



Major Article

Developing a methodology to collect empirical data that informs policy and practices for stockpiling personal protective equipment



Lee A. Greenawald PhD ^{a,*}, Susan M. Moore PhD ^a, Kerri Wizner MPH ^b, Patrick L. Yorio PhD ^a

^a National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, PA

^b MDGuidelines, ReedGroup Ltd. Westminster, CO. Former Association of Schools and Programs of Public Health Fellow, CDC NIOSH NPPTL, Pittsburgh, PA

Key Words:
Personal protective equipment
Health care
Preparedness
Storage conditions
Respirators
Surgical gowns

ABSTRACT

Background: Personal protective equipment (PPE) are stockpiled across the nation to offset supply depletion during public health emergencies. Stockpiled PPE inventories vary across the United States by type, model, quantity, and the conditions in which they are stored. Over the past decade, federal, state, and local stockpile managers have had concerns for the viability of aging PPE.

Methods: To understand factors that may affect stockpiled PPE, we explored the breadth of stockpile storage conditions and respirator and surgical gown inventories through collaboration with the national PPE community, qualitative observations collected at 10 different US stockpiles, and by compiling stockpile PPE inventories and climate data from a convenience sample of US stockpiles.

Results: The aggregated inventory from 20 stockpiles is reported, accounting for approximately 53 million respirators. Most respirators (69% or 35.8 million) have been stored between 5 and 10 years. Upon visiting 10 stockpile facilities, we report on the storage conditions observed and summarize the storage environment data collected.

Conclusions: This is the first study to identify common PPE types, inventories, and storage conditions across federal, state, and local government stockpile facilities as well as health care organization-managed caches. These findings will be leveraged to guide the development of sampling protocols for air-purifying respirators and surgical gowns in US stockpiles to understand the performance viability after long-term storage.

© 2020 Association for Professionals in Infection Control and Epidemiology, Inc. Published by Elsevier Inc. All rights reserved.

BACKGROUND

Eighteen million ¹ US healthcare personnel (HCP) may face high-consequence exposures in a public health emergency response including infectious diseases such as tuberculosis, hepatitis, Ebola, influenza, or human immunodeficiency virus.^{2–8} Personal protective equipment (PPE) is the last line of defense within the hierarchy of controls. PPE used in health care includes clothing and devices worn on the body such as gowns, gloves, goggles, face shields, head covers, respirators, and surgical masks.

In the event of a public health event, there is likely to be a sudden increase in the demand for PPE that exceeds available supplies, with manufacturers needing approximately 3 or more months to increase

production to meet the resulting spike in demand.^{9,10} An example of this occurred during the 2009 H1N1 pandemic, where local respirator shortages were reported for HCP.¹¹ One strategy that emergency response planners use to address potential PPE shortages is to stockpile PPE supplies for use during high-volume use scenarios.^{9,12–15} Given the time between epidemics, stockpiled PPE may remain in storage for many years. This scenario can result in many stockpiled PPE products exceeding their shelf life, where replacement costs of large stockpiles of PPE that have exceeded their shelf life would likely be costly. PPE demand issues are not just limited to respirators—within 2 weeks after the release of an updated Centers for Disease Control and Prevention (CDC) Ebola PPE guidance, an increase ranging from 10 to 200 times that of normal PPE orders was reported,⁹ depending on the PPE product.

One significant challenge stockpile facilities face is the lack of uniform guidance in terms of the type and quantity of PPE that should be purchased for storage within a stockpile. Additionally, there is limited uniform guidance available regarding best practices for PPE

* Address correspondence to Lee A. Greenawald, PhD, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, 626 Cochran's Mill Road, Pittsburgh, PA 15236.

E-mail address: LGreenawald@cdc.gov (L.A. Greenawald).

Conflicts of interest: None to report.

storage conditions and stockpiling management. This has resulted in variability of the stockpiled PPE types, models, and the conditions in which they are stored.

