW Medicine only, and what can be shared externally. The external webpage (launched on March 11, 2020), shared COVID-19 resources with others.⁷

ITS also helped the organization to stay connected by increasing staff at the Help Desk and preparing them to answer questions and quickly resolve issues from clinicians using new telehealth capabilities, and employees are now working remotely.

Supporting Medical Practice

UW Medicine targeted rapid laboratory testing and result notification, adapted our provider workforce to new clinical guidance and working conditions, and minimized face-toface contact to protect patients and health care workers.

COVID-19 Laboratory Testing, Ordering, Interfaces, and Communication

UW Medicine started validating their COVID-19 test in early February and brought their test online on March 2, 2020. The laboratory scaled testing to a capacity of 2,000 tests per day over a 10-day time period.

Laboratory IT had to ensure functional workflows for specimen collection from both traditional sources and from new specimen source locations using provisional collection staff, as some locations had not previously used the EHR (e.g., employee health). We were able to leverage employees' existing EHR records with the guidance of our compliance office by giving employees the option to consent to not separate their employee health data from their patient record. The feasibility of this approach would be dependent on local and state laws.

For other locations which still relied on paper-based and faxed orders (e.g., community screening of nursing homes), workflows to prelog and preprint labels were developed so samples could be accessioned and resulted as quickly as possible upon receipt in the laboratory. New policies guided specimen labeling, and new protocols were developed to ensure safe handling, packaging, and transport of COVID-19 specimens (**-Table 2**).

Our Laboratory IT group and ITS coordinated to manage diagnostic testing. We first created an unambiguously named COVID-19 order and test component names to integrate into EHRs, predicting that most providers would search for COVID. Severe acute respiratory syndrome (SARS)-CoV-2 was also included as a synonym for the orderable. Of note, for FDA and state validation purposes, the laboratory information system lists SARS-CoV-2 in the name, but this name only appears on printed/faxed reports directly from the laboratory information system.

We decided to make this order not require cosignature, to broaden ability to order. Laboratory information system interfaces to EHRs and to external systems (e.g., public health) were configured.

Clinical Decision Support

COVID-19 testing and management guidelines are continually evolving. HICS followed these changes and updated institutional policies and protocols. UW Medicine ITS supported clinicians by working closely with HICS and continually updated order sets and documentation templates to ensure that the information was available to clinicians at the proper time in their workflow.

The COVID-19 order set (**-Fig. 3**) allows direct access to useful hyperlinks, laboratory orders, appropriate International

Document type	Brief description of document(s)
COVID-19 requisition form	Special fillable pdf for clients
Self-collected sample information	Client letter for distribution explaining reasons why the sample is not acceptable
COVID-19 sample processing policy	Streamlined processes for samples for specimen processing services
COVID-19 tiered clients list	Tiered client list for ease of assigning tier in specimen processing services
Process for COVID-19 panel requests	Job aid for validation materials, form to track requests for validation samples
Process for sending positive samples to state health department	Job aid for sending samples
Transplant-related protocols for COVID-19	Job guideline for donor/recipient testing, labels for application on transplant samples for easy identification, courier directions for transplant patient samples
Mitigation plans	Divisional guidelines for pandemic laboratory operations
Policy for nurse draw on COVID-19 inpatients	Phlebotomy to be done by nursing staff to conserve personal protective equipment
Specimen processing volunteer aids	Intake process for volunteers, description of job duties for volunteers, self-serve shift sign up worksheet
Self-attestation for employees	Sign in sheet to attest that employees are symptom-free

Table 2 COVID-19 laboratory documents

Abbreviation: COVID-19, novel coronavirus.

×Re	move Pend Sign
COVID-19 & Personalize *	
▼ Reference Information	
▼ Helpful Links	
- UW Medicine COVID-19 Site - WA DOH COVID-19 Site - UW Telehealth Job Aids	
▼ Reason for Visit	
▼ Reason for Visit	
Breathing Problem (aka Shortness of Breath)	
Cough	
Fever	
Throat Problem (aka Sore Throat)	
✓ Charting	
▼ Charting	
COVID-19 Note (for both Telehealth and non-Telehealth visits)	
COVID-19 Sample Collection Documentation	
• Orders	
▼ Labs	
COVID-19 Coronavirus Qualitative PCR (Normal Status is now being used for Routine, ** DO NOT send in Tube System **	ALL visits)
Influenza A, B and RSV, Rapid PCR (Strongly consider empiric treatment. To b will change clinical management) (\$\$\$\$) Routine	e ordered only if results
Influenza Assay Rapid, Onsite - UWNC only (Strongly consider empiric treatm if results will change clinical management) Routine	ent. To be ordered only
Strep Test Rapid, Onsite (UWNC only) Routine	
• Diagnosis	
Cough [R05]	
Fever, unspecified [R50.9]	
Shortness of breath [R06.02]	
Sore throat [J02.9]	
- LOS	
Level of Service Office Visit	Click for more
 Level of Service Onice Visit Level of Service Telemedicine (GT modifier Visit conducted with live, interactive video & audio) 	Click for more
Level of Service Telephone (Visit conducted with audio only)	Click for more
Patient Instructions	
▼ Patient Instructions	
Patient Instructions for URI and possible COVID-19 testing	
▼ Ad-hoc Orders	
P Search	

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Fig. 3 COVID-19 order set. The UW Medicine COVID-19 order set for our ambulatory electronic health record was built in Epic. We will continue to update this. The latest version can be found at the UW Medicine COVID-19 web site.⁷ (Reprinted with permission of Epic Systems Corporation).

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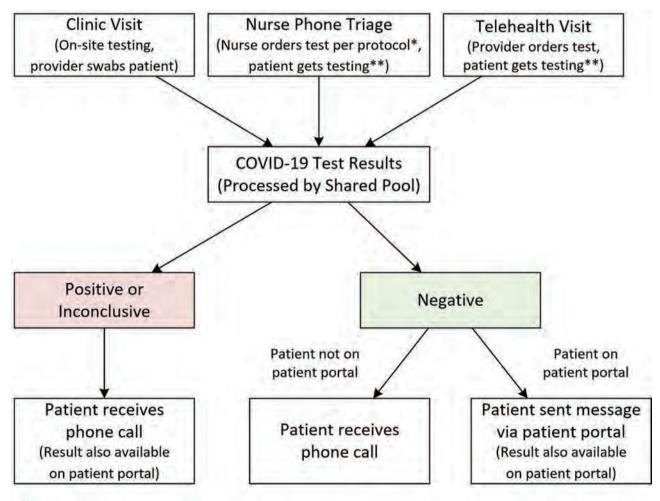
Classification of Diseases, 10th Revision (ICD-10) diagnoses, billing codes, and discharge instructions. The COVID-19 documentation template (**> Supplementary Appendix**, available in the online version) includes a checklist of symptoms and risk factors as well as the latest testing recommendations. The template also supports telemedicine and telephonic visits. The reason for visit is also included, since due to conservation of personal protective equipment (PPE), medical assistants now rarely room patients, and thus do not prepopulate this field.

By making quick changes to EHR documentation, such as a single order set, ITS was able to support patient engagement and triage at several critical intersections. One was the nurse triage line that UW Medicine greatly expanded in early March. Using delegated authority and an order protocol, nurses who had never placed orders in the EHR could use a standardized set of laboratory orders and diagnoses without having to learn complex EHR workflows. Another critical improvement was to give front desk staff the ability to access updated appointment templates and cancellation options. This allowed UW Medicine to track COVID-19 related financial impacts.

Results Review

The COVID-19 test order was integrated into the COVID-19 order set. Results messaging was developed to give ordering providers clinical guidance and to reflect the necessity to err on the side of public health in cases of negative or inconclusive results.

As the major regional referral laboratory for COVID-19, only a fraction of the COVID-19 testing performed was for established UW Medicine patients. The responsibility for communicating results is challenging for patients without an associated UW Medicine primary care provider to perform the follow-up. In response, UW Medicine implemented a centralized results notification process, which uses remote workers instead of front-line clinicians (**-Fig. 4**). All ambulatory results are routed to a centralized EHR inbox pool staffed by trained professionals. By maintaining a small group of responders, tight and consistent messaging was maintained despite changing guidelines. For patients outside of UW Medicine, laboratory medicine contacted the ordering organizations to communicate positive and inconclusive results.



*Only available for COVID-19 testing per protocol

**Patients can get testing from a restricted number of testing sites including drive-through testing

Fig. 4 COVID-19 centralized results notification process.

Patients with positive COVID-19 results were called, while negative results were available on the patient portal within 1 hour for established UW Medicine patients. A centralized number was provided to patients who missed the call to inform them of the results.

Telehealth for Clinic Visits

The need to limit exposure of potentially infectious patients and conserve PPE quickly emerged as a critical consideration when faced with a situation of indeterminate length and global supply shortages. This situation caused our practitioners to follow two courses of action: (1) screening patients before they presented in person or (2) screening them remotely while isolating the patient in a room with telemedicine capabilities.

