

# Inpatient Telehealth Tools to Enhance Communication and Decrease Personal Protective Equipment Consumption during Disaster Situations: A Case Study during the COVID-19 Pandemic

Shawn Y. Ong<sup>1</sup> Lisa Stump<sup>2</sup> Matthew Zawalich<sup>2</sup> Lisa Edwards<sup>2</sup> Glynn Stanton<sup>2</sup>  
Michael Matthews<sup>2</sup> Allen L. Hsiao<sup>1,2</sup>

<sup>1</sup> Department of Emergency Medicine, Yale School of Medicine, New Haven, Connecticut, United States

<sup>2</sup> Information Technology Services, Yale New Haven Health System, New Haven, Connecticut, United States

**Address for correspondence** Allen L. Hsiao, MD, Information Technology Services, Yale New Haven Health System, 789 Howard Avenue, New Haven, CT 06510, United States (e-mail: allen.hsiao@yhhh.org).

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## Abstract

**Background** As the coronavirus disease 2019 pandemic exerts unprecedented stress on hospitals, health care systems have quickly deployed innovative technology solutions to decrease personal protective equipment (PPE) use and augment patient care capabilities. Telehealth technology use is established in the ambulatory setting, but not yet widely deployed at scale for inpatient care.

**Objectives** This article presents and describes our experience with evaluating and implementing inpatient telehealth technologies in a large health care system with the goals of reducing use of PPE while enhancing communication for health care workers and patients.

**Methods** We discovered use cases for inpatient telehealth revealed as a result of an immense patient surge requiring large volumes of PPE. In response, we assessed various consumer products to address the use cases for our health system.

**Results** We identified 13 use cases and eight device options. During device setup and implementation, challenges and solutions were identified in five areas: security/privacy, device availability and setup, device functionality, physical setup, and workflow and device usage. This enabled deployment of more than 1,800 devices for inpatient telehealth across seven hospitals with positive feedback from health care staff.

**Conclusion** Large-scale setup and distribution of consumer devices is feasible for inpatient telehealth use cases. Our experience highlights operational barriers and potential solutions for health systems looking to preserve PPE and enhance vital communication.

## Keywords

- ▶ video devices
- ▶ communication
- ▶ coronavirus
- ▶ telemedicine
- ▶ telehealth

## Background and Significance

As of August 2020, more than 21 million people worldwide have confirmed infection with the novel coronavirus SARS CoV-2,<sup>1,2</sup> which causes coronavirus disease 2019 (COVID-19). The United States alone had over 5.3 million confirmed cases with more than 170,000 deaths.<sup>1,2</sup> The COVID-19 pandemic has funda-

mentally altered the current practice of medicine to deal with the massive surge of patients, particularly in the hospital and emergency department settings.<sup>3</sup>

Strict isolation precautions of COVID-19-infected or suspected patients within the hospital has resulted in unprecedented hardships such as placing severe restrictions on patient

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visitors, drastically escalating the need for personal protective equipment (PPE) by front-line health care workers, and challenging communication barriers for both patients and health care staff. The sharp rise in numbers of patients requiring enhanced PPE usage (gowns, gloves, particulate filtering face-piece respirators, and face shields) has led to a worldwide shortage,<sup>4</sup> resulting in actions at state, local, and even individual levels to either preserve or obtain more supplies.<sup>5,6</sup> The heightened measures also hamper multiple communication channels including between health care workers, patients, and health care staff, and patients and their families. Visitor restrictions due to isolation precautions often mean patients battle their illnesses without family or visitor support in difficult times such as end-of-life situations.