Over the past decade, the National Institute for Occupational Safety and Health (NIOSH) was approached by federal, state, and local stockpile managers regarding concerns for the viability of aging PPE stockpiled for long periods.^{17,18} NIOSH provided near-term support for these concerns by evaluating a small sample of stockpiled respirator straps,¹⁶ gowns,^{17,18} and face shields (unpublished); the need remains to more thoroughly explore the impact of long-term storage on the efficacy of PPE by obtaining larger sample quantities from stockpiles that are geographically dispersed and represent common US stockpile storage conditions.^{19,20}

The objective of this study was to better understand common US stockpile PPE inventories, storage conditions, and geographic locations. These factors were explored through collaboration with the national PPE community, collecting qualitative observations through stockpile site visits by NIOSH researchers, and collecting quantitative facility-specific PPE inventory and climate data. Collecting this type of empirical data may help guide future research, age modeling efforts, shelf life recommendations, and policy decisions. It can also help guide stockpile managers in decisions related to current and future management practices.

OVERVIEW OF STUDY APPROACH

There are a large number of PPE types that are included in stockpiles such as respirators (eg, filtering facepiece, elastomeric half or full facepiece, and powered air-purifying), barrier protection garments (eg, coveralls, isolation or surgical gowns, hazmat suits, gloves, boot covers, and sleeve covers), or face protection (eg, face shields or goggles). Given the cost associated with testing and evaluating the effect of storage conditions on multiple types of PPE, NIOSH worked with the PPE community and stakeholders to identify those PPE that are likely to experience a shortage during large-scale public health emergencies. Additionally, a geographically-representative sample of stockpile sites for inclusion in the study was necessary to understand the potential effect of local climates on direct storage conditions. A range of potential PPE inventories and disparate environmental conditions were considered to assure that the breadth of stockpile characteristics observed would allow generalizability needed for policymakers, product makers, and stockpile managers to base actions and to recommend future research efforts.

METHODS

Establishing a NIOSH stockpile PPE partnership

NIOSH identified the stakeholder groups that have a vested interest in infection control, emergency response, PPE protections, and/or stockpiling and coordinated with these stakeholders throughout information gathering and decision-making. NIOSH's National Personal Protective Technology Laboratory (NPPTL) established a PPE Stockpile Partnership, constituted with relevant stakeholder groups including:

- Federal entities and stockpiles—The Centers for Disease Control and Prevention (CDC) Influenza Coordination Unit, CDC's Deputy Director for Infectious Diseases, The Department of Health and Human Services (HHS) Strategic National Stockpile (SNS), the Occupational Safety and Health Administration, the US Department of Veterans Affairs, and the Food and Drug Administration.
- State-level stockpiles—New York State Department of Health, California Department of Public Health, Rhode Island Department of

Health, Colorado Department of Public Health and Environment, and Washington State Department of Health.

- County-level stockpiles—Caswell County Health Department in North Carolina, and the Harris County Public Health in Texas.
- City-level stockpiles—Chicago Department of Public Health.
- Hospital-related stockpile entities—Johns Hopkins Center for Health Security, University of Pittsburgh Medical Center, Mayo Clinic, Louisiana Hospital Association, and the Joint Commission.
- Manufacturer representation—International Safety Equipment Association.

Here, policymakers are defined as those organizations responsible for (1) developing national and state emergency response strategies, (2) setting product performance and quality requirements, (3) establishing quality assurance guidance for stockpile facilities, and (4) setting hospital requirements. Product makers include not only the manufacturers but also the product component and material suppliers and developers. The stockpile managers include those who perform supply chain activities (eg, sets inventory levels, selects PPE for purchases, and rotates PPE as needed) for local, state, hospital, and federal facilities.

Selecting PPE types

As part of the NIOSH PPE Stockpile Partnership, NPPTL reached out to various CDC work units with a role in emergency response, and to the strategic national stockpile to identify those PPE types that have been associated with shortages. With input from the Partnership members, APRs and Level 3 and 4 surgical gowns were selected to be included in this study because they are stockpiled in large quantities and serve a critical protective function during high consequence events. Recent shortages associated with air-purifying respirators (APRs) during public health emergencies have been well-documented.^{9,10} Additionally, surgical gowns are generally stockpiled to protect workers from blood-borne pathogens and infectious diseases during an epidemic or pandemic. The American National Standards Institute/Association for the Advancement of Medical Instrument PB70 Level 3 gowns are used for moderate risk to the HCP (eg, during blood draws, inserting intravenous IV lines), and Level 4 gowns are used for high risk to the HCP (eg, during long, fluid intense procedures and surgeries).²¹

Isolation gowns were considered by the Partnership members; however, the consensus-based standards for this type of PPE have recently changed thereby making products available to be used as controls for this study manufactured to a different performance specification than the stockpiled products. Therefore, isolation gowns were excluded from the eventual empirical study.