To screen patients for appropriateness of a telehealth visit, UW Medicine aligned our usual screening pathways to match our COVID-19 symptom criteria. Aligned pathways include through scheduling (e.g., appointments through the patient portal, registering for an urgent care appointment online, or calling our contact center to set-up an appointment) and through consultation (e.g., calling our nurse triage line). If patients walked in with respiratory symptoms, they were scheduled for a telehealth visit instead of an in-person evaluation. Language was also added to our web sites and patient portal directing patients with respiratory symptoms to telehealth visits.

UW Medicine moved quickly to provide privileges and train all UW Medicine primary care clinicians in telemedicine. By March 19, approximately 500 providers had been trained and received privileges, including close to 100% of our primary care doctors. UW Medicine expanded COVID-19 telemedicine to clinics who care for vulnerable patients such as oncology, transplant, cardiopulmonary, and end-stage renal patients. Providers were able to access telemedicine training videos,⁸ job aids, and other resources from the UW Medicine intranet. The telemedicine e-learning at UW Medicine is comparable to that offered by the Washington Telehealth Collaborative.⁹ Additional learning topics included signing up for telemedicine, billing documentation, and how to use the EHR in conjunction with the teleconferencing tool are provided to UW Medicine providers on an internal intranet page.

ITS helped to acquire equipment, managed software licenses, supported remote access, trained practitioners, and integrated teleconferencing into our ambulatory EHR. This ensured that the UW Medicine systems could handle the influx of users and increased utilization of our network and resources. We engaged UW Medicine compliance in helping with processes to address billing and privacy related concerns. We worked with clinical leaders to establish a consistent methodology to educate patients on how to connect to telemedicine appointments.

We determined the best tools and workflows to mask the phone numbers of personal devices used with those of the designated clinic or the UW Medicine contact center. To change the caller ID to instead display the phone number of a designated clinic or the UW Medicine contact center, providers were instructed to use either the Doximity Dialer application or use a UW Medicine call forwarding feature

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through our phone system (Avaya/Asterisk). Users could call a designated phone number, enter a numeric password, and proceed to dial the patient's phone number. This allowed more practitioners to work remotely.

Telehealth in Intensive Care Units

UW Medicine moved quickly to launch telemedicine capability in the ICUs, to allow intensivists to engage with patients via tele-ICU carts, rolling devices with two high definition cameras and a screen on a pole with wheels.¹⁰ Tele-ICU capability offered a high degree of flexibility, as the tele-ICU carts were rapidly deployed at three of our four hospitals, allowing UW Medicine to surge capacities of specialists virtually across our different institutions as needed. The tele-ICU carts allowed practitioners to conduct bedside visits, eliminated the time for donning, and doffing PPE, and conserved PPE.

Surge Planning

As COVID-19 spreads, ITS has been involved in surge planning. This includes planning for expedited procedures for granting emergency-level access to systems, changes to the EHRs, and other systems to allow tracking of patients, who may be placed in nonclinical areas, and a process to rapidly extend our network for new clinics and treatment areas.

UW Medicine is planning to convert ambulatory clinic space at the hospitals to inpatient COVID-19 assessment areas. This requires the same level of effort and scrutiny of EHR build effort as establishing a new clinic. The inpatient tracking requirements are much stricter than in ambulatory settings and are critical for assessing who may have encountered presumed or confirmed positive patients. We are working on securing more equipment (desktop computers) to support the IT infrastructure of these surge locations.

ITS also supported mobile testing clinics such as the nation's first drive-through testing site. This meant extending network connectivity and providing systems to support collecting specimens from patients with unknown COVID-19 status while in their cars. Initially, UW Medicine leveraged cellular hotspots normally used for clinics during a power outage and while this worked as a short-term solution, ITS quickly implemented microwave line of sight systems that provided more robust connectivity.

Workforce Issues

ITS leadership recognized the need to quickly leverage telework to keep the workforce healthy, stable, and productive through the pandemic. In early March, ITS pivoted to teleworking for all personnel who did not need to be physically present to perform their job duties. The enterprise already leveraged teleconferencing tools due to UW Medicine's geographic spread and could focus on increasing bandwidth and access to the virtual private network (VPN), teleconferencing tools, and file-sharing resources.

HR quickly released policies and guidance on how to manage a teleworking workforce. Staff checked out their desktop hardware such as monitors, keyboards, and mice. Remote staff were expected to be available via phone, e-mail, and instant messaging.

Security

Security and compliance quickly emerged as focus areas, given the move to teleworking and the rise in attacks by malicious actors during the pandemic.

The speed of the pivot to social distancing coupled with supply chain constraints, meant that many ITS staff used personal devices while teleworking when not handling protected health information. Physicians were able to securely access the EHR via vendor applications. And while ITS was able to surge bandwidth for the system, staff faced local bandwidth constraints from residential internet providers. This placed a unique strain on maintaining security, as the protections offered via our secure VPN were only accessible if staffs logged in to the VPN, an extra step that many in the newly teleworking workforce were unfamiliar with. The technical team pushed out guidance via ITS leadership e-mails and UW Medicine compliance and security worked together to rapidly update, consolidate, and disseminate teleworking guidance.

The COVID-19 pandemic presented a security threat to systems. While UW Medicine regularly faces and fends off cyber-attacks, security saw a rise in phishing and attempts to use COVID-19 to lure health care workers to web sites laced with malware. The security team collaborated with local and regional security partners, including the Federal Bureau of Investigation (FBI), to monitor the health of the UW Medicine network and devices. ITS plans continued workforce education

on good security hygiene, identify procedures for investigating attacks on home computers of teleworking staffs, identifying methods for performing forensics on home computers, and disseminating security software for mobile devices.

Lessons Learned

UW Medicine pivoted quickly to address clinical needs as they arose with COVID-19. There are three areas that UW Medicine would have done things differently, given the benefit of hindsight. First, we would have prioritized the full integration of our video conferencing solution into the ambulatory EHR. Second, we would have placed more emphasis on broadly expanding our telemedicine solution. While we had a foundation to build from given our existing program, we would have benefitted from having more providers trained and more cameras in place. And finally, we would have had a larger supply of equipment on hand to support both teleworking and telemedicine.

Next Steps

IT is a cornerstone of organizational response to coordinating operational and clinical needs and must rapidly rearrange infrastructure, policies, and priorities to remain responsive. At UW Medicine, we anticipate expanding and adapting our response to COVID-19 by using the framework enacted in our initial strategy.

ITS is working with regional and national partners to build solutions that allow organizations to share information

 Table 3
 Top 10 things your health care IT organization can do now

These are the top 10 actions you can take now to help your organization prepare for COVID-19 or future infectious disease emergency scenarios.
1. Establish your new or evaluate your existing IT response structure. Be sure that points of contact and processes will work for this situation. Plan for the long haul. You will need IT services to surge support for weeks or months. Ensure you have a deep bench of experts in key areas to sustain the demand.
All updates to your EHR must be evaluated and centrally disseminated as quickly as possible. Your IT personnel must be able to do this around the clock. Ensure that your information security team has a rapid process to assess, document, and approve risk decisions and exceptions during the emergency.
3. Quickly prepare multiple sites with telehealth capability. This will allow patients and practitioners to flow between different sites. Begin training your practitioners immediately.
4. Assess remote user capability, licenses, software, hardware and bandwidth limitations to connect to your internal systems to ensure your systems can handle the influx of users and increased utilization of your network and resources.
5. Assess how your organization can be nimble with granting access to systems and sites in emergencies. Start planning now for emergency-level access that allows people to surge and flow between sites.
6. Make patient screening tools accessible prior to presenting. Priority needs to be on ensuring your patients know how to self-screen.
7. Establish a centralized intranet site for disaster management and communication. This includes an incident command dashboard of automated metrics to help assess the evolving situation.
8. Identify the role of IT in sending communication to the workforce. Test dissemination methods to ensure they reach your entire workforce. Review communication distribution lists to ensure that they accurately reflect the internal, external, partner, and other groups that are critical to your response.
9. Prepare for increased help desk support requirements, and ensure your staff are prepared to answer questions. Quickly resolve issues with clinicians using new telehealth capabilities and newly teleworking employees.
10. Plan for large scale remote work. This will require workforce provisioning of equipment and policies and procedures for managing a remote workforce.

Abbreviations: EHR, electronic health record; IT, information technology.

about open beds, capacity, and current stock of key items such as masks and ventilators. This work may support the use of predictive analytics to forecast patients at different levels of acuity, which will allow for a calculated response and the ability to divert patients to different hospitals in the region based on clinical presentation and available resources.

Timeliness of communication between patients and the health care team is critical. This can be accomplished through increased enrollment in web portals and transitioning to patient text-based messaging and telemedicine visits. Increasing portal access may improve the ability to exchange medical records with additional care providers for patients diverted to other facilities as the result of matching patients to community providers.