In response to these extraordinary changes, recommendations and guidance were published for leveraging creative technology solutions to address communication and PPE challenges.<sup>7-11</sup> Various medical specialties took notice and increased utilization of inpatient telemedicine for consultations such as palliative care, orthopedic surgery, urology, and dermatology.<sup>12-15</sup> One recent study used video systems, mobile devices, and digital stethoscopes to reduce both PPE use and exposure of health care workers in the intensive care unit (ICU).<sup>16</sup> These actions are in line with the Centers for Disease Control and Prevention's recommendation that hospitals develop protocols to manage patients with COVID-19 using telehealth or telemedicine methods as part of a comprehensive preparedness checklist.<sup>17</sup>

Despite these efforts, much is unknown about the utilization of existing technology capabilities and the details of implementing digital solutions at scale in hospitals during a short time period for disaster responses such as COVID-19. At Yale New Haven Health System (YNHHS), an integrated delivery network, the PPE inventory was quickly depleted due to usage for the increased number of patients requiring contact and airborne isolation precautions. To help meet the shortage of PPE and high volume of patients, we deployed various devices and technologies for audio, video, and text correspondence to address communication challenges and reduce PPE usage. Here we report the technical details, challenges, and lessons learned while implementing those different technologies in a large integrated health care system.

## Objective

We present and describe our methods in evaluating various consumer products to rapidly meet the needs providing high-level care and reducing PPE use during a disaster situation. We discuss our approach to addressing implementation barriers to inform other health systems, as they consider similar options.

## Methods

### Case Description

YNHHS consists of five delivery networks in seven hospital locations across Connecticut and Rhode Island. YNHHS has more than 26,000 employees with 6,685 medical staff. As of

August 2020, YNHHS had hospitalized 4,247 COVID-19 patients, of which 707 were treated in the ICU and 521 required intubation and mechanical ventilation at some point in their hospitalization. A total of 3,662 patients were discharged and there were 585 deaths. With an overall average length of stay (LOS) of 10.8 days, 17.0 days if admitted to the ICU, the isolation precautions, workflow, and PPE burdens were significant. At the peak of COVID-19 for YNHHS on April 21, 2020, there were 786 COVID-19-positive patients hospitalized and several under investigation. During the course of treatment for these patients, clinical workflow challenges amenable to technological solutions were revealed, which we termed use cases, and are detailed in [Table 1](#).

Use cases were presented by front-line clinicians to a governance structure created in response to COVID-19 called System Incident Management (SIM). SIM was an unprecedented formation of centralized leadership from the areas of Infection Prevention, Occupational Health, Inpatient Units, Ambulatory Units, Yale School of Medicine, Telehealth, Information Technology Services (ITS), Finance, Human Resources, Supply Chain, Facilities, Call Center, Operations, and Public Information. Use cases spanned all hospital locations, including temporary facilities and repurposed areas, and were prioritized by SIM meeting daily during the pandemic. The increased volume and longer LOS for patients intensified some existing use cases that previously occurred at a lower frequency and exposed new use cases that arose from disaster response operations.

### Technology Options and Assessment

A coordinated strategy between clinicians, ITS, and the Office of Information Security (OIS) led to the evaluation of various health care and consumer electronics to address the needs that quickly arose during the disaster response ([Table 2](#)). Even before COVID-19, an OIS review of mobile device platforms found the iOS software from Apple (Cupertino, California, United States) to be more secure and less vulnerable to exploits. iOS devices thus were the preferred platform for YNHHS and iPhones for secure messaging using the Mobile Heartbeat application (Waltham, Massachusetts, United States). iPads also have the ability to run FaceTime and Zoom, both of which fall under the Health Insurance Portability and Accountability Act (HIPAA) rules related to the good faith provision of telehealth during the COVID-19 nationwide public health emergency.<sup>18</sup> Amazon (Seattle, Washington, United States) devices were chosen because of their availability, features, and competitive pricing. Products from Google (Mountain View, California, United States) were considered but thought to likely have lower privacy protection, since the flexibility of the more open Android operating system has corresponding disadvantages such as increased susceptibility to malware and virus attacks.<sup>19,20</sup> YNHHS also had existing equipment and a robust telemedicine software platform from InTouch Health (Santa Barbara, California, United States) already in use for telestroke, tele-ICU, and teleconsultation purposes. Given the experience and establishment of an existing inpatient telemedicine