Identifying stockpile facilities

To seek collaborating stockpile facilities, NPPTL solicited nationwide input through a published Federal Register Notice requesting US stockpile facilities to provide information about their facility conditions and inventories, specifically for APRs and surgical gowns.²² Some stockpile managers provided detailed inventory information (eg, model type, quantity, manufacturer year, and storage time), where others only provided model type and/or quantity. Stockpile managers willingly provided their perspective of their facility storage conditions through descriptions or by pictures, as well as providing their inventories to help the researchers with prioritizing collaborating sites. The described approach identified a total of 39 different stockpile facilities that provided either storage condition and/or inventory data, including 13 local, 5 hospital, 11 state, and 10 federal spread across all 10 Department of Health and Human Services (HHS) regions (Fig 1). Contact information for each facility was obtained.

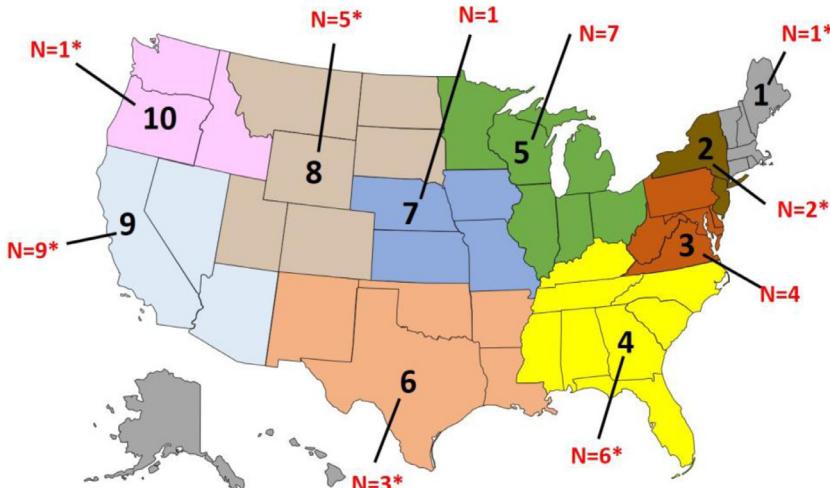


Fig. 1. Figure shows locations of stockpile facilities that provided inventory data, shown by the Department of Health and Human Services (HHS) national regions. The *** denotes that at least 1 stockpile facility was visited by NIOSH researchers within that region.

Although, many additional facilities are expected to exist across the United States, this marks a significant step forward in identifying common PPE inventories and storage conditions across many facilities. Additionally, identifying this number and variety of facilities provided the opportunity to solicit additional collaborating facilities likely to have disparate storage conditions (environmental and inventory) to include in the study and conduct site visits.

Each collaborating facility provided information for their facility related to topics such as PPE inventory and storage conditions (Appendix Table A1). The 10 HHS geographic regions were targeted, as these regions are often used for regional emergency planning.

Conducting stockpile facility site visits to confirm climate and storage condition information

With consideration to resources, NIOSH identified 10 stockpile facilities to visit between August 2017 and January 2019, where selection was based on consideration for disparate storage conditions, but common APR and surgical gown inventories. Prior to visiting these facilities, NIOSH devised a series of checklists to facilitate visual inspections of the facility, including site, pallet, case, box, and product inspections. The checklists (Tables A2–A5) focused on environmental parameters perceived to be most relevant to PPE performance based on input from stockpile managers and product manufacturers. The checklists were used to document (1) the presence of dust on PPE packaging, shrink-wrapping, proximity of chemicals to packaging, and moisture; (2) exposure to sunlight and direct light; (3) proximity to fans, windows, doors, and ventilation systems; (4) damage to pallet and product packaging; and (5) location of pallet on storage rack (eg, top, bottom) and location of PPE product on pallet (eg, top/not load-bearing, bottom load-bearing). These checklists were preliminarily tested by NIOSH researchers in a large open room with example PPE product packaging. NIOSH researchers evaluated the checklist for clarity, consistency between evaluators, and efficiency. Draft checklists were then presented to the Partnership members for technical input.