There are additional opportunities to engage more providers should the epidemic continue for a longer period. Key considerations include streamlining onboarding and decreased training time, improving organizational security, providing health care workers with information about phishing and other attacks, and providing resources to report them.

Conclusion

The unfolding pandemic of COVID-19 necessitated a previously uncharted reorganization of health care system infrastructure, processes, and priorities. Surge capacity planning, patient triage, infection control, supply chain management, communication, and online patient management were identified as key challenges in the recent experience of health systems in Asia.^{11,12} UW Medicine leveraged established HICS command methodologies to rally the resources of our organization in response to this unprecedented event. Through a shared sense of purpose and nimble response to clinical and operational requests, the ITS team played an integral role in responding to this public health emergency. Some recommendations for other organizations to consider are in **~ Table 3**. More detailed, regularly updated information can be found on our external website.⁷

Clinical Relevance Statement

This paper provides lessons learned and guidance for hospital IT leaders to consider while positioning their organizations to support clinical needs for the COVID-19 pandemic response.

Multiple Choice Questions

- 1. An effective metric to determine the burden of COVID-19 on the health system might be
 - a. Number of COVID-19 tests by facility per day
 - b. Laboratory turnaround time
 - c. Outpatient no shows per day
 - d. Emergency department length of stay

Correct Answer: The correct answer is option a. The number of COVID-19 tests by facility per day is the

most direct measure of the burden of COVID-19 on the health system, although each of the metrics listed may be affected by COVID-19 burden. Testing reflects the number of patients being seen throughout the health system (and the region in the case of regional laboratories) with a clinical suspicion for COVID-19. The other metrics all have the potential to be impacted by factors unrelated to COVID-19 burden.

- 2. COVID-19 disease is caused by
 - a. 229E (α coronavirus)
 - b. MERS-CoV
 - c. SARS-CoV-2
 - d. HKU1 (β coronavirus)

Correct Answer: The correct answer is option c. COVID-19 (coronavirus identified in 2019) is caused by SARS-CoV-2 (the second identified severe acute respiratory syndrome associated with coronavirus), to distinguish it from the SARS epidemic caused by SARS-CoV-1 identified in 2002. There are many other coronavirus isolates that cause human disease, notably, MERS (Middle Eastern Respiratory Syndrome identified in 2012), and the common seasonal coronavirus types 229E (α CoV) and HKU1 (β CoV).

- 3. Close contact to a patient with COVID-19 is contact within approximately this distance for a prolonged amount of time
 - a. 1 m
 - b. 2 m
 - c. 3 m
 - d. 5 m

Correct Answer: The correct answer is option b. The CDC identifies close contact as "being within approximately 6 feet (2 m) of a COVID-19 case for a prolonged period of time" (*https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html*, accessed March 28, 2020).

Note

A previous version of this work is available on the UW Medicine COVID-19 web site at *https://covid-19.uwmedicine.org/*. In the interest to publish this paper while the COVID-19 pandemic is still ongoing to share lessons learned with others as quickly as possible, this paper has undergone an abbreviated and unblinded peer review. Users are advised to use the recommendations in this paper in a judicious manner.

Protection of Human and Animal Subjects

We reviewed this work with our Human Subjects Division. They concluded it was not human subject research.

Funding

None.

Conflict of Interest

M.G.L. reports his FTE is partly paid by UW Medicine IT Services.

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EXHIBIT "25"



Viewpoint

March 12, 2020

Supporting the Health Care Workforce During the **COVID-19 Global Epidemic**

James G. Adams, MD^{1,2}; Ron M. Walls, MD^{3,4}

» Author Affiliations | Article Information

JAMA. 2020;323(15):1439-1440. doi:10.1001/jama.2020.3972

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evere acute respiratory syndrome coronavirus 2 (SARS-CoV-2) continues to spread internationally. Worldwide, more than 100 000 cases of coronavirus disease 2019 (COVID-19, the disease caused by SARS-CoV-2) and more than 3500 deaths have been reported. COVID-19 is thought to have higher mortality than seasonal influenza, even as wide variation is reported. While the World Health Orga (WHO) estimates global mortality at 3.4%, South Korea has noted mortality of about 0.6%.¹⁻³

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Vaccine development and research into medical treatment for COVID-19 are under way, but are many months away. Meanwhile, the pressure on the global health care workforce continues to intensify. This pressure takes 2 forms. The first is the potentially overwhelming burden of illnesses that stresses health system capacity and the second is the adverse effects on health care workers, including the risk of infection.

In China, an estimated 3000 health care workers have been infected and at least 22 have died.

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6/8/2020 Case 2:18+pk+20151emRcareDoor4849pringFiilem006/09/2001EpEnterredui06/09/20115:39:08 JANDeservork Main Document Page 247 of 290 multiple family members.⁴ These reports underscore the need for prevention of cross-infection. Evidence related to transmissibility and mortality inform the clinical community of the importance of vigilance, preparation, active management, and protection.

Adherence to the Centers for Disease Control and Prevention's (CDC) recommended guidelines advances safety.⁵ SARS-CoV-2 is spread by droplet and contact. It is not principally an airborne virus. Therefore, ensuring routine droplet barrier precautions, environmental hygiene, and overall sound infection prevention practice is indicated. To ensure minimal risk of infection when treating patients with COVID-19, the CDC recommends the use of personal protective equipment including a gown, gloves, and either an N95 respirator plus a face shield/goggles or a powered, air-purifying respirator (PAPR). However, airborne precautions are not used in daily, routine care of patients with general respiratory illness.

The widespread use of recommended barrier precautions (such as masks, gloves, gowns, and eye wear) in the care of all patients with respiratory symptoms must be of highest priority. In emergency departments, outpatient offices, homes, and other settings, there will be undiagnosed but infected patients, many with clinically mild cases or atypical presentations. There is limited availability of N95 masks, respiratory isolation rooms, and PAPR, particularly in outpatient offices, to feasibly evaluate every patient with respiratory illness and such measures are not routinely necessary.

Protection is achievable even without N95 masks or PAPR. In a study of outpatient health care personnel in diverse ambulatory practices, medical masks applied to both patient and caregiver provided effectively similar protection as N95 masks in the incidence of laboratory-confirmed influenza among caregivers who were routinely exposed to patients with respiratory viruses.⁶ Adherence to CDC evidence-based guidelines for masks, hand hygiene, and environmental hygiene enhances the safety for health care workers.

Many additional questions and concerns remain, especially in high-risk sites and clinical settings. One problem is in the emergency department, where crowding is identified as a major concern. Rigor in the use of recommended precautions for all patients with respiratory illness is especially important. Placin facemask on the patient at arrival, supplying tissues, promoting cough etiquette, and providing for hygiene and surface decontamination are all important steps. Those patients with symptoms of suspected cOVID-19 should be rapidly triaged and separated from the general population ideally in a well-ventilated space with a distance of at least 6 feet from others until they can be placed in an isolation room. Caregivers who encounter any patient with respiratory illness should wear a mask and gloves, with goggles as recommended. Even when COVID-19 is not suspected, it may be present so routine use of these precautions and increased environmental and personal hygiene is advised. Strict adherence to guidelines is of elevated importance for the protection of health care workers. A focus on worker protection through specific training and encouragement of adherence to barrier precautions and hygiene recommendations may help provide a priority focus. Telling caregivers to focus on their safety and being clear and specific

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6/8/2020 Case 2:18+++20151eaterRcareDockf48+49uringFilectb06/09/201 Eptentenedti6609/20115:39.08 JANDeservork

Main Document Page 248 of 290 In addition to recommended masks for patients and other barrier precautions, enhanced hand hygiene and surface decontamination are key to safety. The coronavirus is known to live on surfaces for hours or days,⁷ but it is also effectively killed by available disinfectants when properly used. Masks, goggles, gloves, and other barrier precautions will fail to protect caregivers who later encounter contaminated surfaces and fail to wash their hands. Health care personnel must focus on meticulous hand hygiene, avoiding contaminating workspaces. Clinical staff should clean workspaces and personal items such as stethoscopes, mobile phones, keyboards, dictation devices, landlines, nametags, and other items with hospital-provided disinfectants or alcohol-based disinfectants.⁵ It is sensible for environmental services workers to increase the frequency of cleaning of commonly touched surfaces such as light switches, countertops, chair arms, escalator railings, elevator buttons, doorknobs, and handles. Active decontamination is not merely a technical issue, it also is reassuring to stressed and concerned caregivers, patients, and visitors.

The consequences of delayed recognition of a patient with COVID-19 are significant. Contact tracing for exposure to a case of COVID-19 is no longer routinely recommended, so health care workers must consider themselves at elevated risk of exposure. Health care workers must self-monitor, report signs of illness, and not engage in patient care while exhibiting infectious symptoms.