**Table 1** Technology use cases at Yale New Haven Health System

Number	Use-case title	Use-case description	Hospital location
1	Bedside registration	Patients are isolated but registration needs to be done at the bedside	All hospital locations
2	Nursing collaboration	Registered nurse (RN) at bedside needs to communicate with someone outside of isolation precaution room, such as the charge RN, without removing PPE	All hospital locations
3	Hands-free communication	Bedside caregiver (e.g., RN, respiratory therapist) is performing a task using both hands but needs to communicate or request assistance from outside of the room without pausing the task or exposing an on-person device to infectious agents	All hospital locations
4	Patient resuscitation	Minimize number of clinicians in a room during resuscitation to decrease exposure numbers and PPE usage while maintaining ability of external team members to provide support, procure supplies, and obtain expert consultation	Emergency department trauma/resuscitation rooms, ICUs, patient rooms
5	Patient and support system communication	Enable patient ability to interact with families and friends despite visitor restrictions or isolation precautions	All hospital locations
6	Repurposed area connectivity	Staff communication in temporary setups or modified clinical locations (e.g., lower acuity areas converted to ICU beds)	Pop-up patient care locations (outdoor triage and testing tents, other nonmedical buildings such as gymnasiums)
7	Patient rapport	Allow patients (especially children) to see the clinician's face on screen before they enter the room with PPE to decrease anxiety and improve rapport	Emergency departments
8	Patient visual contact	Need to maintain visual contact with patients in rooms that have been repurposed into ICU rooms but lack glass doors or any ability to easily see inside room	Medical/surgical floors, operating and recovery rooms
9	End of life	Adjust treatment for end-of-life and comfort care situations	All hospital locations
10	Clinical consultation	Consults from physician specialists, pharmacists, social workers, care managers, and others, while minimizing medical staff exposure and PPE usage	All hospital locations
11	Medication consultation	Pharmacy consult for patient's own medications from home	Medical/surgical wards, ICU locations
12	Medical device visualization	Need visualization of ECMO units along with bidirectional communication in and out of patient room	ICU rooms (permanent and temporary facilities)
13	Disposition planning	Social work and care management communication with patients for disposition planning	All hospital locations

Abbreviations: ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit; PPE, personal protective equipment.

platform combined with the clinical and time pressures necessitating a nimble response to COVID-19, no new evaluation of alternate platforms was performed.

### Device Procurement and Deployment

A stepwise approach was taken for deployment across the health system, beginning with a pilot phase followed by multiple rounds of equipment procurement and installation as staff requests increased or patient care locations were created or transformed. For video carts, five were initially installed and tested in the emergency department and inpatient units at the hospital that initially had the highest

volume of patients with COVID-19 (confirmed and under investigation). After receiving very positive staff feedback, more were purchased and distributed across the health system in subsequent waves. Similarly, with Amazon Echo Show devices, we initially piloted five devices in one emergency department, which expanded over five more rounds to four other locations based on staff requests. A few Echo Show devices were also piloted in one of the ICUs to complement the InTouch platform by assisting with voice-activated communication, but ICU leadership felt only voice capabilities were necessary and Echo Dot devices were subsequently very successfully piloted there. Some initial Amazon devices

**Table 2** Mobile technology devices utilized at Yale New Haven Health System for disaster response operations

Manufacturer	Device(s)	Cost per unit (approximate)	Functionality
Telehealth platform provider	Branded mobile video carts	\$19,000	Initiate audio and video calls into patient room, camera with pan/scan and zoom functions
N/A	Mobile video carts (built by ITS)	\$2000–\$4,000	Audio and video capabilities for health care staff
Apple	iPad tablet	\$400–\$1,000	Audio, video, and text capabilities for patients to communicate with friends/family
Apple	iPhone	\$279–\$400	Audio, video, and text capabilities especially using HIPAA compliant secure messaging through Mobile Heartbeat
Various	Baby monitors	\$125–\$200	Video to track physiologic monitors in nontraditional areas used as inpatient space such as the PACU
Amazon	Echo Flex, Echo Dot	\$25–\$50	Hands-free voice assistive capability
Amazon	Echo Show	\$70–\$220	Audio and video, hands-free voice assistive capability
Amazon	Fire tablet	\$75–\$100	Audio, video, and text capabilities for patients to communicate with friends/family

