The effects of the COVID-19 pandemic on risk management practice: A report from the epicenter of the epicenter in New York City

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Health care organizations have had to respond to the Coronavirus disease 2019 (COVID-19) pandemic in unprecedented ways. In the United States, where health risk management is an established profession, health care risk managers (HRMs) contributed to the response by supporting organizations and frontline workers. HRMs advised administrative and clinical leadership on decisions and policies aimed at addressing the medico legal, ethical, and operational dilemmas raised by this public health emergency. This article describes these challenges from the perspective of a New York City (NYC) public hospital located in the “epicenter within the epicenter” of the pandemic and aims to provide practical guidance for HRMs on the front lines of this crisis.

INTRODUCTION

New York City Health + Hospitals (NYC H+H) is the largest public health care system in the United States (US). Its mission, to deliver “high-quality health care services to all New Yorkers with compassion, dignity and respect, without exception,” is accomplished through a network of hospitals, outpatient programs, and long-term care facilities. The system’s institutions serve as teaching centers for future physicians, nurses, and other health care personnel through academic affiliations with several leading universities in NYC and beyond. Counted among the NYC H+H network’s 11 hospitals is Elmhurst, a 545-bed, level I trauma and academic medical center located in Queens, the most culturally and economically diverse of the city’s five boroughs.1

By April 1, 2020, the number of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, the virus that causes coronavirus disease 2019 [COVID-19]) positive patients being treated in the NYC H+H system had grown exponentially. NYC H+H/Elmhurst, had the bulk of these patients, more than any of the other facilities in the network. This led New York City Mayor Bill DeBlasio to refer to Elmhurst as the “epicenter within the epicenter” of the pandemic.2

The hospital’s transformation to a COVID-19 receiving and treating facility was rapid and urgent. Concurrent
with this transition was a myriad of medicolegal, ethical, and operational dilemmas, which were presented to our risk management (RM) practice. This article provides a snapshot in time, as the hospital confronted this public health emergency. It describes the many issues we considered, and includes an account of our approach in the context of core risk management principles.

**UNCHARTED TERRITORY: LEGAL AND REGULATORY IMPLICATIONS OF COVID-19**

Soon after the pandemic hit NYC, it became apparent that the resultant surge of patients presenting with COVID-19-related concerns would thrust the clinical staff into situations that would raise their concern about medicolegal liability. As the surge arrived, our department was approached with two issues: (1) the best way to obtain much needed consultations from specialty services when there was limited information about treatment options and (2) how best to ease the high volume of patients arriving on a daily basis.

As noted by the Centers for Disease Control and Prevention (CDC) in its February 2020 guidelines to health care facilities on transmission of the virus in communities, there were few medications available to treat COVID-19 and no vaccines to prevent it. Since there was little evidence or consensus on treatment guidelines at the time, the specialists drew upon their experiences and expertise in their respective fields to develop and recommend the best treatment regimens for this novel coronavirus. Due to the high number of patients requiring consultation, the specialists also had difficulty documenting every consultation in the record. The usual consultation practice would have involved an order by the primary team, an in-person clinical evaluation, and a consultation note. Instead, to decrease the documentation burden on the specialists, and maximize the number of patients receiving consultation, the primary teams recorded the advice and the name of the consultant in the record. To help ease the volume of admitted patients (some of whom were ventilated) who were awaiting beds in the emergency department, the hospital also prioritized the discharge of inpatients who could be sent home or to alternate care sites. This strategy was implemented not only to respond to the surge of patients, but also to reduce the risk of exposure for those without COVID-19 symptoms. The complexity of the situation was aggravated by some admitted patients demanding to be discharged due to fear of contagion, as the media reported that by some admitted patients demanding to be discharged.

As public health officials in the United States became more aware of the spread of COVID-19, both governmental and private agencies began issuing advisories to the health care community on the COVID-19 response. These pronouncements resulted in successive actions at both the federal and state levels that eased administrative requirements for hospitals and relaxed practice restrictions for clinicians. Table 1, provides a timeline of COVID-19 related events.

While the facility was grappling with the surge of patients with COVID-19, one of New York's largest health care advocacy groups, the Greater New York Hospital Association (GNYHA), with more than 160 member hospitals and health care systems in the greater New York area, was lobbying on behalf of its member hospitals and health care organizations in New York State for immunity legislation. GNYHA's advocacy efforts culminated in Executive Order (EO) No. 202.10, signed by Governor Cuomo on March 23, 2020.

Governor Cuomo's EO No. 202.10 provided, among other things, (1) that hospitals were permitted to use all measures to increase bed availability for patients; (2) that most providers, including all physicians, physician assistants, specialist assistants, nurse practitioners, registered nurses, and licensed practical nurses, were granted immunity from civil liability for any injury or death that is a direct result of providing medical services in support of the State's response to the COVID-19 pandemic, unless the injury or death was caused by the gross negligence of the provider; and (3) relieved health care providers of recordkeeping requirements as necessary to perform duties in response to COVID-19. The Governor's EO addressed our physicians' concerns.

The immunity from liability granted by the Governor’s EO became law when the New York State (NYS) legislature added Article 30-D to the State Public Health Law on April 3, 2020. This law broadened immunity to include health care facilities such as hospitals, nursing homes, and other facilities authorized to provide health care services under Article 28 of New York's Public Health Law. The new legislation remains in effect in New York, but was modified by Senate Bill 8835 which limited the scope of the liability protections granted by Article 30-D.