Recognizing that symptoms of COVID-19 may be mild, the development of pragmatic policies for health care workers who have respiratory illness should be considered. When health care workers exhibit respiratory symptoms, they should not provide direct patient care. When testing, vaccination, and treatments become available, the health care workforce should be considered a priority for evaluation and treatment. Because workforce safety is a high priority, active training in the proper use of barrier precautions and hygiene practices is important.

Many health care workers have conditions that elevate risk for severe infection or death if they become infected with COVID-19, so organizations will need to decide whether such workers, including physicians, should be redeployed away from the highest risk sites. It is not possible to entirely eliminate risk, prudent adjustments may be warranted. New sites may need physician and nurse expertise, include Help telemedicine services, patient advice lines, and augmented telephone triage systems.

Recognizing the risk of health care worker shortages, organizations are banning travel to medical meetings, canceling conferences, limiting nonessential travel, and recommending that personal travel be curtailed. The travel restrictions are not just to affected regions but to domestic and international sites to keep caregivers close and available. Avoiding travel and crowds may also decrease risk of infection.

While health care workers often accept increased risk of infection, as part of their chosen profession, they often exhibit concern about family transmission, especially involving family members who are elderly,

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6/8/2020 Case 2:18:#pk:#201651ediffCareDoot48:49:ringFiledD06/09/201EpEntereduc66/09/20165:39:008 JANDeservork Main Document Page 249 of 290 safety in the current environment. Health care workers may ask whether their family members can receive priority for testing, vaccination, and treatment when the testing becomes available. Ensuring care of health care workers' family members would enhance workforce confidence and availability, but the feasibility and advisability of family priority is yet to be determined. For front-line caregivers, the concerns about transmitting the virus to family members will need to be addressed.

Conversations with front-line caregivers may help reduce anxiety. Topics for discussion might include protective planning for the home such as separation of living spaces and bathrooms and when such separation should be implemented. Protocols for routine arrival home after duty will be a point of discussion, including the benefits of taking off shoes, removing and washing clothing, and immediately showering. These protocols are optional because evidence is unclear, but they may be sensible. Some discussion might be given to changing from personal clothing to hospital-supplied scrubs on arrival to work and changing back to personal clothes to return home. Facility experts may provide guidance about home surface decontamination, including effective products and techniques. There is a need to strike a balance, however, because these ideas might increase anxiety among overworked caregivers. Long work hours make any additional home preparations and extra home cleaning a significant challenge. On the other hand, it can be sensible and reassuring. The focus should be on supportive conversations, clear guidance when recommendations exist, attempts to minimize misinformation, and efforts to reduce anxiety.

Hospital personnel, including caregivers, support staff, administration, and preparedness teams, all will be stressed by the challenges of a prolonged response to COVID-19, and leadership must emphasize the importance of self-care as the center of the response. Transparent and thoughtful communication could contribute to trust and a sense of control. Ensuring that workers feel they get adequate rest, are able to tend to critical personal needs (such as care of an older family member), and are supported both as health care professionals and as individuals will help maintain individual and team performance over the long run. Liberating clinicians and administrative team members from other tasks and commitments allows them to focus on the immediate needs. Provision of food, rest breaks, decompression time, and adequate to PDF may be as important as provision of protocols and protective equipment as days turn into weeks, to Help months. Frequent information and feedback sessions with local managers and the broader facility community, complemented by clear, concise, and measured communication, will help teams stay focused on care and secure in their roles.

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Conflict of Interest Disclosures: None reported.

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March 13, 2020

Important Practical Advice

Shlomo Monnickendam, University of Tel Aviv | Maccabi Healthcare Services

Thank you for this timely, much needed practical advice. You addressed the concerns I have as a (older) primary care physician, especially how to deal with patients with "simple" colds and what to do in order to protect my family.

CONFLICT OF INTEREST: None Reported

March 13, 2020

Importance of Viral Load in Mortality of Health Workers

Babak Tf Tf, Assistant Professor of Medicine | Isfahan University of Medical Sciences

Until this time in our University Hospital, specially linked for coronavirus in the center of Iran, we fortunately have had a low mortality among medical staff & health personnel despite the experience of other hospitals in Iran. I think type of exposure to virus load is an important factor because in spite of our national self-protecting guideline and recommendations of the government there is a notable difference in health worker mortality in the north compared to southern parts. We had a surge of infections in the North part of Iran about 1 week ago, and during this week our local ...



March 13, 2020

Contingency planning

Packard Day, Ph.D.

Using the Great Influenza pandemic of 1918-19 as a template, let me suggest that hospitals/healthcare agencies should begin immediately to plan for how they will reinforce their existing palliative care work

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6/8/2020 Case 2:18 http://www.201651earreDoor/48490ringFridered/06/09/2001 EpEinterred/106/09/200145:39:08 JANDesework of 1/3 of its numbers due to general sickness, death, or overwork. Now imagine another 1/3 that fails to show up for work and is thereby lost due to personal fear, panic, selfishness, or anxiety. The remaining 1/3 of RNs are then left to care for a new patient cohort ...

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March 19, 2020

Droplet Not Airborne, Still?

Dvora Inwood, MA, BA | Arena.io, Healthcare Staffing

Is this guidance still correct in light of the possibility that COVID-19 may be more airborne than previously thought? Is there any way the general public can support efforts that health systems are struggling with when it comes to supply chain/FDA approval? We heard about the debacle with university tests sitting unattended at FDA for approval weeks into the situation. The general public will want to mobilize and help in whatever way the acute care sector wants, we just have not had traditionally clear communication from that sector as to what is needed. Perhaps articles like this can serve that ...

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March 25, 2020

Comforting

Sharon Argenbright, MSN RN | Group Homes

This thoughtful piece provides me comfort. I know these precautions like the back of my hand. I've got this. Now if we could just get the equipment through the pipeline, stat, and reinforce Doctors Adams and Walls' message over and over: we can do this. Thank you for your sensitivity to what it is the front PDF living through.

CONFLICT OF INTEREST: None Reported

April 22, 2020

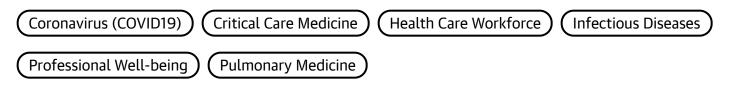
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6/8/2020 Case 2:18+pk+20151e#RcareDoot4849uringFiile@06/09/2001 EpEntenedti06/09/20145:39:08 JANDesovork Main Document Page 253 of 290 Nailya Bulatova, MD, PhD, Professor | The University of Jordan, School of Pharmacy, Department of Biopharmaceutics and Clinical Pharmacy, Amman, Jordan

Although I am not personally involved in care of patients with COVID 19, I have watched the process of donning and then removal and disposal of personal protective equipment recommended by a number of professional bodies (e.g., NHS), which led me to the thought that one additional step may be recommended before the PPE removal. Simply having a shower with warm water mixed with liquid soap which can neutralize the virus effectively could be an easy and non-expensive measure, when resources are limited, that can protect healthwork force from being infected. Or, it could be using a chamber ...

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EXHIBIT "26"

Case 2:18-bk-20151-ER Doc 4849 Filed 06/09/20 Entered 06/09/20 15:39:08 Desc Main Document Page 257 of 290 CONCEPTS IN DISASTER MEDICINE

Translating COVID-19 Pandemic Surge Theory to Practice in the Emergency Department: How to Expand Structure

Matteo Paganini, MD (); Andrea Conti, MD (); Eric Weinstein, MD, MScDM; Francesco Della Corte, MD; Luca Ragazzoni, MD, PhD

ABSTRACT

Multiple professional societies, nongovernment and government agencies have studied the science of sudden onset disaster mass casualty incidents to create and promote surge response guidelines. The COVID-19 pandemic has presented the health-care system with challenges that have limited science to guide the staff, stuff, and structure surge response.

This study reviewed the available surge science literature specifically to guide an emergency department's surge structural response using a translational science approach to answer the question: How does the concept of sudden onset mass casualty incident surge capability apply to the process to expand COVID-19 pandemic surge structure response?

The available surge structural science literature was reviewed to determine the application to a pandemic response. The on-line ahead of print and print COVID-19 scientific publications, as well as gray literature were studied to learn the best available COVID-19 surge structural response science. A checklist was created to guide the emergency department team's COVID-19 surge structural response.

Key Words: COVID-19, pandemics, SARS-CoV-2, surge capacity, translational science

uring the 20th century, health care has radically evolved due to new discoveries and changes in global politics, while the percentage of population that gained access to health care has dramatically increased. Despite this achievement, governments strain to fulfill the overwhelming request for medical assistance. Each government deploys resources trying to meet United Nations' Sustainable Development Goal No. 3 (Ensure healthy lives and promote well-being for all at all ages)¹ while balancing health-care expenditure within their gross domestic product.² Health-care systems oscillate between 2 key elements: demand and available resources. Similar to living organisms, health care has complex mechanisms to achieve and maintain a "stability of the internal environment" (milieu intérieur), despite external stressors.³ The resulting equilibrium could resemble cellular homeostasis during normal conditions.⁴ However, extraordinary events can result in a significant imbalance.