Abbreviations: HIPAA, Health Insurance Portability and Accountability Act; ITS, Information Technology Services; PACU, postanesthesia care unit.

were purchased from local electronics stores and after several rounds of deployments with Echo Dot and Show devices, Amazon learned of our efforts and donated 250 additional Echo Show devices.

An initial purchase of 20 InTouch Health devices with audio and video capabilities were deployed within patient rooms. It quickly became apparent that the number needed to appropriately scale was cost-prohibitive, so ITS repurposed 150 existing clinical workstations plus audio and video devices into our own telehealth carts. After all available equipment on-hand was deployed, ITS worked with existing technology vendors to purchase more components and built additional custom carts by combining off-the-shelf consumer electronics such as computer processors, webcams, speakers, microphones, and mobile stand parts. One version was an all-in-one computer with an added external speaker for enhanced audio quality (→Fig. 1). Another cart used a similar setup but with an added multifunctional camera with 40 megapixel resolution capable of reading labels on medication bags (→Fig. 2). A third type of cart was a laptop on wheels, also with an external speaker (→Fig. 3). When the market supply of computer parts was depleted, Apple iPads were attached to poles to further meet demand. iPads, iPhones, and Amazon Fire tablets were also distributed to enable patient video communication with family members for routine conversation as well as to facilitate the virtual presence of relatives during end-of-life scenarios. Handheld devices had advantages such as lower cost and familiar user software interfaces.

Use cases that benefited from hands-free capabilities were addressed with devices such as Amazon Echo Dot (audio only) or Echo Show (audio and video), which have Alexa voice-assistive software technology. These devices enabled hands-free voice-activated commands at a cheaper cost with robust multiple omnidirectional microphones to make phone calls or initiate video sessions between caregivers.

Due to the prioritization of patient care, a systematic method was not available to measure the amount of PPE



**Fig. 1** Example cart built for medical/surgical units, all-in-one computer with built-in fixed camera.

conserved. Therefore, an estimated number was calculated using interviews with clinician leadership, number of admitted patients with COVID-19, the average LOS, and the number of times telehealth cart software was used. Numbers were obtained from health system dashboards built for the pandemic. Staff feedback was recorded informally given the speed of operations.



**Fig. 2** Example cart built for intensive care units with high-resolution pan, tilt, and zoom camera.



**Fig. 3** Laptops on carts with external speaker and microphone for higher audio quality.

## Results

### Implemented Solutions and Benefits

The resulting setup included a total of 1,147 video devices installed with licensed, commercially available telehealth software, set up in various locations (ICU, operating rooms, emergency department, postanesthesia care units, inpatient

units) across our seven hospital campuses. We deployed over 250 Amazon Echo Show devices in the patient rooms of eight of the emergency departments of our hospitals, including the Children's Hospital. A total of 112 Amazon Dot devices were deployed in five different ICUs and over 300 Apple iPads were distributed to hospital units for patient use. We started with approximately 5% of the telehealth cart numbers at baseline, which increased to 25% after repurposing existing equipment. The remainder of the equipment was purchased during the pandemic. ITS estimated an overall savings of \$19 million by building our own telehealth carts.