The EO also eliminated the supervisory requirements for nurse anesthetists and physician assistants, and the practice agreement or collaborative relationship requirements for nurse practitioners. This facilitated unencumbered and expanded access to these health care providers for the hospital's COVID-19 response.

In a public health emergency, federal and state declarations are vehicles employed to maximize health care resources. These proclamations have significant impact on a
Table 1: COVID-19 events timeline

| Date        | Event                                                                                                                                                                                                 |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| January 7, 2020 | On the same day that Chinese officials confirmed that a cluster of cases of acute respiratory illness was associated with COVID-19, the Centers for Disease Control and Prevention (CDC) created a COVID-19 Incident Management Structure, the purpose of which was to manage and investigate any cases in the US.  
  
January 21, 2020 | The United States announced its first confirmed case of COVID-19.  
The CDC activated its Emergency Operations Center for coordination of both the domestic and international COVID-19 response efforts.                                                                 |
| January 23, 2020 | The American Hospital Association (AHA) issued a “Quality Advisory” for hospitals and health care systems. The Advisory recommended that hospitals and health care systems implement processes during triage that would allow for immediate identification and isolation of patients at risk for COVID-19.  
  
January 31, 2020 | The US Department of Health & Human Services (HHS) Secretary, issued a press release in which he declared COVID-19 a public health emergency.                                                                 |
| February 29, 2020 | The CDC issued guidelines to health care facilities on how to prepare for transmission of the virus in the community. This guidance “outlines goals and strategies for all US health care facilities to prepare for and respond to community spread of coronavirus disease-2019 (COVID-19).” |
| March 7, 2020   | New York Governor Andrew M. Cuomo signed Executive Order (EO) No. 202 in which the Governor declared “a State disaster emergency for the entire State of New York.”                                                     |
| March 13, 2020  | The White House issued a proclamation declaring a national emergency concerning COVID-19, retroactive to March 1, 2020 stating, “[i]t is incumbent on hospitals and medical facilities throughout the country to assess their preparedness posture and be prepared to surge capacity and capability.” |
| March 23, 2020  | New York Governor Andrew Cuomo signed Executive Order No. 202.10 which modified or suspended laws relevant to COVID-19.                                                                                     |

range of concerns, including expansion of hospital space and reimbursement for clinical services, and will continue to be issued, amended, or withdrawn as the needs of the pandemic evolve. While a full discussion of these declarations is beyond the scope of this article, Table 2, provides links to several organizations that track these administrative and legislative developments. It is incumbent upon the HRM to follow these updates in order to advise hospital leadership and staff about rapidly changing guidelines.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The privacy issues raised by COVID-19, in our experience, included (1) disclosure of protected health information (PHI), (2) privacy of employees who tested positive for SARS-CoV-2, and (3) staff contact with the media.

Most patients affected by COVID-19 arrived at the facility alone, in varying states of capacity. Many were immigrants, some undocumented and fearful of providing contact information for family or friends. Those with family locally could not be accompanied because visitor restrictions had been implemented for infection control reasons. As a result, identification of surrogate decisionmakers became a difficult and time-consuming task for the clinical teams. Relatives or friends who later inquired about loved ones had to be verified to be eligible to receive PHI. In the early days of the pandemic, there was a temporary pause on the performance of autopsies on confirmed or suspected COVID-19 related deaths due to concern about disease transmission. As some families requested autopsies for deceased relatives, the staff was unsure whether the diagnosis of COVID-19 could be disclosed as the reason the autopsies could not be done.

HIPAA has some provisions for disclosure that are in effect at all times, regardless of the declaration of a disaster. These provisions allow patient information to be shared for limited purposes under limited conditions. Included is the treatment exception, whereby a covered entity can disclose PHI, as necessary, to treat the patient. Treatment includes coordination of health care and services by one or more providers, consultation between providers, and referral of patients. The HIPAA privacy rule
| Organization | Description | Link |
|--------------|-------------|------|
| American Health Lawyers Association | Health law information hub and analysis | https://www.americanhealthlaw.org/publications/health-law-hub-current-topics/coronavirus-pandemic |
| American Society for Health Care Risk Management | Tools and resources for the health care risk manager | https://www.ashrm.org/resources-novel-coronavirus-covid-19 |
| Centers for Disease Control and Prevention: Hospital Legal Preparedness Relevant Resources | Legal resources for hospital disaster planning | https://www.cdc.gov/phlp/publications/topic/hospital.html |
| Centers for Disease Control and Prevention: Resources for Clinics and Health Care Facilities | Clinical and operational guidance | https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html |
| Centers for Disease Control and Prevention: Public Health Preparedness Capabilities: Medical Surge | Public health preparedness planning standards | https://www.cdc.gov/cpr/readiness/healthcare/spacestuf.htm |
| Centers for Medicare and Medicaid Services: Current Emergencies/Coronavirus Disease 2019 | CMS guidance (including reimbursement) for clinicians and facilities | https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page |
| ClinicalTrials.gov (Search terms: SARS-CoV-2, 2019-nCoV, and 2019 novel coronavirus) | Repository of federally funded studies | https://www.clinicaltrials.gov/ct2/results?cond=covid-19&Search=Apply&recrs=a&recrs=e&age_v=&gndr=&type=&rslt= |
| Drug Enforcement Administration (US) | Prescribing policies and guidance | https://www.deadiversion.usdoj.gov/coronavirus.html |
| Federation of State Medical Boards | Resource regarding physician licensure in the US | http://www.fsmb.org/advocacy/covid-19/ |
| Greater New York Hospital Association | Topic specific tools and guidance for administrative staff and clinicians | https://www.gnyha.org/topics/#coronavirus |
| Kaiser Family Foundation | Case repository and database of policy actions | https://www.kff.org/coronavirus-covid-19/issue-brief/state-data-and-policy-actions-to-address-coronavirus/ |
| National Council of State Boards of Nursing | Resource regarding nurse licensure in the US | https://www.ncsbn.org/covid-19.htm |
| The Hastings Center | Ethical issues and guidance | https://www.thehastingscenter.org/ethics-resources-on-the-coronavirus/ |
| The Joint Commission | Regulatory updates and resources | https://www.jointcommission.org/en/covid-19/ |
| National Conference of State Legislatures | Database of State legislative action | https://www.ncsl.org/research/health/state-action-on-coronavirus-covid-19.aspx |
has also always recognized the need of health authorities and any other entity responsible for ensuring public health to have access to PHI to carry out their mission, such as disclosures to prevent or lessen a serious and imminent threat. This includes disclosure to a public health authority, such as the CDC, or local, city, or state health departments; a foreign government collaborating with the public health authority; and persons at risk of contracting or spreading a disease. The statute further permits disclosures about the patient’s status or death to family and friends involved in the patient’s care with the patient’s consent, or without, but with inference that the patient would not object, or in emergency circumstances. The permissible purpose for disclosure covers the identification, location, and notification of family and others involved in the patient’s treatment.