The novel coronavirus (SARS-CoV-2) pandemic is currently threatening several national health systems.⁵ To date, Italy has been one of the most affected countries⁶ where public health departments, emergency medical systems, and hospitals are struggling to deal with the surge of patients affected by 2019-nCoV. Unfortunately, contagion rates are estimated to rise exponentially in many countries, regardless of their health-care delivery system. Urgent actions are required to modify both health-care systems configurations and hospitals' capacity and capability to respond. In such situations, high-quality data are limited. The application of translational science in this disaster medicine setting can provide stakeholders and clinicians with acceptable evidence-based medicine concepts.^{7.9}

- T0 = Identification of opportunities and approaches to a health problem. How does the concept of sudden onset mass casualty incident (MCI) surge capability apply to the process to expand COVID-19 pandemic surge structure response? Structure refers to the physical location of the space where providers attend to the patient.
- T1 = Basic research for clinical effect and/or applicability, human physiology knowledge, and potential for intervention. Review prior MCI surge literature for specific references to surge structure reconfiguration guidance.
- T2 = New interventions to form basis for clinical application and evidence-based guidelines. Scoping Literature Review of available COVID-19 peer review and gray literature.¹⁰

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FIGURE

Pandemic Surge T	imeline.			
	Structure		Spac	е
Conventional	Same	0		
Contingency	Same	0	0	
Crisis	Additional	0	0	0
dependent	e in a pandemic is on rate of contagi	10 M 1 A		e
Structure Emergency	The second second second			
Space Room or area to	o attend to a patient of	patients		
 During a pandemic in response to the dema 				r time

- T3 = Implementation of research findings in clinical practice. Creation of a checklist for COVID-19 Surge Structure Planners.
- T4 = Effects on practice influencing populations and policy. Collection of completed checklists to improve the COVID-19 Surge Structure Planning.

THE TO QUESTION

A marked increase in demand for medical resources, known as "surge,"11 can have detrimental effects on health-care systems if the supply of available resources to meet this demand, known as surge capacity, is not sufficient.¹² Surge capability is how surge capacity is used to meet the unexpected surge.¹¹ With this perspective, the concept of resilience is more appropriate to represent the properties of health-care systems during disasters or MCIs. Initially, this engineering concept described the elastic deformation of materials under physical strain.¹³ This term was implemented in sociology as the ability of groups or communities to cope with external stresses and disturbances.¹⁴ Resilience can be applied to public health to illustrate the adaptations at individual, community, and system levels.¹⁵ A resilient health-care system must be able to limit and cope with stressors and events (absorptive capacity), to adapt itself toward external events (adaptive capacity), to forecast events and take action to minimize effects (anticipatory capacity), and to change the structures and operations to better address results (transformative capacity).15 Altogether, the improvement of surge capability and resilience are critical steps of disaster mitigation and preparedness, to achieve an adequate response toward sudden and high-impact events, such as disasters or outbreaks.¹⁶

THE T1 REVIEW Mass Casualty Incidents

After the Oklahoma City Bombing in 1995,¹⁷ there was renewed interest in MCI management, specifically to create plans to meet the demand of a sudden supply of patients after a sudden onset terrorist disaster. Emergency Departments (EDs) would have to be able to rapidly expand the operational staff, stuff, and structures.¹⁸ This study led to the terrorism MCI response to factor the resilience of the first responders and the first receivers to not become terrorist victims in addition to being able to treat the overwhelming demand of injured patients. The staff, stuff and structures would have to protect all concerned.

The MCI planning and response to chemical (Aum Shinrikyo¹⁹) and biologic (Anthrax²⁰) terrorism added to the mitigation, preparation, and response calculus. Materials to protect staff, personal protective equipment, along with training and competencies, would have to be funded and maintained for all potentially affected staff. The Severe Acute Respiratory Syndrome (SARS) epidemic of 2002-2004²¹ moved the MCI discussion from sudden onset disaster (SOD) planning and response to the unique variables to meet the demand of a sudden onset of patients with a novel disease, or a disease caused by an agent that was not known and had no specific diagnostic test or treatment. This response entailed a new calculus to prevent transmission to Emergency Medical Services (EMS) staff or emergency department (ED) and hospital patients, visitors, and staff. The 2009 H1N1/09,²² Middle East Respiratory Syndrome (MERS) in 2012,²³ and Ebola in 2013²⁴ tested the mettle of governments, first responders, and receivers, as well as those health-care systems.

Pandemic Surge Capacity

In 2009, planners began to adapt the structural phases in the timeline²⁵ of a sudden onset MCI. Adapting this to the timeline of a COVID-19, with days to weeks before the overwhelming demand of patients present with hypoxia and respiratory failure (Figure 1).

Conventional

When the ED is operating with typical volume or even if the ED is boarding patients, the staff can divert patients that fit the COVID-19 "person under investigation" from the entrance to the ED, bypassing triage into a room with a door or an Airborne Infection Isolation Room (AIIR) if available with standard precautions.²⁶ During the time this patient or a few more present with similar symptoms and are evaluated, other typical ED patients are also arriving. The ED staff resilience features: strict efforts to not expose any ED patients and staff while creating ED space for these patients through an expedited discharge process of all other patients to designated

ED areas waiting for rides; hospital admission process, including abbreviated reports or orders to the in-patients units; and other creative efforts, such as moving patients to the hallways that typically are not used when the ED is overcrowded. The ED structure adapts to meet the demand with present ED patients continuing to be processed accordingly, albeit delayed, without compromising care.

Contingency

Sudden onset disasters typically have a finite number of patients involved, although the treating first responders and first receivers are not aware of this as the MCI evolves. When this demand exceeds the daily supply of staff, stuff, and structures due to sheer volume and presenting pace of patients layered on the usual daily census, the conventional MCI response expands. Circumstances such as patient acuity or particular incidents such as burn, blast, or chemical injuries, as well as accompanying familiar blunt or penetrating trauma, now has exceeded the configured space within the structure of the ED. ED staff resilience will seek other structures with space to accommodate the staff and stuff to attend patients within the hospital, approximate to the ED or in the space outside the ED itself. This may have been planned and exercised, or discussed during exercises, to be adapted to meet the demand. If the MCI has not been encountered, exercised, or planned, then ED leadership will discover and adapt as the MCI unfolds: nearby hallways, a family conference room, ED offices that are empty or easily emptied to accept the staff and stuff to attend to an MCI patient. Current ED rooms are repurposed or patients are cohorted,²⁷ those pending test results or rides home are placed in nontreatment areas; ED staff coordinates to adapt other treatment structures like the preoperative and postoperative units, or intensive care unit (ICU) level of care rooms. While the MCI efforts are within the ED or have expanded, the current ED and newly arriving ED patients continue to occupy their initial structure, although space may have contracted to continue to deliver functionally equivalent medical care, with minimal increase in risk to the patient.²⁸

These strategies are used for the continued rise in the number of patients presenting with COVID-19 symptoms that requires the strict measure to limit exposure. Rooms with doors are a must, personal protective equipment must be available, and the flow of staff has to be managed to limit exposure.

Crisis

Sudden onset disasters have a finite number of patients concentrated in an initial peak, with the supply of staff and stuff that arrive over time to meet the demand. Most patients can be treated and discharged, while those admitted can be cohorted into space that suits their needs without the strict requirement of standard precautions, unlike the COVID-19 response that will require proper standard precautions. The overall MCI visits will decline over time, MCI hospital admissions will decrease, and the ED volume will eventually resume usual operation levels. This is in distinction to a viral outbreak that will have a gradual onset of those seeking medical attention. While facing an incoming epidemic or pandemic, hospitals can adapt progressively as long as the contagion rates are predictable through estimates that guide stakeholders in the process.²⁹

An earthquake in a major metropolitan area could create a catastrophic scenario that would require resources that would have to come from outside the region due to the sheer number of patients. As the COVID-19 pandemic has progressed in each city, the sheer number of patients arriving has been described as "like an earthquake every day"³⁰ with an unpredictable increase while there is a lack of inpatient discharges. The resilience of the ED will require a formal process to create the structures with the space to accommodate the COVID-19 oxygen requiring patients, noninvasive ventilators, or ventilators that are accumulating due to a lack of in-patient space.

T2: SCOPING LITERATURE REVIEW OF CURRENT COVID-19 LITERATURE

The publication of COVID-19 peer-reviewed articles and gray sources is ongoing. This information will demonstrate how hospitals are expanding their surge structure. A literature review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist,³¹ to include manuscripts published up to 22 March 2020; and if not in print then accepted for online publication ahead of print.