To ensure that its facility sample was diversified, NIOSH used a 3-level stratified sampling strategy based on technical input received from members of NIOSH's PPE Stockpile Partnership. The strategy leveraged the environmental storage condition data provided by the stockpile managers to select facilities with a range of temperature and humidity conditions, including those that:

- 1 Had a well-controlled environment, demonstrated through available temperature and/or humidity data
- 2 Had few existing environmental controls OR no controls; temperature and/or humidity monitoring may or may not have existed
- 3 Did not control or monitor temperature and/or humidity

The first 3 stockpiles visited were strategically selected based on preliminary discussions with the stockpile managers to identify those stockpiles that had a range of the storage conditions listed above.

Using the checklists from each facility, a stratified matrix of potential environmental conditions was developed to better describe site conditions (Table 1). This form allowed the calculation of a "facility environmental condition score" which could be used in the analysis of the empirical data. Temperature and percent relative humidity (%RH) data for stockpiles lacking this data was collected using data-logger left in the facility for 1 year or by using facility-maintained climate records when available. Storage conditions are dependent on the PPE type and model. Generally for filtering facepiece respirators, manufacturer-recommended temperature and %RH storage conditions are to stay above -4°F and below 95°F and below 80%RH, respectively,²³ but stockpile managers must also take into account the different types and models of PPE, as well as medications that may also be stockpiled.

RESULTS

Stockpile site visit findings

During the 2017 Partnership Kick-Off meeting with the NIOSH PPE Stockpile Partnership, NIOSH proposed the PPE types to be included and an appropriate strategy for assuring the diversity of stockpile facilities to be included in the study. The 10 HHS geographic regions were targeted, as these regions are often used for regional emergency planning. NIOSH's sample of facilities were geographically dispersed across the United States, had various levels of oversight, and varied in terms of local climate considerations and facility temperature and %RH levels. Geographical distribution of the 39 facilities included in this study occurred are shown in Figure 1. Ten facilities were selected to participate in site visits, noted by the *** in Figure 1. These facilities were spread across the HHS regions and varied regarding oversight with one facility being federal, 2 being regional, 6 being state, and one being county-level. There were differing levels

Table 1

Characteristics of environmental conditions at the 10 US stockpile facilities that NIOSH researchers visited and evaluated using the checklists that were developed, pilot tested, and revised after technical input from members of NIOSH's PPE Stockpile Partnership

	Light in contact with containers	Dust deposited on containers	Additional protective packaging around containers	Chemical spills near containers	Moisture in contact with containers	Weight/force applied to containers
Range of Conditions	A = Not near containers or lights generally off w/o windows B = Shines near but not directly on containers C = Directly shines on containers	A = Practically nonobservable B = Observed on surfaces a thin film C = Observed on surfaces a thick film	A = Shrink wrap generally applied to all containers B = Shrink wrap generally applied to most containers C = Shrink wrap generally not applied to containers	A = No evidence chemicals spilled in product area B = Chemical spills were localized and immediately remediated C = Chemical spills may have covered a large area or were not immediately remediated	A = No evidence of moisture making contact with containers B = Evidence of moisture making contact with very few containers C = Evidence of moisture making contact with multiple containers	A = Minor percentage of inventory being under a weight/force B = Strategy led to a moderate percentage of inventory being under a weight/force C = Large percentage of inventory being under a weight/force
Facility 1	A	B	A	A	A	A
Facility 2	B	B	A	A	A	A
Facility 3	A	A	C	A	A	A
Facility 4	A	C	B	A	A	A
Facility 5	C	B	B	A	A	A
Facility 6	A	A	A	A	A	C
Facility 7	A	B	B	A	B	B
Facility 8	A	A	B	A	A	A
Facility 9	A	A	C	A	C	A
Facility 10	A	A	A	A	A	A

of resources available to manage these facilities and various climate conditions were expected to result in disparate environmental conditions within these facilities. A team of NIOSH researchers visited these 10 facilities to document the environmental conditions using the checklists previously described, where a general description of each of the 10 facilities can be found in NIOSH's PPE conformity assessment studies and evaluations (PPE CASE) Report.²³

The 10 stockpile facilities identified were preliminarily categorized into the following categories:

- 1 Controlled environment, demonstrated through available temperature and/or humidity data (n = 3 facilities);
- 2 Had few environmental controls OR no controls existed; temperature and/or humidity monitoring may or may not have existed (n = 3 facilities);
- 3 Did not control or monitor temperature and/or humidity (n = 4 facilities).

