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PPE during a pandemic: The experience of obtaining PPE and lessons learned from a department of obstetrics and gynecology in New York city

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ABSTRACT

The COVID-19 Pandemic is an ongoing crisis that has strained hospitals and health systems around the globe. The provision of personal protective equipment (PPE) for frontline health-care workers is of utmost importance in sustaining an effective response to this crisis. New York City has experienced one of the most devastating outbreaks of the SARS-CoV-2 virus. In this article we report the experience of the Department of Obstetrics and Gynecology at Columbia University in New York City in managing the supply of PPE for providers and staff during the height of the outbreak. We describe the types of equipment used and aspects of PPE regulation and certification. We also describe our practices in extended use and reuse of PPE in light of the current understanding of the virus characteristics and modes of transmission.

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Introduction

The first documented case of COVID-19 occurred in the United States on January 22, 2020 in Washington State.¹ It would be over a month before the first case was confirmed in New York State, but New York would soon become the epicenter of the outbreak in the US. Just like virtually every department and healthcare system across the country, our Department of Obstetrics and Gynecology at Columbia

University in New York City (NYC) had not encountered a public health crisis of this magnitude for generations. Working within the NewYork-Presbyterian (NYP) multicampus system, we navigated the challenges of providing care for our patients and protecting our staff from becoming infected with SARS-CoV-2 by working on clinical, logistical, and resource levels. One of the most publicized limitations of providing care at the onset of the COVID-19 pandemic was the availability of Personal Protective Equipment (PPE). In this chapter we describe our experience and share what we have

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learned in our efforts to address the supply and appropriate use of PPE.

Pre-pandemic setting

In the 1–2 months prior to the first confirmed case of COVID-19 in NYC, the supply of PPE was already tenuous due to the effects of the pandemic on the Chinese manufacturing sector. Our hospital system initially requested that PPE be conserved in routine surgical cases by limiting the role of non-essential personnel such as medical students.

In anticipation of local cases, initial recommendations by the hospital system were that any patient with suspected or confirmed COVID-19 should be masked and moved to a negative pressure room (if available) and placed on airborne, contact, and droplet precautions. Staff were advised to wear N95 respirators, gowns, gloves and eye protection when entering these patients' rooms.

On March 1st, 2020, a 39-year-old woman residing in Manhattan who had returned from a trip to Iran became the first confirmed case of COVID-19 in NYC. The following day on March 2nd, NYP confirmed its first COVID-19 case at the Columbia University Irving Medical Center Campus (CUIMC).² Over the following weeks in NYC, the number of new COVID-19 cases increased daily reaching a peak on April 6th when 6,212 residents were diagnosed with the disease and 1,682 patients were hospitalized. On April 7th the largest number of daily deaths was recorded at 577.³ Throughout the month of April, the burden of the disease remained high with thousands of new cases diagnosed each day along with hundreds of new hospitalizations and deaths.

Challenges with PPE

In the weeks following confirmation of New York's index case of COVID-19, it became clear that the availability of PPE would be unpredictable. The media reported a dramatic and sudden increase in demand for PPE across the country and around the globe as health systems and individuals attempted to procure this equipment. During daily briefings, NYP leadership attempted to reassure staff that the hospital had sufficient supplies, while simultaneously communicating the concerning problems with the supply chain and, therefore, the need to conserve PPE. On a department level, the availability of PPE was uncertain owing to several factors:

1. A continued increase in COVID-19-related admissions and an inability to predict the magnitude and timing when the number of infected patients would peak;
2. Uncertain amounts of available PPE at the hospital, coupled with uncertainty related to obtaining additional supplies from commercial sources, the state, or the Strategic National Stockpile;
3. Evolving recommendations from federal agencies and the hospital system, related to PPE conservation including re-use, extended use, and substitution of items used for this purpose (as described further below);

4. A sudden influx of donations of PPE from public businesses and individuals, with substantial variation in the type and uncertainty regarding the quality of equipment being donated.

The underlying uncertainty relating to the availability of and specific types of PPE needed to protect our patients and staff was daunting. Forecasting models showed that without effective social measures to limit the spread of the virus, healthcare facilities in New York City would become overwhelmed. Our response had to take into consideration the evolving PPE recommendations from the CDC as well as the unique nature of care in a Labor and Delivery Unit.

Women who present in labor must be admitted and treated, often without having been previously tested for laboratory evidence of infection. Early in the course of this pandemic 2 asymptomatic patients in labor on our service, who had not been tested for SARS-CoV-2 on admission, went on to develop symptoms during or after their delivery, and subsequently tested positive.⁴ This led to the inadvertent exposure of nearly 30 members of our staff, some of whom became infected. The role of asymptomatic carriers in exposure and transmission gained attention as researchers in China and in Washington State described a similar experience in their populations.^{5,6} Recognition that asymptomatic patients could be infectious resulted in our testing all laboring patients who were not already known to be infected on admission to the service, with guidelines on how to manage these low suspicion patients until the results of their tests were obtained. This policy required us to provide appropriate PPE to the staff caring for these women until their SARS-CoV-2 status had been determined.