Search Strategy

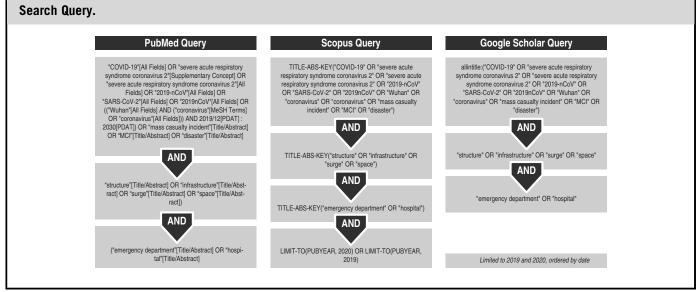
The controlled vocabulary of Medical Subject Headings (MeSH) from PubMed, including subheadings, publication types, and supplementary concepts, was used to identify the entry terms for the search (Figure 2).³²

The search was performed on PubMed/MEDLINE, Scopus, and Google Scholar from the 15 to 22 March 2020. A search of the gray literature was conducted at the same time.

Table 1 and Figure 3 were developed to extract data based on the above review of prior MCI and pandemic surge capacity as discussed earlier.

Inclusion criteria were as follows: (1) studies describing hospital reaction to the SARS-CoV-2 pandemic and specifically detailing structural changes and infrastructural remodeling to cope with the new challenges imposed by the outbreak; (2) any study design, reports included; and (3) gray literature, also including professional society guidelines, protocols, or consensus statements, peer-reviewed blog posts, and podcasts. Case 2:18-bk-20151-ER Doc 4849 Filed 06/09/20 Entered 06/09/20 15:39:08 Desc Expand Structure During Pandemic Surge Main Document Page 260 of 290

FIGURE 2



Exclusion criteria were as follows: (1) contents in languages other than English, French, or Italian; and (2) literature without available abstract or full-text.

Search Findings

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Our search did not identify manuscripts to be included in the qualitative analysis. The records identified through gray literature scanning $^{30,33-41}$ are summarized in Table 2.

The retrieved materials were mostly found on websites of national and international professional societies. Of note, 2 podcasts^{30,33} and 1 blog post³⁴ were found reporting structural adaptations of the ED of the hospital of Bergamo, Italy.

Sources wrote of the need to create dedicated pathways to divide potentially infectious patients (COVID-19) the others (Clean) presenting to the ED. Among the other suggestions made, the management of spaces should take into account the increased prevalence of the disease, thus requiring a track dedicated to respiratory symptoms (reported as approximately 90% of current ED activity in Bergamo hospital).³⁰ Physical barriers should actively separate the 2 fluxes of patients.

The 2 articles are pending online publication ahead of print in the *Disaster Medicine and Public Health Preparedness* journal (personal communication). Medicine relies on tradition, and this is evident in the observation of Faccincani⁴² of his experience in Milan. Treatment of hemorrhagic shock calls for transfusion of "2 units of packed red blood cells and tell the blood bank to stay 2 units ahead" theory applies to his experience to stay 1 ventilator ahead. Extending this to the awareness of when to start seeking more structure for treatment space is when you are comfortable to be aware of the period of time that would require a structure to be adapted, repurposed, or created. The number of references that assign number of patients to be prepared to treat during the timeline of surge, from conventional to contingency to crisis, in peer-reviewed literature, professional societies, nongovernment and government publications is far too great to cite. Only a hospital that is studying their trends can determine when to begin the reconfiguration of a structure. The caution to stay "1 structure ahead" seems to be prudent. When the team has identified structures within their facility to reconfigure, the time that this would take is part of the calculus when prioritizing when to expand the ED COVID-19 footprint.

Gagliano et al.⁴³ wrote of their experience in the Northern City of Lodi, the epicenter of the pandemic in Italy. Their management team relied on accurate data to guide their surge response from the first recognition that the SARS-CoV-2 virus was in the community as COVID-19 patients began to appear. Their conventional management was to cohort patients based on their oxygen requirements and potential for aerosol (noninvasive ventilator treatment) as well as those placed on ventilators to maximize similar structure and space. As the ICU structure was filling up, they turned to the operative theater to increase their ventilator and monitoring space after the first days. While this required minimal investment of resources to reconfigure to limit exposure to staff and to have sufficient supplies, the team was identifying structures that could be adapted, repurposed with little creation to have space to manage the ventilator-dependent patients. The ward (structure) identified already had monitoring capability with the approach to create a filter zone between contaminated and noncontaminated spaces, increased warehouse (stuff), and sanitary (environmental services/housekeeping) space. By the 8th day, they had completed the transformation with cohort structures with space for oxygen-dependent patients.

TABLE 1

Search Tool		
Team Member ED physician ED nurse Respiratory therapy Radiology Pharmacy Engineering IT Housekeeping Logistic/warehouse Registration Nutrition Security Administration	Concern Aerosol Droplet PPE: store/waste PPE: don/doff Traffic: patient Traffic: staff Traffic: radiology Traffic: materials	Mechanism Adapt Repurpose Cohort Create

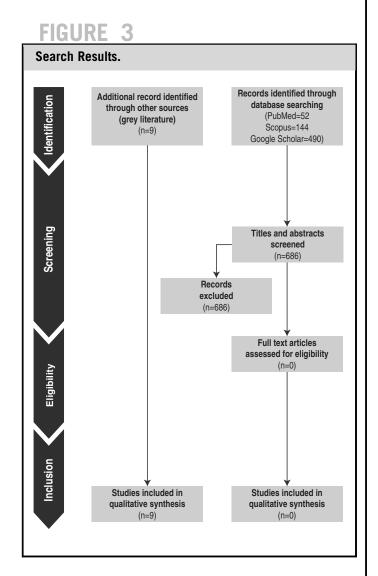
This tool was used to screen literature for relevant content. ED, emergency department; IT, information technology; PPE, personal protective equipment; don, donning (putting); doff, doffing (removing).

$\label{eq:creation} \begin{array}{l} \textbf{T3} = \textbf{CREATION OF A CHECKLIST FOR COVID-19 SURGE} \\ \textbf{STRUCTURE PLANNERS} \end{array}$

Through a review of prior MCI surge capacity literature, this study seeks to find guidance that can be used to understand the mechanisms⁴⁴ to provide the structures necessary to meet the demands of the COVID-19 pandemic (Table 1). The creation of an expert team²⁸ to provide critical infrastructure recommendations beyond the scope of the treatment team is imperative. Once the assembled team (Table 1) understands the likely timeline of the COVID-19 patient load demands on their hospital from conventional to contingency to crisis, they can grasp the challenges understanding the limitation of their structure to provide the necessary space to treat these patients while limiting exposure to staff while treating other patients and limiting their exposure.

This process begins with an agreement on how to create a single path *into* the ED. Saturation messaging in the community is crucial to prevent the ED from becoming a vector, overwhelmed with patients that do not require a detailed evaluation. The external tent structures now ubiquitous outside Italian EDs have become a fundamental screening space. This study does not address the creation or deployment of these or any other external structure or alternate care sites.

The team has to account for exposure by means of droplet from the patient's arrival in the parking lot. Patients should notify staff of their arrival while still in the car to obtain a surgical mask or to use another form of barrier over the face to limit droplets. Space for this staff can be created in or near the ED entrance. The team can do a walk-through as if they were the patient approaching the ED to understand where signage should be placed to direct the patient on a COVID-19 path in distinction from the "Clean" patient path, or all other patients. This can be done with poles and ropes if available or tape on the floor with arrows, especially if either the Clean or



COVID-19 areas are not in the usual ED location in the hospital. Volunteers wearing masks or facial barriers that are more than 6 feet from either path can direct the patient to their treatment destination. Space for volunteers will require consideration if that is outside the entrance or within the structure of the ED to ensure they can manage their activities.