On March 15, 2020, the US Department of Health and Human Services (HHS) exercised its authority to waive sanctions and penalties against a covered hospital, of which NYC H+H/Elmhurst is one, where there are violations of HIPAA. These special provisions were instituted strictly for the COVID-19 disaster. Specifically, the waivers applied to 45 CFR 164.510(b), which requires obtaining a patient’s agreement to speak with family members or friends involved in the patient’s care; 45 CFR 164.510(a), which has a requirement to honor a patient request to opt out of the facility directory; 45 CFR 164.520, which requires the hospital to distribute a notice of privacy practices; 45 CFR 164.522(a), which provides for the patient’s right to request privacy restrictions; and 45 CFR 164.522(b), the patient’s right to request confidential communications. Of note, the waiver only applies to hospitals, in the emergency area identified in the public health declaration, that have instituted a disaster protocol and for up to 72 hours of implementation of the hospital disaster protocol.

Applying the standard HIPAA provisions and waiver from HHS, the staff was able to identify persons with whom the medical teams could communicate about patients. The teams were advised to ensure that the identity of the person to whom the PHI was released, was verified and recorded, and the nature of the relationship documented in the chart. Where possible, identification documents were scanned into the electronic record.

A second scenario involved the disclosure of a staff member’s positive test result to the employee’s supervisor for timesheet coding. Federal Law, the Families First Coronavirus Response Act (FFCRA) and the New York State COVID-19 Sick Leave Law were both enacted on March 18, 2020 requiring covered employers to provide paid sick leave related to the coronavirus. This paid leave was separate from an employee’s accrued sick leave.

To address employees’ privacy concerns, guidance to reinforce the protection of patient and employee privacy during the COVID-19 emergency was released by the health care system. The guidelines advised that disclosures about an employee’s COVID-19 status, whether as a patient of NYC H+H or not, must be kept to a minimum. Consistent with worker protection laws, managers, supervisors, and department heads were not permitted to disclose the test results to other employees.

Third, there was intense curiosity about the conditions at the hospital due to the pandemic. Some staff, in the interest of advocating for additional resources, took to social media and granted interviews with print and television outlets. This coverage will be forever etched in the public’s collective memory as the first scenes of COVID-19 in NYC. As the pandemic advanced, the interest extended to memorializing staff lost to COVID-19, and to commemorating their service. In general, disclosures to the media or those with no involvement in the care of the patient may not occur without authorization. While staff were not restricted from interacting with the press, the corporation emphasized the HIPAA privacy provisions with respect to photographs or videos of patients. In the case of deceased employees, no disclosures were made without permission from family or personal representatives.

Scale-up of health care capacity

In a public health emergency, health facilities are required to rapidly transform to meet demands on infrastructure and operations imposed by the rising tide of patients. In 2005, the Agency for Health care Research and Quality (AHRQ) prepared AHRQ Publication No. 05–0043 entitled Altered Standards of Care in Mass Casualty Events. This report was prompted by the events of September 11, 2001 and was a summary of findings gleaned from discussions by a panel of experts on the provision of health and medical care in a mass casualty event. The report included recommendations for planning the appropriate actions that might be taken to provide an effective response. The two mass casualty scenarios developed by the panel were (1) the simultaneous detonation of a series of dirty bombs and (2) the release of a highly-lethal and communicable biological agent with an unknown incubation period into a densely populated area. In this scenario, diagnosis was dependent upon lab tests; the use of personal protective equipment was required by medical staff; management strategies included patient isolation and the use of ventilators, but the effect of the treatment was unknown. This second scenario had an uncanny resemblance to the COVID-19 pandemic. Many of the changes in delivery of care that would take place during a mass casualty scenario were precisely the changes faced by NYC H+H/Elmhurst and hospitals throughout New York City.