The NYP system worked aggressively to procure PPE, and an email account "masks@nyp.org" was created to collect information on potential PPE sources from individuals both inside and outside the system. In line with CDC guidelines, NYP recommended that staff conserve PPE by using it only when appropriate and re-using PPE whenever possible.

At the department level, we recognized the importance that PPE would play in protecting our staff in addition to the obvious issues relating to optimal patient care. Donations of PPE to our department were sent or brought in almost daily from civic minded individuals and groups. These donations included surgical masks, respirators, gowns, welder style face shields, glasses, and goggles. Faculty and staff tapped a large network of friends and contacts who in some cases were able to quickly manufacture PPE such as face shields from 3-D printing technology. One of the department's fellows started a crowd-sourcing campaign and raised substantial funds to purchase PPE.

To address the influx of resources received by our department, a small committee was formed and tasked with organizing the PPE being sent to us. Donated supplies were collected, inventoried, and placed together in a secure location. With reports of large amounts of PPE being stolen from sites across the system, we limited access to our supply of donated PPE. The largest number of donations we received were N95 respirators and surgical masks. Given the nature of our specialty, the potential contamination of masks from

blood or fluid splatters meant that our ability to re-use PPE was limited. The welder style face shields were especially valuable to protect masks and N95 respirators being worn behind them. The crowd sourced funds were used in part to purchase more of these shields. Thus, our department was able to obtain appropriate PPE elements from generous donors and specific manufactures, and this equipment was then available for distribution to all those with direct patient contact on the Labor and Delivery floor.

The supply of N95 respirators we received, however, varied enormously in terms of style, certification, and size and were not always the N95 respirators that staff had been fit tested for. Not having any previous experience with the classification and certification process for PPE we had to quickly learn some technical aspects relating to the items of equipment in order to determine what could and could not be safely supplied to our staff. In the following section, we review some aspects of what was learned.

Regulatory bodies for PPE

During the pandemic a number of scams were reported when illegitimate PPE was sold or was attempted to be sold to healthcare systems and workers. Less nefarious, but still pertinent, was that portions of PPE donated was either impractical or did not have any designation deemed acceptable by the standards of the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC). Understanding the various standards and certifications involved proved helpful for our department in navigating this challenge.

Notably, the regulatory environment for PPE is both confusing and complex. Multiple federal agencies have various roles in PPE regulation and issue a myriad of standards, protocols, and recommendations. The Occupational Safety and Health Administration (OSHA) is the federal agency responsible for ensuring safety and protection for both healthcare and non-

healthcare workers. OSHA is a regulatory agency, meaning OSHA's standards and regulations are enforceable under US law. As defined by OSHA, PPE is "equipment worn to minimize exposure to hazards that cause serious workplace injuries and illness" and includes gloves, gowns, masks, N95 respirators, and safety glasses or goggles.⁷

OSHA's regulations for PPE generally relate to the use of equipment meeting a specified standard often determined by a non-regulatory agency or organization such as the American National Standards Institute (ANSI) or National Institute for Occupational Safety and Health (NIOSH).

Surgical masks are designed to be worn as PPE by healthcare personnel during procedures to prevent contamination by liquid droplets. A key feature of these masks is that they are fluid resistant. A respirator is a device used to reduce the wearer's risk of inhaling hazardous airborne particles. While several types of respirators exist, disposable or filtering face piece particulate respirators which filter out airborne particles are the most common type used in the healthcare setting. These are designed to have a very tight fit to the wearer's face and filter out very small particles from the air. The most common way to classify respirators is by filtration efficiency which is the device's ability to remove a certain percentage of a contaminant from the air, typically ranging between 94 and 100%. The NIOSH designation of N95 means that when tested, the respirator blocks 95% of very small particles (0.3 microns). The N portion of the name means the respirator is not resistant to oils.

OSHA mandates that N95 respirators meet standards set by NIOSH which is part of the CDC and is responsible for conducting research and making recommendations for prevention of workplace injuries and illnesses. However, when PPE is used in healthcare, it meets criteria for being a medical device and is thus regulated by the FDA. In Fig. 2, image A shows N95 respirators that are certified by NIOSH and FDA approved for use in healthcare settings. Shown in images B and C are N95 respirators that meet NIOSH standards but are



Fig. 1 – Examples of eye protection and surgical masks. A) Donated welder-style face shield worn over N95 respirator B) Hospital procured surgical mask with integrated eye shield C) Donated safety goggles with surgical mask.