Typically, the ED waiting space is crowded with patients who are waiting to be assessed in triage, have been triaged and waiting to be examined, or waiting for results of tests or images ordered at triage. These patients are usually not sequestered or removed from patient family members. Now the team has to create a COVID-19 waiting space *separate and distinct* from the Clean waiting space. A distance of at least 6 feet from any COVID-19 family member should be ensured, because they may have been exposed and able to transmit the SARS-CoV-2 virus, and preferably not even close to any Clean patients or family members. The COVID-19 space should be well ventilated and in proximity to staff that can monitor those patients waiting to go to the ED treatment space. Some EDs feature vending machines and televisions

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Expand Structure During Pandemic Surge

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TABLE 2				
Scoping Search Results	~			
Title Covid-19 Podcast From Italy	Source (Journal, Website) St. Emlyn's Blog	Team Member/Actor Emergency department	Concern Surge	Mechanism (How To) Split ED into "Lung Diseases Unit" and "Other Discossed Lists"
	nups://www.sterniynsplog.org/covid-19- podcast-from-italy-with-roberto-	priysicians	Timing for structural modifications	Prepare in time - during the onset phase because
	cosentini-st-erniyus/		Treatment of COVID-19 patients depending on oxygen and ventilation	presentation rate grow exponentially Divide the "Lung Diseases Unit" (contaminated path) into a high, medium, and low intensity
COVID-19 Update: An	EMplify Emergency Medicine Podcast	Hospital medical direction Emergency department	Hospital admission increase Spread of the disease	areas Create spaces Create a contaminated/dirty Area and dedicated
Interview With Andrea Duca, MD ³³	https://blubrry.com/emplify/57487286/ episode-38-covid-19-update-an-	physicians	Timing to create dirty area	pathway Progressively adapt to the increasing surge of
	ווונפו אופּא-אווז ו-מוומנפק-ממכק-ווומ		Not enough space	patients Create open space wards and waiting areas where patients are treated while waiting for hospital
				boarding Cohort patients with COVID-19 to gain space
			PPE shortage Shortage of equipment and supplies	Change gloves between patients Rationalize use of equipment and materials
COVID-19: A Powerful Massage From Halv ³⁴	REBEL EM Blog https://rehelem.com/covid_10_a_	Emergency department	Spread of the disease	Creation of 2 divided paths inside the ED: a
	powerful-message-from-italy/	si na	Change in respiratory diseases	Adapt and repurpose spaces to the increasing
			prevalence	prevalence, remodeling on the base of oxygen
				department to see acute respiratory patients.
				Leave a small clean area of the ED for non-suspect
			Timing of changes	Progressively change but expect an exponential increase of presentations so enact changes
		Hospital medical direction	PPE shortage	quickly. Reduce shifts and dedicate personnel to the dirty
			-	path to reduce PPE wastage
COVID-19 Emergency	American College of Emergency	Emergency medicine	Uxygen snortage Risk of contamination/exposure;	Pay attention to oxygen administration Reduce episodes of donning and doffing/patient
Department Response Strategies ³⁵	Physicians https://www.acep.org/globalassets/new-	physicians	PPE shortage	encounter Increasing intercommunication and "door" exam
	pdfs/covid-19-for-emergency- denartment-resnonse-strategies ndf			Create a screening point outside of the hospital
Duty to Plan: Health Care, Crisis Standards of Care,	National Academy of Medicine https://nam.edu/duty-to-plan-health-	Emergency medicine physicians	Increasing presentation rates	Repurpose current rooms/areas to isolation rooms and infectious care areas
and Novel Coronavirus SARS-CoV-2 ³⁶	care-crisis-standards-of-care-and- novel-coronavirus-sars-cov-2/			Cohorting patients Boarding, discharge, and admission waiting areas.
National Strategic Plan for Emergency Department	American College of Emergency Physicians	Emergency medicine physicians and hospital	Spread of disease	Separate areas for patients with respiratory symptoms
Management of Outbreaks Of COVID-19 ³⁷	https://www.acep.org/globalassets/sites/ acep/media/by-medical-focus/covid-19-	medical direction		Maximize distance between patients (at least 6 feet)
	national-strategic-plan_0320.pdf			Protocols for people accompanying patients in waiting areas and visitors

Disaster Medicine and Public Health Preparedness

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TABLE 2				
Continued				
Title	Source (Journal, Website)	Team Member/Actor Emergency medicine physicians, hospital medical direction, cleaning service Hospital medical direction	Concern Spread of disease Increased presentation and	Mechanism (How To) Protocols for decontamination Opening unused areas,
EUSEM Position Paper on Emergency Medical Systems Response to COVID-19 ³⁸	European Society of Emergency Medicine https://eusem.org/news/505-eusem- position-paper-on-emergency-medical- systems-response-to-covid-19	Emergency department	admission rates Spread of the disease	patient cohorting, doubling up inpatient rooms Increase number of isolation rooms, possibly with negative pressure and adequate ventilation Favor physical barriers between patients Specific triage areas for suspect patients Create patient dedicated waiting areas for suspects before boarding Minimization of movements for suspect patients (ED, radiology, bathrooms) Cohorting of patients is reasonable Maintain a distance of at least 1 meter
		Cleaning service	Spread of the disease	Don't allow visitors or co-operators in the area Specific decontamination protocols Treat waste from the contaminated area as a high risk biological material
		Emergency department	Increased presentation rate	Limit access to ED to patients with severe symptoms. Asymptomatic or mild symptomatic patients should seek advice to GP Increase shockniles and sumplies
COVID-19 First Line – 10 Topics From the EDs During Corona ³⁹ (<i>Prima Linea COVID-19 - 10</i>	Italian Society of Emergency Medicine (Società Italiana Medicina d'Emergenza-Urgenza) https://www.simeu.it/w/articoli/	Emergency department	Increased presentation rate Spread of the disease	Prepare to the surge at least 10 days before Repurpose areas increasing possibility of ventilatory support Reduce visits and activities to essentials
cose dai PS ai tempi del Corona) COVID-19 First Line Report – Organizational Structure of EDS Before and During the Outbreak ⁴⁰ (Rapporto prima linea COVID- 19 - Assetto organizzativo gestionale dei PS/DEA nell'ambito di focolaio epidemico o pre-epidemico)	leggiArticolo/3992/leggi https://www.simeu.it/w/articoli/ leggiArticolo/3964/leggi		PPE shortage Oxygen shortage	Create "filter zones" (forward triage or screening areas) Separate Areas for Suspect infectious patients Increase stockpiles and supplies Increase stockpiles and supplies
Checklist for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response ⁴¹	Centers for Disease Control and Prevention https://www.cdc.gov/coronavirus/2019- ncov/hcp/checklist-n95-strategy.html	Emergency Department	Spread of the disease, PPE shortage	Use isolation rooms Use physical barriers between patients Maintain adequate ventilation

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to occupy those waiting, and the team will have to address the allocation and maintenance of these in relationship to the prior adapted, repurposed, or created triage waiting area structure or space. Registration of COVID-19 patients should be separate and distinct from Clean patients. This can be accomplished in the prior registration space or space that has been adapted, repurposed, or created to accommodate a computer desktop, a portable device on wheels, or a tablet for the registration personnel.

The depth and breadth of treating COVID-19 patients requires oxygen, compressed medical air, and vacuum for suction.⁴⁵ Outlets and piping may be hidden behind walls created when space was repurposed to become an office, conference room, or other nontreatment areas. Ventilators and other machines may require different electrical outlets or local grids to avoid overloading any circuits. The treatment team members, physicians, and nurses are encouraged to discuss with the engineer team member the specific vital components of a reconfiguration.

Similarly, contaminated solid and fluid waste, as well as contaminated laundry and other trash, will require proper positioning in structures or spaces that were not designed for the sophisticated support required to treat the COVID-19 patients. The team's attention to this detail will provide the opportunity to maintain a secure infection control loop. Environmental services or housekeeping standard operating procedures during COVID-19 are essential with droplet control paramount to reduce exposure to all as well as rapid turnaround of space for the next patient. They will require pathways from their base of operations through the structure to their duty location with their advanced materials with the need to resupply at a location that may be closer than their base. Because these supplies may be of limited stock and valued by many, a secure location in the structure is required.

Central monitors may be able to be moved from 1 structure to another to create adapted repurposed or created space. This reconfigured space will have to accept computers or charging stations for portable electronic health record devices. The information technology and engineering team members may have innovative solutions to deploy these support assets with minimal cost and time to deploy, in safe and convenient locations.

The path that a patient takes from their ED space, with a door if available, unless in a cohort of similar patients, to radiology or their in-patient destination should be clearly marked as COVID-19 patients, with plastic or other barriers to prevent aerosol droplets landing on Clean hallways, walls, or doors along the way. The creation of filter zones, as mentioned by the team in Lodi using available construction plastic or plastic strips similar to the barriers in refrigeration compartments of

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stores that hang from the ceiling to the floor, provide a droplet barrier. Ideally, these can be obtained and stored before the need with anchor points along the locations in the structure.

Portable imaging machines are cumbersome and to be factored into the process of surge structure design. Also, beds, gurneys, and the associated IV poles, tables, and other materials that are required for a patient in the treatment space are to be accounted. One may best be served to take a gurney or bed with you to a structure that was not designed for in-patient treatment, such as a clinic or IV infusion center where there are only incline chairs or exam tables, to see if these patient support devices can maneuver in the tight spaces.

Most structures within a hospital have a just-in-time process to manage stuff to maintain organization, as a means to know what is used to restock and to charge the patient. In a pandemic, this will likely not be entirely possible to implement, although both the storage and resupply have to remain convenient, secure, and free from contamination unless approximate as necessary to maximize patient treatment. The pharmacy storage and distribution process will rapidly outpace any automated medication dispensing system (eg, BD Pyxis⁴⁶). The team's reliance on the guidance of the pharmacy and nursing representatives will be necessary to assure an efficient loop for the treatment team to have what they need in the reconfigured structure.