In the context of COVID-19, adaptations included cancelation of elective procedures; accelerated discharge planning; and expansion of bed and surge capacity through repurposing of nontraditional spaces into medical and intensive care units; expansion of telemedicine.
Telemedicine and state licensure

During the COVID-19 pandemic, telemedicine has served to ensure continued access to care while decreasing risk of infection through reduced in-person visits. The two main financial and risk management-related barriers around implementation of telehealth services are concentrated around reimbursement policies which specify geographic and technology qualifications, and limitations imposed by state licensing laws.32

On March 6, 2020, the Centers for Medicare and Medicaid Services relaxed its reimbursement requirements in response to the COVID-19 crisis.28 The revised rules eliminated the physical location restrictions for patients and providers, and widened the list of telecommunication applications that could be used to deliver telemedicine, including non-HIPAA compliant modalities. The list of health care practitioners eligible for telehealth reimbursement was also expanded. In response, states acted to accommodate the need for expanded telehealth services during the public health emergency.29

Some states also issued waivers of state licensing laws, allowing providers the ability to practice telemedicine in states where they are unlicensed, provided they are actively licensed elsewhere in the country. Prior to these changes, providers could only engage in telemedicine with patients in states where they held licensure. There is wide variation in these state waivers, and it is prudent to advise clinicians to check local regulations to avoid being charged with a violation of state practice laws. The Federation of State Medical Boards and National Council of State Boards of Nursing have issued a compilation of state actions related to licensure waivers.30,31

The state waivers differ from the Interstate Medical Licensure Compact for physicians and the Nurse Licensure Compact for registered nurses and licensed practical nurses.32,33 These compacts predate COVID-19, and provide a pathway to streamline health professional licensing across state lines. There is movement for a similar Advanced Practice Registered Nurse (APRNs) compact, but this has not been implemented.34 The state waivers are also distinct from the Emergency Management Assistance Compact, which only applies to state actors, and the Uniform Emergency Volunteer Health Practitioners Act, which has advance registration requirements.35

In addition to the state waivers for practice, HRMs need to remind health care providers about local requirements regarding prescriptive authority, and the Drug Enforcement Agency (DEA) regulation of controlled substance prescriptions which requires separate registration.36 Lastly, HRMs need to be aware of the state-to-state variation in disclosure and informed consent requirements for telehealth.37

CLINICAL AND PATIENT SAFETY ISSUES

Changes in occurrence reporting and consulting service volume

The Risk Management department receives and reviews occurrence reports submitted by hospital staff. Each occurrence is tracked in a database to log the departmental workflow associated with the event; its organization is based on the reportable event criteria from the New York Patient Occurrence Reporting and Tracking System (NYPORTS),38 and the hospital’s occurrence report policy.

Compared to March and April 2019, we observed a 51% decrease in the number of occurrences reported to our office during the same period in 2020, at the height of the COVID-19 emergency. The reduction in formal reporting through the occurrence tracking system paralleled the activity of the department’s risk management consultation service. From March to April 2020, we saw a decrease in the number of calls to our risk management consultation practice, which declined by 62% compared to the same time period in 2019. As the volume of patients with COVID-19 increased, however, the department saw an equivalent rise in the concentration of COVID-19-related consultations. Since many of the hospital’s clinical services had effectively ceased all activity but for COVID-19-related care, this was predictable. The complexity of these consultations is reflected in other sections of this article and cannot be overstated. Each consultation required careful consideration and collaboration with other hospital departments, especially Ethics, Palliative Care, and Human Resources, and when indicated, the health system’s corporate counsel.

Separate from NYPORTS, the New York State Office of Mental Health (OMH) requires all OMH-licensed
facilities to report the death of a patient receiving services from its programs. In March and April 2020, occurrences submitted included COVID-19-related deaths occurring in the community among patients enrolled in outpatient behavioral health programs. This was likely a manifestation of community spread in the hospital’s catchment area and socioeconomic vulnerabilities associated with this population.

Advance directives and ethical concerns

Under normal circumstances, one of the most stressful conversations for patients, families and providers is the discussion of end-of-life preferences. In the context of COVID-19, the challenges around these conversations were made more complex by several factors: (1) many patients had not expressed their preferences in advance and lacked capacity to do so upon arrival, (2) the rapidity of decline to multisystem organ failure left little opportunity for loved ones to be prepared, and (3) the risk of infection precluded conversations with health care surrogates from taking place in person, and instead occurred via video conference or telephone. Treatment decisions by health care proxies or surrogates were further complicated by relatives living overseas or in different states, often across several time zones. There was a sense of urgency to these conversations that was unmatched, as the volume of patients grew, and the demands on clinical care stretched providers’ ability to engage in conversations about advanced directives. In response, the hospital’s palliative care and ethics teams rose to support their colleagues and facilitate many of these discussions. The teams reassured families that the best possible care was being given to their loved ones, while providing evidence when indicated, of the unlikely prospect of recovery. All of these discussions were guided by the principles of patient-centered care.

An interdisciplinary team including the hospital’s Associate Executive Director of Risk Management, who holds a certificate in bioethics, and members of the hospital’s ethics committee met several times daily to clarify and simplify the hospital’s resuscitation and withdrawal of care policies. A policy requiring paper forms to memorialize conversations around these decisions was eliminated as unnecessary since electronic documentation of the conversation and decision in the medical record was sufficient. The committee recommended conversational guidelines for approaching patients and family members on advanced directives, to ensure patient rights were respected. As is the usual practice, a concerted effort was made to approach patients and families on arrival at the hospital to confirm their advanced directives and to insure compliance with the New York State Family Health Care Decisions Act when patients had no health care proxy. Health care decisions for incapacitated patients without advance directives (“the unbefriended”) for whom no surrogate decisionmaker could be found, received thorough review by the ethics committee with input from senior attending physicians and the clinical teams.