This 3-level stratified sampling strategy substantially increased NIOSH's confidence that the facilities selected for site visits would reflect disparate temperature and humidity conditions; however, the extent of the differences for these conditions and other relevant conditions (eg, dust, light, and moisture) remained unknown until site visits were conducted at all 10 facilities using the developed checklists. For each of the 6 environmental characteristics (ie, light, dust, protective packaging, chemical spills, moisture, and weight/force), NIOSH established 3 classification levels to capture the variability in conditions that were observed during its site visits. NIOSH then applied the classification scheme to each of the 10 facilities to document the spread of environmental conditions expected to exist in US stockpiles.

In conjunction with these site visits, NIOSH also obtained detailed inventory data (eg, product model, manufacturing year, years in storage, and quantity) for each site. Examples of environmental conditions with potential to affect stockpiled PPE performance are discussed below.

Light in contact with containers

Some facilities had skylight windows that directly shined on the pallets with stockpiled PPE, while other facilities had fluorescent lights directly above the pallets; only the pallets on the top shelving were directly affected. Many facilities left the lights off except when activated by motion sensors other facilities shared the warehouse with other entities, and therefore lights were on in at least half of the warehouse on a regular basis.

Dust deposited on containers, chemical spills near containers, and moisture in contact with containers

Nine of the 10 facilities used pallets to secure PPE within the same lot or model, where one facility used Rubbermaid containers instead of pallets, where individual respirator boxes were sitting on top of the containers; no dust was observed on these respirator boxes. Other facilities had shrink-wrap around the sides of the pallet but not the top (allowing dust to settle on the tops of the pallet boxes), and other facilities had shrink-wrap around the sides of the pallet and the top. Two facilities used a heavy plastic pallet cover to go over each pallet, minimizing dust settlement on product packages. Minimal dust was found on individual PPE boxes, and none was found on the individual PPE itself.

None of the facilities showed evidence of large chemical spills that could have contacted the PPE containers. More localized chemical exposures resulted from pesticide control spraying (inside and outside the facility), annual floor cleaning using industrial cleaners, and pesticide/rodent traps. Moisture damage was observed on some PPE containers and around one wall of a physically substandard warehouse.

Weight/force applied to containers

Some facilities stacked pallets directly on top of each other with no shelving metal between pallets, resulting in the weight of over 4 pallets on the bottom pallet. Other facilities separated each pallet with metal shelving. At one facility, an entire pallet that was not separated by metal shelving toppled over onto the floor. Within pallets,

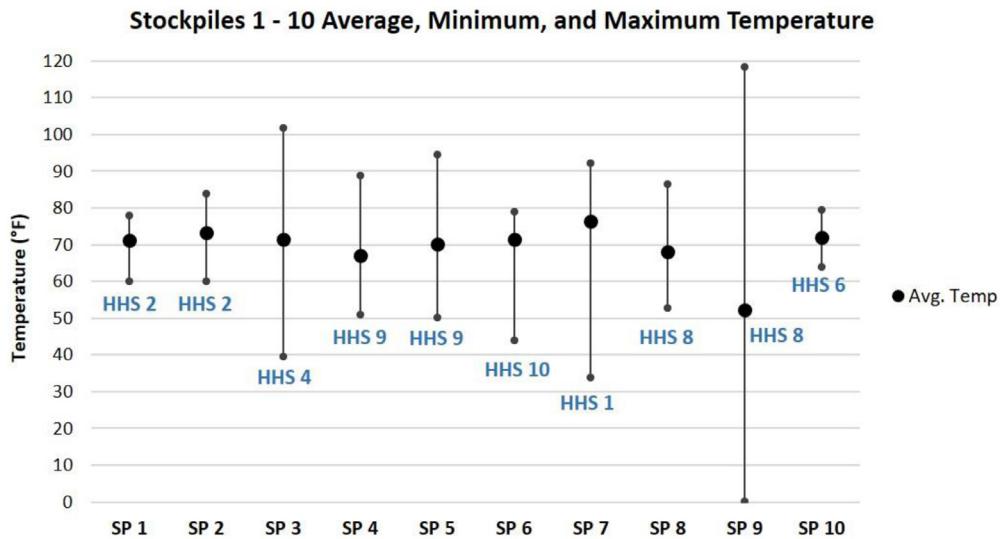


Fig. 2. Average, minimum, and maximum temperature across all 10 stockpile facilities visited in this study.