T4 = COLLECTION OF COMPLETED CHECKLISTS TO IMPROVE THE COVID-19 SURGE STRUCTURE PLANNING

There is no argument that the evidence-based medicine approach using the Delphi method would have been in line with prior research in the field.^{27,28,36,38,39} These are extraordinary times, and the authors accept this limitation to produce a checklist to guide the team that has been tasked to reconfigure their structure for their surge COVID-19 response. The translational science intention is to create a checklist guide where none existed previously, fully aware that this checklist has not been vetted or verified or tested through simulation or live exercise. Translational science calls for feedback using the checklist (Table 3; an editable version is available as Online Supplemental Material 1) for the authors to continue this study to use to perform the T2 PRISMA review after a COVID-19 research body of work has been published on this topic. The checklist is to be used to collaborate with all relevant actors in real-time as the pandemic is unfolding to maximize the surge structure response in a timely manner, with minimal disruption to the non-COVID-19 patients in the facility, using available staff and stuff with the intent to return the structure to the prior state as soon as possible to resume the activities before this pandemic.

TABLE								
Surge Struct	ure Chec	klists						
TEAM MEMBER ED PHYSICIAN ED NURSE RESPIRATORY T RADIOLOGY PHARMACY ENGINEERING INFORMATION T HOUSEKEEPING LOGISTIC/WAREH REGISTRATION NUTRITION SECURITY ADMINISTRATIO	ech. (IT) House		NAME		CELL		EMAIL	
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Supplementary material

To view supplementary material for this article, please visit https://doi.org/10.1017/dmp.2020.57

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EXHIBIT "27"

Case 2:18-bk-20151-ER

Can J Anesth/J Can Anesth https://doi.org/10.1007/s12630-020-01617-4

CORRESPONDENCE

What we do when a COVID-19 patient needs an operation: operating room preparation and guidance

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To the Editor,

We read with interest the recent review in the Journal by Wax and Christian¹ on coronavirus disease 2019 (COVID-19). The first case of COVID-19 in Singapore was confirmed on 23 January 2020.² In the week of February 13-19, the World Health Organization reported that Singapore had more cases of COVID-19 than any other country outside of mainland China.³ We wish to share the protocol that we use in our hospital in preparing an operating room (OR) for confirmed or suspected COVID-19 patients coming for surgery.

An OR with a negative pressure environment located at a corner of the operating complex, and with a separate access, is designated for all confirmed (or suspected) COVID-19 cases. The OR actually consists of five interconnected rooms, of which only the ante room and anesthesia induction rooms have negative atmospheric pressures. The OR proper, preparation, and scrub rooms all have positive pressures (eFig. 1 in the Electronic Supplementary Material [ESM]). Understanding the

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s12630-020-01617-4) contains supplementary material, which is available to authorized users.

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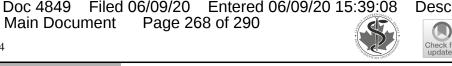
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airflow within the OR is crucial to minimizing the risk of infection.

The same OR and the same anesthesia machine will only be used for COVID-19 cases for the duration of the epidemic. An additional heat and moisture exchanger (HME) filter is placed on the expiratory limb of the circuit. Both HME filters and the soda lime are changed after each case. The anesthetic drug trolley is kept in the induction Before the start of each operation, the room. anesthesiologist puts all the drugs and equipment required for the procedure onto a tray to avoid handling of the drug trolley during the case. Nevertheless, if there is a need for additional drugs, hand hygiene and glove changing are performed before entering the induction room and handling the drug trolley.

A fully stocked airway trolley is also placed in the induction room. As far as possible, disposable airway equipment is used. The airway should be secured using the method with the highest chance of first-time success to avoid repeated instrumentation of the airway, including using a video-laryngoscope.⁴ Equipment in limited supply, such as bispectral index monitors or infusion pumps, may be requested but need to be thoroughly wiped down after use.

The Figure details the roles and responsibilities of each OR team member. Hospital security is responsible for clearing the route from the ward or intensive care unit (ICU) to the OR, including the elevators. The transfer from the ward to the OR will be done by the ward nurses in full personal protective equipment (PPE) including a wellfitting N95 mask, goggles or face shield, splash-resistant gown, and boot covers. For patients coming from the ICU, a dedicated transport ventilator is used. To avoid aerosolization, the gas flow is turned off and the endotracheal tube clamped with forceps during switching



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L. K. Ti et al.

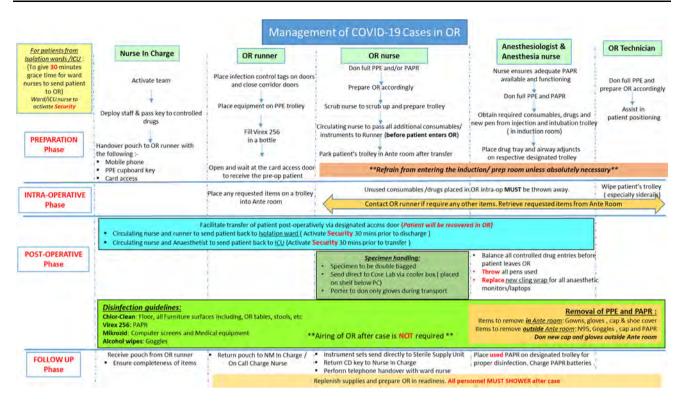


Figure Complete operating room workflow for a coronavirus disease 2019 (COVID-19) case. CD = controlled drugs; ICU = intensive care unit; NM = nurse manager; OR = operating room; PAPR = powered

of ventilators. The ICU personnel wear full PPE with a powered air-purifying respirator (PAPR) for the transfer.

In the induction room, a PAPR is worn during induction and reversal of anesthesia for all personnel within 2 m of the patient. For operative airway procedures such as tracheostomy, all staff keep their PAPR on throughout the procedure. For other procedures, regional anesthesia is preferable, but if general anesthesia is required, the principles of management are similar to those previously published.^{1,4}

During the procedure, a runner is stationed outside the OR if additional drugs or equipment are needed. These are placed onto a trolley that will be left in the ante room for the OR team to retrieve. This same process in reverse is used to send out specimens such as arterial blood gas samples and frozen section specimens. The runner wears PPE when entering the ante room.

Personnel exiting the OR discard their used gowns and gloves in the ante room and perform hand hygiene before leaving the ante room (ESM, eFig. 2). Any PAPR will be removed outside the ante room. Patients who do not require ICU care postoperatively are fully recovered in the OR itself. When the patient is ready for discharge, the route to the isolation ward or ICU is again cleared by security.

A minimum of one hour is planned between cases to allow OR staff to send the patient back to the ward,

air-purifying respirator; PC = personal computer; PPE = personal protection equipment; pre-op = preoperative

conduct through decontamination of all surfaces, screens, keyboard, cables, monitors, and anesthesia machine. All unused items on the drug tray and airway trolley should be assumed to be contaminated and discarded. All staff have to shower before resuming their regular duties. As an added precaution, after confirmed COVID-19 cases, a hydrogen peroxide vaporizer will be used to decontaminate the OR.

In summary, as healthcare workers are at increased risk of coronavirus infection, a comprehensive and robust infection control workflow has been put into place.⁵

Conflicts of interest None.

Funding statement None.

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PROOF OF SERVICE OF DOCUMENT

I am over the age of 18 and not a party to this bankruptcy case or adversary proceeding. My business address is:

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A true and correct copy of the foregoing document entitled (*specify*) **APPENDIX OF LITERATURE AND ARTICLES IN SUPPORT OF TENTH REPORT BY PATIENT CARE OMBUDSMAN, JACOB NATHAN RUBIN, MD, FACC, PURSUANT TO 11 U.S.C. §** 333(b)(2) be served or was served (a) on the judge in chambers in the form and manner required by LBR 5005-2(d); and (b) in the manner stated below:

1. <u>TO BE SERVED BY THE COURT VIA NOTICE OF ELECTRONIC FILING (NEF)</u>: Pursuant to controlling General Orders and LBR, the foregoing document will be served by the court via NEF and hyperlink to the document. On (*date*) June 9, 2020, I checked the CM/ECF docket for this bankruptcy case or adversary proceeding and determined that the following persons are on the Electronic Mail Notice List to receive NEF transmission at the email addresses stated below:

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On June 9, 2020, I served the following persons and/or entities at the last known addresses in this bankruptcy case or adversary proceeding by placing a true and correct copy thereof in a sealed envelope in the United States mail, first class, postage prepaid, and addressed as follows. Listing the judge here constitutes a declaration that mailing to the judge <u>will</u> <u>be completed</u> no later than 24 hours after the document is filed.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

June 9, 2020Jason Klassi/s/ Jason KlassiDatePrinted NameSignature

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