As the supply of ventilators became a focus of media coverage, there were reports concerning the ways in which other facilities rationed healthcare resources. In a public health emergency, it would be irresponsible not to have these discussions. At NYC H+H/Elmhurst, those conversations never moved beyond the theoretical, as staff and equipment reinforcements arrived before demand exceeded capacity. Recognizing that the allocation of health care resources is a daily reality for providers who work in resource-limited settings, it is difficult to imagine what the situation would have been like had that point been reached. There are several excellent resources for HRMs who might have to confront these questions. These include the Hastings Center and an article in the New England Journal of Medicine specifically addressing the allocation of health care resources in the context of COVID-19.

The facility recognized that it was equally important for the involved teams to receive support as they wrestled with difficult circumstances. To this end, the Corporation scaled-up its “second victim” health care provider employee wellness program called Helping Healers Heal (H3). At the very beginning of the crisis, the hospital also created a COVID-19 staff support room where members of the H3 team assisted employees dealing with the mental toll in caring for so many sick and dying patients. Additionally, a helpline was created for staff to seek other types of help or mental health counselling.

Informed consent

Typically, procedural consent is obtained following an informed consent discussion with a patient. Consent is then memorialized by the patient’s witnessed signature on a consent document. Although an electronic medical record system is available, a hard copy form was used to capture procedural consent. For infection prevention reasons, it was essential that the use of paper informed consent forms during the COVID-19 period was evaluated. After a review, the process was revised to recommend that during the pandemic, verbal consent was sufficient, and should be noted on the form, together with the reason for the patient’s inability to sign the document. Additionally, due to visitor restrictions, telephone consent was often sought from the proxy or health care decision surrogate for those patients without capacity. Staff was instructed to document the details of the informed consent discussion in the chart including witnesses to the conversation. The hospital policy on emergency situations permitting the clinician to proceed without consent was also reemphasized to all staff, together with the need to document clearly in the electronic medical record the emergency circumstances or rationale for proceeding in the best interest of the patient. Of note, during the pandemic, most consent discussions took place with surrogates or proxies over the telephone or facetime.
A related topic to informed consent that required consideration was the use of waivers of liability for transmission of COVID-19. While the use of liability waivers in recreational facilities and other businesses is common practice, the necessity, enforceability and ethics of using such waivers in the health care context are questionable. First, the risk of SARS-CoV-2 transmission in health care facilities is likely lower than in the community at large because patients are in contained units, and strict infection control measures are in place. Second, whether these waivers are enforceable in the context of COVID-19 has never been tested. Generally, enforceability for these liability waivers has varied by state, with some states more permissible than others. Lastly, the ethical use of such a waiver when applied to health care is suspect. It is not evident that patients who need medical procedures can bargain away their risk of an adverse event in a contract. Thus, it seems that a liability waiver is superfluous. Additionally, as the number of patients deferring necessary treatment due to COVID-19 is on the rise, a liability waiver may lead to a decision to postpone care which can result in unfavorable patient outcomes.

Instead of using a COVID-19 liability waiver, clinicians were advised to apply informed consent principles, wherein the risk of transmission of SARS-CoV-2 would be discussed as a component of the informed consent process, when relevant, taking into consideration risk of transmission specific to the procedure being undertaken and patient factors. This is a more prudent approach, in that the patient makes an informed choice based on their particular situation.

**Unauthorized departure of SARS-CoV-2 positive patients**

Pursuant to Section 11.03 of the NYC Health Code, hospitals are required to report to the State Department of Health (DOH) all positive cases of novel coronavirus. The health code Section 11.17(a) also requires hospitals to isolate these patients during evaluation and while admitted. In theory, a situation could arise involving a SARS-CoV-2 positive patient who requests to leave against medical advice (AMA). Under normal circumstances, absent concerns about capacity, a patient who requests AMA discharge may leave a facility after an informed discussion of the risks of leaving AMA and a reasonable attempt to arrange for outpatient care.

In the context of COVID-19, the New York State Department of Health (NYSDOH), could serve a hospital with an order requiring the facility to keep a patient hospitalized. In accordance with Section 11.23, a patient could be held at the hospital until medically appropriate for discharge release, and then be required to further self-isolate. The patient has a right to appeal such an order. It is unclear how many isolation orders were issued by the NYSDOH but similar retention orders are routinely served in tuberculosis cases.

**LEGAL MATTERS**

**Treatment over objection and other court petitions**

Once Governor Cuomo placed “New York on PAUSE,” the court system ground to a halt, with only “essential” and emergency matters allowed to proceed. The Risk Management Department at NYC H+H/Elmhurst oversees emergency applications requiring court assistance, so it was important that these petitions, including for medication over objection, discharge from involuntary admissions, and for assisted outpatient treatment, could be submitted. The applications were accepted electronically. However, the hearings on the petitions were initially delayed.