Large-scale deployment of technology devices had benefits for our health system's needs in the inpatient setting. Specifically, video carts addressed the use cases of bedside registration, patient resuscitation, repurposed area connectivity, patient rapport, end of life, disposition planning, and clinical and medication consultations since health care workers outside the room could communicate audibly and visually with patients or staff inside an isolated patient's room and avoid donning PPE. Tablets from Apple and Amazon allowed patients to maintain connections with their support system during isolation since some patients did not have their own personal mobile devices during hospitalization. Speech-activated devices from Amazon enabled nursing staff to initiate hands-free conversations, thus allowing them to continue clinical tasks while initiating calls and avoiding exposure to their mobile devices and clothing, reducing fomite transmission risk. Mobile phones facilitated secure text messaging for clinician communication in all locations, and Amazon Echo Show devices enabled clinician video communication even in repurposed areas such as mobile tents in parking lots. Baby monitors helped staff visualize equipment from outside patient rooms such as smaller display screens where numbers were not easily seen from a distance.

Using the numbers listed earlier for hospitalized patients with COVID-19 and average LOS, both with and without ICU admission, the cumulative duration was 50,542 days. We estimated that the inpatient telehealth technology saved nursing staff at least two uses of PPE per patient per day, with PPE consisting of a filtering facepiece respirator, one gown, one face shield, and two gloves. In addition, inpatient telehealth carts were used by providers a total of 25,200 times across the health system, with each use saving at least one set of PPE. This resulted in a total estimated preservation of 631,426 PPE items for the inpatient setting alone.

### Challenges and Lessons Learned

Many issues and concerns arose around the setup, deployment, and usage of the various devices. Time constraints of a rising patient surge coupled with a widely distributed network of hospitals elucidated unforeseen obstacles that became apparent as the inpatient telehealth technology was scaled upward. The process to configure, test, and distribute hundreds of mobile devices across the health system resulted in valuable lessons learned, which are detailed in ► **Table 3**. Issues were grouped into five main categories: security/privacy, device availability and setup, device features, physical setup, and workflow and device usage.

**Table 3** Issues, barriers, and solutions from the implementation of various audio and video solutions to facilitate communication in the hospital

Issue domain	Barrier or concern	Solution
Security, privacy, HIPAA	<ul style="list-style-type: none"> <li>• Amazon devices with Alexa software are constantly listening</li> <li>• Data storage in cloud services</li> </ul>	Data from video calls are not stored in cloud memory. For consumers there is a log of calls made but for health care, the logs are wiped every 24 hours. Efforts in process to sign business associate agreement with Amazon.
	Federal regulations	The Department of Health and Human Services Office for Civil Rights has temporarily relaxed enforcement restrictions. <sup>18</sup> HIPAA exceptions apply to any non-public facing remote communication products.
	Use of staff personal devices	Must divulge personal phone numbers if using apps such as FaceTime. New FaceTime functionality from Apple helps to address this.
Device availability and setup	Branded videocarts from telehealth software solution provider sold out with no additional inventory	YNHHS ITS created videocarts using parts such as computer processors, webcams, speakers, microphones, and mobile stands.
	Amazon products require a phone number for setup confirmation text thus associating a personal phone number to a device	Amazon is providing an updated software adapter from their fleet services for the hospitality industry to allow health care devices to bypass the confirmation text step and have more robust management tools
	Time required to set up and configure large number of devices	Utilize an adapted fleet management software platform (detailed above) that allows for parallel setup of multiple devices at once
Device functionality	Telehealth solution software/carts cannot initiate calls from inside patient room	Supplement with an inexpensive complementary device such as Amazon Dot
	Some custom-built carts did not have pan, tilt, and zoom cameras	Deployed carts with limited camera functionality to non-ICU areas
	Amazon Echo Show cameras cannot zoom or pan/scan (e.g., to view numbers on a monitor)	Branded videocarts from telehealth solution offer cameras that pan, tilt, and zoom
	Audio feedback if Amazon Echo Show devices are placed too close in proximity	Move device outside of room to a further location such as the medication-dispensing area or central unit desk, turn down volume, or use a device with a less sensitive microphone such as Amazon Flex
	Devices require reliable WiFi connections	Ensure adequate WiFi coverage or use mobile phones as WiFi hotspots where no coverage exists (such as outdoor tents), Mi-Fi access points as needed
Physical setup	Some devices require stands	Purchased or obtained hundreds of stands and rolling carts for hospital-assembled video conferencing devices
	Devices without batteries need location setup near electrical outlet and cannot be moved easily (need to unplug/replug and takes about 1 minute to reboot and use again)	None available
	Large number of devices and locations needed for coverage in hospital	Set up one receiving phone number per unit tied to a dedicated phone (such as mobile phone for unit charge nurse)
Workflow and device usage	Video call out to the unit front desk may go unanswered due to staffing shortages leading to breaks in communication	Set up devices to contact a dedicated phone number (such as mobile phone for unit charge nurse)
	Smartphone use by staff inside patient room requires exposure to environment	Use voice-assistive devices such as Amazon Echo Dot or Show for hands-free phone or video communication
	Smartphone use by staff inside patient room difficult to use with PPE	Use voice-assistive devices such as Amazon Echo Dot or Show for hands-free phone or video communication