Fig. 2—A variety of masks were received by our department early on in the pandemic. A) Hospital procured N95 respirator with both NIOSH and FDA approval B) Donated N95 respirator with NIOSH approval but not FDA approved for healthcare settings C) Donated duck-billed style N95 respirator with NIOSH approval but not FDA approved for healthcare settings D) Donated KN95 respirator.

not FDA approved. Notably, on April 3, 2020, the FDA issued an Emergency Use Authorization (EUA) for healthcare personnel to use non-NIOSH approved N95 respirators manufactured in China. Some of these devices are labeled as KN95 respirators, reflecting certification by Chinese testing standards. Examples of these are shown in image D of Fig. 2. On May 7, 2020, the FDA modified the EUA because it was recognized that some of these respirators failed to demonstrate minimum particle filtration efficiency of 95% in testing performed by NIOSH.⁸

Extended use and reuse of PPE in setting of low PPE supply

NYP's Department of Infection Prevention and Control worked collaboratively with the obstetrical and nursing leadership as well as frontline staff to provide guidance on infection prevention as new data became available.

To provide PPE for staff, it was crucial for our hospital system to measure PPE 'burn' and continually seek alternative sources and types of PPE. For example, access to different

Table 1 – PPE Extended Use and Reuse.

Type of PPE	Extended Use of PPE	Reuse of PPE	Cleaning and Disinfection	Storing Reusable PPE between Uses
Surgical mask	Can be worn <i>continuously</i> during care of multiple patients with COVID-19 in same room	- Clean and intact - Protected by welder-style face shield	<i>Cannot be cleaned or disinfected</i>	Keep clean Discard if soiled, torn, or elastics break
N95 respirator	Can be worn <i>continuously</i> during care of multiple patients with COVID-19 in same room	- Clean and intact - Protected by surgical face mask or face shield - Successful fit check upon re-donning		Avoid damage or bending by placing in paper bag and store in secure, clean location, e.g., locker, lab coat pocket
Eye protection		- Goggles or face shield: able to clean and disinfect exposed surfaces	Clean inside, outside, and strap with hospital-approved disinfectant <i>Cannot be reused or disinfected</i>	Store in a clean bag, e.g., paper bag
Gown Gloves	Gloves <i>must be changed</i> between patients			

types of eye protection changed rapidly and included eye protection attached to surgical masks, various types of reusable goggles, and reusable face shields that were produced by 3-D printers (examples shown in Fig. 1). Additional measures, informed initially by the CDC and further supported by the Infectious Disease Society of America (IDSA) and OSHA, advocated using the same PPE across multiple patient encounters, through extended use and reuse. Extended use refers to the continued use of PPE during multiple consecutive patient encounters without removal between encounters. Reuse refers to using the same PPE element among multiple encounters, but removal between encounters (Table 1).⁹ Extended use and reuse were particularly important to conserve N95 respirators which have previously become depleted during respiratory outbreaks.¹⁰ Different types of NIOSH-approved N95 respirators were intermittently available and some sizes, e.g., “small” masks were less available. It was important to recognize that KN95 respirators, which are regulated by the Chinese government, might be suboptimal and not equivalent to NIOSH-approved devices. At times, surgical face masks, gowns, and eye protection were also at risk for severe shortages as the number of patients with COVID-19 surged in New York City.

The risk of transmission with extended use and reuse has not been well described. We advocated changing PPE if it became visibly soiled or torn or if the N95 respirator failed a fit check (Table 2). N95 respirators were covered by either a face shield or by a surgical mask to keep them clean. Gloves

were changed after performing hand hygiene between encounters between different patients. Education for donning and doffing PPE was developed using videos, infographics, memos, and huddles. An additional measure offered by IDSA and CDC entails reprocessing strategies to decontaminate N95 respirators allowing for their reuse. Such strategies include decontamination using vaporized hydrogen peroxide, ultraviolet germicidal radiation, or dry heat, although further data are needed to determine efficacy and safety of reprocessed N95 respirators.⁹

Conclusions

Eventually NYP obtained enough PPE to provide for all of the staff that were caring for inpatients on our service, and we were then able to provide elements from our stockpile to the remainder of our staff that were seeing potentially affected women as outpatients.

Hopefully our departmental experience will allow other institutions to properly prepare for an unanticipated influx of patients who are at risk of spreading infection through either respiratory droplets or airborne transmission. It is necessary to understand what type of transmission is operant, what kinds of PPE that will necessitate, and roughly how much equipment will be required.

Disclosure statement

Arnold Advincula

Consultant: Abbvie, Baxter, ConMed, Cooper Surgical, Eximis Surgical, Intuitive Surgical, Titan Medical

Royalties: Cooper Surgical

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Table 2 – Steps for Respirator Fit Check.

Choose a respirator that fits the face. When available, a respirator the wearer has been fit tested for should be chosen.
Inspect respirator for damage or tears.
Put on mask ensuring straps are behind head.
Gently cover mask with hands and block paths for air to escape.
Perform positive pressure check by exhaling and checking that facepiece is slightly pressurized before there is leakage.
Perform negative pressure check by inhaling sharply and checking that facepiece slightly collapses.
If respirator fails positive or negative check or is visibly damaged, alternative respirator should be checked and worn.

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