On April 13, 2020, the Chief Judge of the state of New York, Judge DiFiore announced an expansion of the virtual court process to address nonemergent matters. She indicated that judges could conduct court conferences by video and telephone to resolve outstanding issues, move cases forward, and entertain settlement negotiations. The judiciary was tasked with addressing all outstanding motions on their docket, without oral argument. The court directive requires these conferences to be administered exclusively through Skype for Business. NYC H+H/Elmhurst has always had the ability to hold remote arraignments for any patient brought for treatment under police custody, so it was uniquely positioned to transition to virtual-only hearings. Once the court expanded its own capabilities, virtual hearings commenced from the hospital on pending applications. Clinicians and patients were located at the hospital for the hearing, but counsel appeared remotely. After the hearings, an order was promptly issued by the Court, and the signed final order was sent by electronic mail to the corporation’s counsel and certification office.

These are unprecedented times for the legal system. To illustrate how much COVID-19 has impacted New York court proceedings, virtual technology was also approved to install new attorneys, who had passed the state bar exam, as members of the state bar. Discussions are ongoing for recent law graduates to engage in limited law practice until they can sit for the bar.

**Claims and litigation**

The malpractice fallout from COVID-19 remains to be seen, although it is reasonable to predict that there will be an increase in claims filed. A recent article by Ann W. Latner, JD suggests that four types of lawsuits can be anticipated: (1) treatment-related claims regarding clinical decisions, (2) claims related to the postponement of nonessential care or procedures, (3) class action or
individual lawsuits from front line workers or their families around PPE availability, or other failure to protect health care workers, and (4) for violations of HIPAA. In New York, while Courts have yet to interpret the application of the liability protections discussed above, we believe the immunity from liability in the temporary state law, PHL 30-D, Section 3082 will be protective, absent gross negligence. And, proving gross negligence in medical practice is a very high bar to overcome.

**Letters testamentary and letters of administration**

An unanticipated consequence presented by COVID-19 was the amount of deceased patient property that accumulated quickly. Since visitors were not permitted to come to the hospital to collect belongings, the Department was consulted on managing the return of this property to family by mail. Deceased patient property is routinely released to someone presenting letters testamentary or letters of administration. Given the court closures, most family members could not obtain such letters. It was recommended to the property office that the information in the medical record could be relied upon to locate and contact next of kin who would be asked to provide identification and proof of relationship. For example, a sister of the decedent could show her sibling’s birth certificate as well as her birth certificate listing at least one parent in common; or a significant other can show proof of the partnership, like a joint bank account or lease.

For those situations where next of kin could not document the relationship, a decedent’s personal property release form was drafted to permit and document the release to an appropriate person. The intention was for the property to be sent to an individual who would be an estate distributee under the New York Estates, Powers, and Trusts Law. The following information was requested: statement of presence or absence of a personal representative (pursuant to Letters of Administration), statement permitting release of personal effects, contact details of the recipient, decedent’s information, relationship to the affiant, and signature of the person completing the form.

**Donations**

The local community has assisted the hospital throughout this crisis with letters of encouragement, hand-made cards from schoolchildren, an artists’ fundraiser that benefitted the hospital auxiliary, and even a giant “thank you” tied to a park fence across from the hospital entrance. This outpouring of support has carried the staff through these extraordinary times.

Shortly after the facility began treating patients with COVID-19, many offers for donated face masks were received. While some donors eagerly brought what they had to the hospital, curiously, a certain number of these donations came with a request for written waivers of liability. The waivers were unnecessary and not thought to be legally binding. A process was implemented by the administration to manage all donations without waivers.

**CONCLUSION**

Navigating risk management issues during a public health emergency can be a daunting task for any health care risk manager. During a pandemic, amendments to laws and regulations will be made by federal and state agencies to facilitate operational flexibility so that the monumental demands of the emergency can be met. Simplified, practical guidance, in the interpretation of the range of legal, regulatory, operational, and clinical challenges is required from HRMs. This is crucial for seamless implementation of all health care activities during a public health emergency. Our experience reinforced our belief that HRMs are integral in guiding the facility and clinical response during public health emergencies. HRMs play a crucial role in understanding rapidly changing regulations, and in communicating their implications to hospital leadership and clinicians alike.

**ACKNOWLEDGMENT**

We thank David M. Walker, MD, FAAP, FACEP, Joseph L. Halbach, MD, MPH, and Susan Goldberg RN, BSN, MPA, for their support and valuable feedback.

**REFERENCES**

1. New York State. Queens. https://www.ny.gov/counties/queens. Accessed December 8, 2020.

2. Vick R. The scene outside Elmhurst Hospital, epicenter of the Covid crisis. The Queens Daily Eagle. March 30, 2020. https://queenseagle.com/all/the-scene-outside-elmhurst-hospital-epicenter-of-the-covid-19-crisis?q=Elmhurst%20hospital. Accessed March 30, 2020.

3. Healthcare Facilities: Preparing for community transmission. Centers for Disease Control and Prevention Website. https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-hcf.html. Accessed April 19, 2020.

4. Patel A, Jernigan DB. Initial public health response and interim clinical guidance for the 2019 Novel Coronavirus outbreak — United States, December 31, 2019–February 4, 2020. MMWR Morb Mortal Wkly Rep 2020; 69:140–146.

5. Bryant JL, Sosin DM, Wiedrich TW, Redd SC. Emergency operations centers and incident
management structure. In: Rasmussen SA, Goodman RA, eds. The CDC Field Epidemiology Manual. New York: Oxford University Press; 2019.

6. Centers for Disease Control and Prevention. Press Release: First travel-related case of 2019 Novel Coronavirus detected in United States. Centers for Disease Control and Prevention Website. https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html. Accessed May 19, 2020.