**Table 3** (Continued)

Issue domain	Barrier or concern	Solution
	Room-based device cleaning and decontamination	Devices dedicated for use in patient rooms and tethered/discouraged from being transported elsewhere to reduce infection risk and need for frequent device cleaning. Routine room disinfection methods were utilized after use by each patient including all the devices in the room and their components (screens, keyboards, cameras, and speakers).
	Mobile device cleaning and decontamination	Mobile devices were cleaned between patients using disinfectant sprays or wipes. CaviWipes (Metrex Research LLC, Orange, California, United States) were avoided since touch screens can be damaged.
	Difficult to clean the cloth portion of Amazon Echo Show devices	Cloth portion still wiped using alcohol-based wipes and discussed with Amazon development of commercial-grade devices
	Difficult for health care workers to gain access information for specific wards and connect to devices inside patient rooms for communication with patients	Physical device name labels on devices and outside rooms, plan to identify ideal place in electronic health record system to document and make visible the video device name corresponding to patient room and phone number

Abbreviations: HIPAA, Health Insurance Portability and Accountability Act; ICU, intensive care unit; ITS, Information Technology Services; PPE, personal protective equipment; YNHHS, Yale New Haven Health System.

**Health Care Worker Feedback**

Comments from clinicians included a nurse manager stating “Our ICU nurses felt a large sense of relief with the technology since they had a way to communicate from inside repurposed rooms with heavy wooden doors and only one small window. In one case, a patient self-extubated and the nurse was manually bagging, but still able to call for help from inside the room. That would not have been possible without the Alexas.” The Nursing Transformational Lead replied to an update request saying, “I was with the Nursing Informatics Council and also heard very positive feedback. I definitely feel we should expand on this.” One intensivist recalled a case of a patient with COVID-19 needing reintubation and ICU staff was able to arrange a video call with the patient’s family before resuming mechanical ventilation. “With the visitor restrictions in place,” the intensivist said, “that could have been the last time the patient saw their family. The technology enabled us to provide more humane care. Isolation of COVID is very real and not to be underestimated.”

**Discussion**

**Modernized Operational Structures**

We rapidly tested then iteratively deployed over 1,800 inpatient telehealth devices across seven hospitals in five delivery networks. This widespread effort was possible due to the creation of SIM, a new governance structure borne out of the pandemic response. The SIM structure provided agility through daily meetings that prioritized system needs, evaluated inpatient telehealth pilot results, and scaled solutions that received positive feedback from front-line clinicians. Normal budgetary approval processes were deferred so that reasonable COVID-related inpatient telehealth solutions could be purchased by ITS members. Another strength that

contributed to the deployment effort is a centralized ITS model, led by clinical informaticians, that already existed as a result of supporting a single electronic health record instance. This allowed our health system to act nimbly, quickly add to existing inventory of devices, and meet increasing demands.