7. American Hospital Association. Quality Advisory: Update and resources on Novel Coronavirus (2019-nCoV) for U.S. hospitals. American Hospital Association website. https://www.aha.org/advisory/2020-01-23-quality-advisory-update-and-resources-novel-coronavirus-2019-ncov-us-hospitals. Accessed April 17, 2020.

8. U.S. Department of Health & Human Services. Public Health Actions: Determination that a public health emergency exists. U.S. Department of Health & Human Services website. https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx. Accessed April 19, 2020.

9. Centers for Disease Control and Prevention. Coronavirus Disease 2019 (COVID-19): Healthcare Facilities: Preparing for community transmission-summary of recent changes. Centers for Disease Control and Prevention Website. https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-hcf.html. Accessed April 19, 2020.

10. New York State. Executive Order: New York State Governor’s Executive Order No. 202. Declaring a Disaster Emergency in the State of New York. https://www.governor.ny.gov/news/no-202-declaring-disaster-emergency-state-new-york. Accessed April 19, 2020.

11. White House.gov. White House Proclamations: Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. White House website. https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/. Accessed April 19, 2020.

12. New York State. Executive Order: New York State Governor’s Executive Order No. 202.10. Continuing Temporary Suspension and Modification of Laws Relating to the Disaster Emergency. New York State Governor’s website. https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency. Accessed April 19, 2020.

13. Overley J. Interview: Coronavirus q&a: greater NY Hospital Association’s GC. Law 360. https://www.law360.com/health/articles/1268818/coronavirus-q-a-greater-ny-hospital-association-s-gc?nl_pk=cc949814-bd84-4f3b-b508-dd65ac4699b2"utm_source=newsletter"utm_medium=email"utm_campaign=health. Accessed May 14, 2020.

14. N.Y. PHL §3080-D. https://www.nysenate.gov/legislation/laws/PBH/A30-D. Accessed June 12, 2020.

15. N.Y. PHL Article 28. https://www.nysenate.gov/legislation/laws/PBH/A28. Accessed June 12, 2020.

16. 45 CFR 164.502(a)(1)(ii).

17. 45 CFR 164.506(c).

18. 45 CFR §164.501.

19. 45 CFR §164.512(b)(1)(i).

20. 45 CFR §164.512(b)(1)(iv).

21. 45 CFR §164.510(b).

22. United States Department of Health and Human Services. Bulletin: Limited waiver of HIPAA sanctions and penalties during a nationwide public health emergency. Health and Human Services website. https://www.hhs.gov/sites/default/files/hipaa-and-covid-19-limited-hipaa-waiver-bulletin-508.pdf. Accessed May 9, 2020.

23. Congress.gov. H.R. 6201 Families First Coronavirus Response Act. N.Y. Congress’ website. https://www.congress.gov/bill/116th-congress/house-bill/6201/text. Accessed June 10, 2020.

24. New York State. The Governor of N.Y. New York’s COVID-19 sick leave law. The Governor of N.Y.’s website. https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/GPB_9_PAID_SICK_LEAVE_BILL.pdf. Accessed June 10, 2020.

25. 45 CFR §164.508.

26. AHRQ. Altered Standards of Care in Mass Casualty Events. Publication No. 05–0043. Rockville, MD. April 2005. Accessed May 15, 2020.

27. Lee NT, Karsten J, Roberts J. Removing regulatory barriers to telehealth before and after COVID-19. Brookings John Locke Foundation Published May 6, 2020. https://www.brookings.edu/research/removing-regulatory-barriers-to-telehealth-before-and-after-covid-19/. Accessed May 9, 2020.
28. Centers for Medicare and Medicaid Services. Medicare telemedicine healthcare provider fact sheet. https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet. Accessed May 9, 2020.

29. Center for Connected Health Policy. COVID-19 related state actions. Published May 13, 2020. https://www.cchpca.org/resources/covid-19-related-state-actions. Accessed May 15, 2020.

30. Federation of State Medical Boards. U.S. states and territories modifying licensure requirements for physicians in response to COVID-19 (Out-of-state physicians in-person practice; license renewals). Federation of State Medical Boards website. https://www.fsmb.org/siteassets/advocacy/pdf/state-emergency-declarations-licensure-requirementscovid-19.pdf. Accessed May 15, 2020.

31. National Council of State Boards of Nursing. State response to COVID-19. National Council of State Boards of Nursing website. https://www.ncsbn.org/State_COVID-19_Response.pdf. Accessed May 15, 2020.

32. Interstate Medical Licensure Compact. Website. https://www.imlcc.org/. Accessed May 15, 2020.

33. Nurse Licensure Compact. Website. https://www.ncsbn.org/nurse-licensure-compact.htm. Accessed May 15, 2020.

34. National Council of State Boards of Nursing. Advanced Practice Registered Nurse Licensure Compact. National Council of State Boards of Nursing website. https://www.ncsbn.org/aprn-compact.htm. Accessed May 15, 2020.

35. American Medical Association. Sustainability. Liability protections for health care professionals during COVID-19. American Medical Association website. https://www.ama-assn.org/practice-management/sustainability/liability-protections-health-care-professionals-during-covid-19. Accessed May 15, 2020.

36. Drug Enforcement Administration. DEA’s response to COVID-19. DEA Website. https://www.dea.gov/press-releases/2020/03/20/deas-response-covid-19. Accessed May 12, 2020.

37. Center for Connected Health Policy. National policy. Informed consent. COVID-19. Center for Connected Health Policy website.

38. New York State. The New York Patient Occurrence Reporting and Tracking System (NYPORTS) website. https://www.health.ny.gov/facilities/hospital/nyports/. Accessed May 12, 2020.

39. Goldstein J, Rothfeld M, Weiser B. Patient has virus and serious cancer. Should doctors withhold ventilator? New York Times. April 1, 2020. https://www.nytimes.com/2020/04/01/us/coronavirus-doctors-patients.html. Accessed May 5, 2020.

40. Baker, M, Fink S. At the top of the Covid-19 curve, how do hospitals decide who gets treatment? New York Times. March 31, 2020. https://www.nytimes.com/2020/03/31/us/coronavirus-covid-triage-rationing-ventilators.html. Accessed May 5, 2020.

41. Park, A, Kluger J. The Coronavirus Pandemic Is Forcing U.S. doctors to ration care for all patients. Time. April 22, 2020. https://time.com/5825145/coronavirus-rationing-health-care/. Accessed May 5, 2020.

42. Luna T. California sets guidelines on which patients are prioritized if hospitals overwhelmed by Coronavirus. Los Angeles Times. April 21, 2020. https://www.latimes.com/california/story/2020-04-21/california-healthcare-guidelines-shorthages-coronavirus-treatment. Accessed May 5, 2020.

43. Berlinger N, Wynia M, Powell T, et al. Ethical framework for health care institutions responding to Novel Coronavirus SARS-CoV-2 (COVID-19). Guidelines for Institutional Ethics Services responding to COVID-19. Managing uncertainty, safeguarding communities, guiding practice. The Hastings Center website. https://www.thehastingscenter.org/ethicalframeworkcovid19/. Accessed May 11, 2020.

44. Emanuel JE, Persad G, Upshur R, et al. Fair allocation of scarce medical resources in the time of Covid-19. N Engl J Med 2020; 382 (21): 2049–2055. https://doi.org/10.1056/NEJMsb2005114. https://www.nejm.org/doi/full/10.1056/NEJMsb2005114?query=featured_coronavirus. Accessed May 11, 2020.

45. Wei, E, Segall J, Villanueva Y, et al. Coping with trauma, celebrating life: reinventing patient and staff support during the COVID-19 pandemic. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.0929. Accessed November 4, 2020.
46. Carpenter SA, Hall III CW, Hardee KA. Reopening the economy and getting back to business: will liability waivers protect my business? The National Law Review. May 12, 2020. https://www.natlawreview.com/article/reopening-economy-and-getting-back-to-business-will-liability-waivers-protect-my. Accessed May 15, 2020.

47. Bernstein L, Sellers FS. Patients with heart attacks, strokes and even appendicitis vanish from hospitals. The Washington Post. April 19, 2020. https://www.washingtonpost.com/health/patients-with-heart-attacks-strokes-and-even-appendicitis-vanish-from-hospitals/2020/04/19/9ca3ef24-7eb4-11ea-9040-6898f488eed_story.html. Accessed April 20, 2020.

48. Hamel L, Kearney A, Kirzinger A, Munana C, Brodie M. KFF health tracking poll-May 2020. https://www.kff.org/report-section/kff-health-tracking-poll-may-2020-health-and-economic-impacts/. Accessed June 9, 2020.

49. New York State. New York City Health Code Article 11, §11.03. Reportable Diseases and Conditions. https://www1.nyc.gov/assets/doh/downloads/pdf/about/healthcode/health-code-article11.pdf Accessed May 28, 2020.

50. New York State. New York City Health Code Article 11, §11.17(a). Reportable Diseases and Conditions. https://www1.nyc.gov/assets/doh/downloads/pdf/about/healthcode/health-code-article11.pdf Accessed May 28, 2020.

51. The New York State Senate. New York Public Health Law Article 28, § 2803-C. Rights of patients in certain medical facilities. https://www.nysenate.gov/legislation/laws/PBH/2803-C. Accessed June 9, 2020.

52. NYC.gov. New York City Health Code Article 11, §11.23. Reportable Diseases and Conditions. https://www1.nyc.gov/assets/doh/downloads/pdf/about/healthcode/health-code-article11.pdf

53. New York State. New York State Office of the Governor. Governor signs the ‘New York State on PAUSE’ executive order. https://www.governor.ny.gov/news/governor-cuomo-signs-new-york-state-pause-executive-order. Accessed April 27, 2020.

54. DiFiore J. Message from Chief Judge DiFiore. nycourts.gov. https://www.nycourts.gov/whatsnew/pdf/Message-ChiefJudge-4620ver6.pdf. Accessed April 27, 2020.

55. Seyfarth Shaw LLP. COVID-19: New York courts go virtual. https://www.seyfarth.com/news-insights/covid-19-new-york-courts-go-virtual.html. Accessed April 27, 2020.

56. Latner AW. Lawsuits in the time of COVID-19: An overview. MPR. https://www.empr.com/home/features/lawsuits-in-the-time-of-covid-19-an-overview-healthcare-worker-protections/. Accessed May 12, 2020.

57. The New York State Senate. New York Public Health Law Article 30-D, § 3082. Limitation of liability. https://www.nysenate.gov/legislation/laws/PBH/3082. Accessed June 9, 2020.

58. The New York State Senate. New York Consolidated Laws, Estates, Powers & Trusts Law - § EPT/A7P1. https://www.nysenate.gov/legislation/laws/EPT/A7P1. Accessed May 15, 2020.

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DOI:10.1002/jhrm.21461