**Limitations**

We are confident this suite of technology devices resulted in decreased PPE use, which contributed to our health system meeting the vast demand required by the pandemic. However, the exact number of PPE saved may be grossly underestimated since our numbers only include inpatient units and do not account for usage in patients under investigation. Exact numbers are also difficult to discern since inpatient telehealth was just one practice change out of many that were concurrently deployed.

Due to the speed and magnitude of changes implemented in a short period of time, we were unable to formally assess health care worker feedback. Overall consensus was deemed positive, however, based on repeated requests for device deployments after pilot trials, informal feedback from clinicians, and interviews with local news reporters.<sup>21</sup>

**Future Plans**

The large-scale effort delivered by our health system resulted in implementation of a fleet of technology devices that will continue to provide value as our health system resumes temporarily halted operations and seeks to build upon the gains we observed during this crisis response. Audio/visual mobile carts will continue to drive efficiency gains in registration, care coordination, or remote patient monitoring. Carts can be repurposed for enhanced patient translator services as well as virtual consults in both inpatient and

ambulatory locations to support social distancing guidelines. Handheld devices can continue to augment patient communication capabilities to ensure they remain well connected with distant relatives or those unable to visit even after visitor restrictions are relaxed. Tablets can deliver disease information, imaging test procedures, patient instructions, or care updates while patients receive care. They can also enable delivery of consumer-based applications to provide comfort or entertainment during the hospital stay. Voice-assistive devices can continue to provide utility for health care workers in complex environments where hands-free communication results in safety and efficiency gains and may reduce technology-related stressors.

## Conclusion

The high patient volume requiring isolation precautions, caused by the COVID-19 pandemic and resulting in high consumption of PPE, led to the identification of hospital use cases highlighting needs that were addressed by telecommunication devices. Our implementation of enhanced inpatient telehealth coverage using existing technology solutions uncovered many challenges to deployment and scalability. Understanding operational barriers and potential solutions highlighted by our experience can help health care systems appropriately anticipate issues and plan accordingly.

Our response to these challenges underscores how technology can enable more efficient and compassionate care for thousands of patients infected with COVID-19. This case report highlights the ability of large health care organizations to quickly adapt and utilize multiple solutions to enhance inpatient communication and conserve PPE in situations of increased patient isolation precautions and patient census. Overall, these measures increase the safety of front-line health care workers while providing enhanced capability to deliver care.

## Clinical Relevance Statement

This article provides lessons learned and potential solutions to rapidly scale and deploy inpatient telehealth technologies to address the use cases revealed as a result of the COVID-19 pandemic. Our strategy preserved supplies of PPE while maintaining vital health care worker and patient communication channels and can be adapted for use in other health care systems.

## Multiple Choice Questions

1. What type of contract is signed between health systems and separate companies that specifies safeguards for protected health information (PHI)?
  - a. Purchased service agreement
  - b. Business associate agreement
  - c. Under arrangement agreement
  - d. Management services arrangement

**Correct Answer:** The correct answer is option b, business associate agreement or BAA. Business associates are a person or entity that has access to PHI. BAAs clarify the permissible uses and disclosures of PHI.

2. What component of the U.S. Department of Health and Human Services is responsible for Health Insurance Portability and Accountability Act (HIPAA) enforcement?
  - a. Office of Health Reform
  - b. Office of the Assistant Secretary for Health
  - c. Office for Civil Rights
  - d. Office of Inspector General

**Correct Answer:** The correct answer is option c, Office for Civil Rights (OCR). The OCR is a law enforcement agency that began enforcing the Privacy Rule in 2003 and the Security Rule for HIPAA covered entities in 2009.

### Protection of Human and Animal Subjects

Yale Institutional Review Board (IRB) determined this activity did not meet the regulatory definition of research and therefore IRB review was not required.

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None.

### Conflict of Interest

None declared.

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