damage to the external PPE case was found on multiple cases, likely from how tight the shrink-wrap was applied.

Temperature/humidity

A summary of the temperature and %RH data collected from the 10 stockpile facilities is shown in *Figures 2* and *3*, respectively. There was considerable variance between stockpiles on the control or monitoring of temperature and/or humidity—ranging from a person recording data by hand monthly to computer-prompted notifications and hourly data recording. Some of the stockpiles shared space with other groups that would verbally communicate if the facility had a major problem, but not know more specific details if the facility went out of temperature or humidity range. Although some sites monitored for humidity, no one controlled for humidity beyond ambient geographic climate or building architecture. Facilities that also stored medications had air-conditioning/heating capabilities. Other control measures included evaporative coolers, HVAC filtering, and large and small ceiling fans. One facility stored APRs in a trailer that was outside year-round (the respirators were more recently moved to the

basement of a health department); the appearance of mold was found on these APR boxes.

Many facilities that controlled temperature had back-up power generation systems that were relied upon if the air-conditioning/heating unit failed. Accompanying the robust environmental control systems, some stockpiles maintained documentation of temperature and %RH to demonstrate that PPE was kept within prespecified standards over time. The control systems in place at these facilities were robust enough that large temperature and %RH deviations occurred infrequently. Other facilities were unable, due to lack of funding or resources, to continuously maintain an ideal temperature and humidity within the storage environment. Stockpile managers reported that lapses in environmental control could be due to system maintenance issues or a failure in the primary power system without having back-up power systems available. These lapses resulted in numerous instances in which temperature and/or humidity spiked outside of general manufacturer-recommended values for APR and surgical gowns. In some instances, stockpile managers also reported less than adequate system quality could lead to similar spikes during

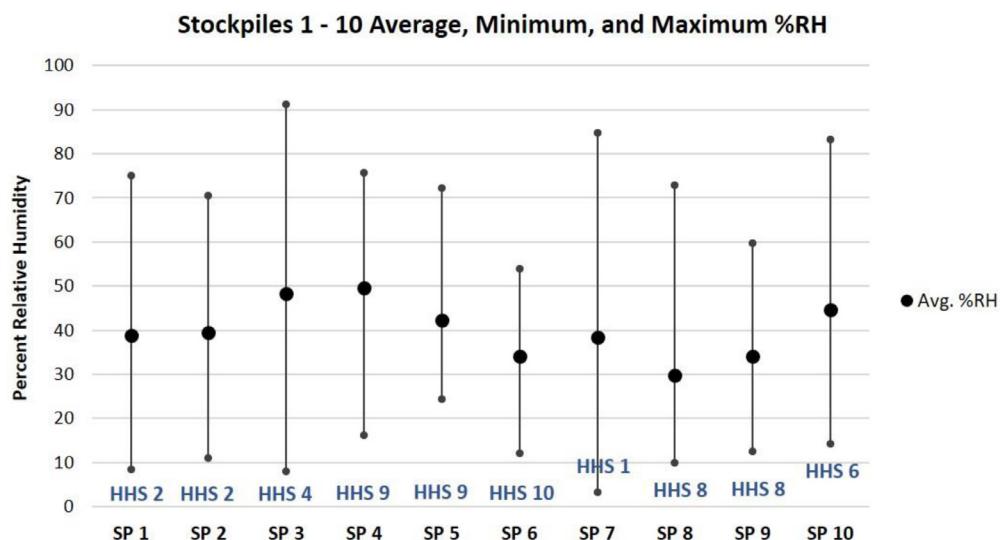


Fig. 3. Average, minimum, and maximum %RH across all 10 stockpile facilities visited in this study.

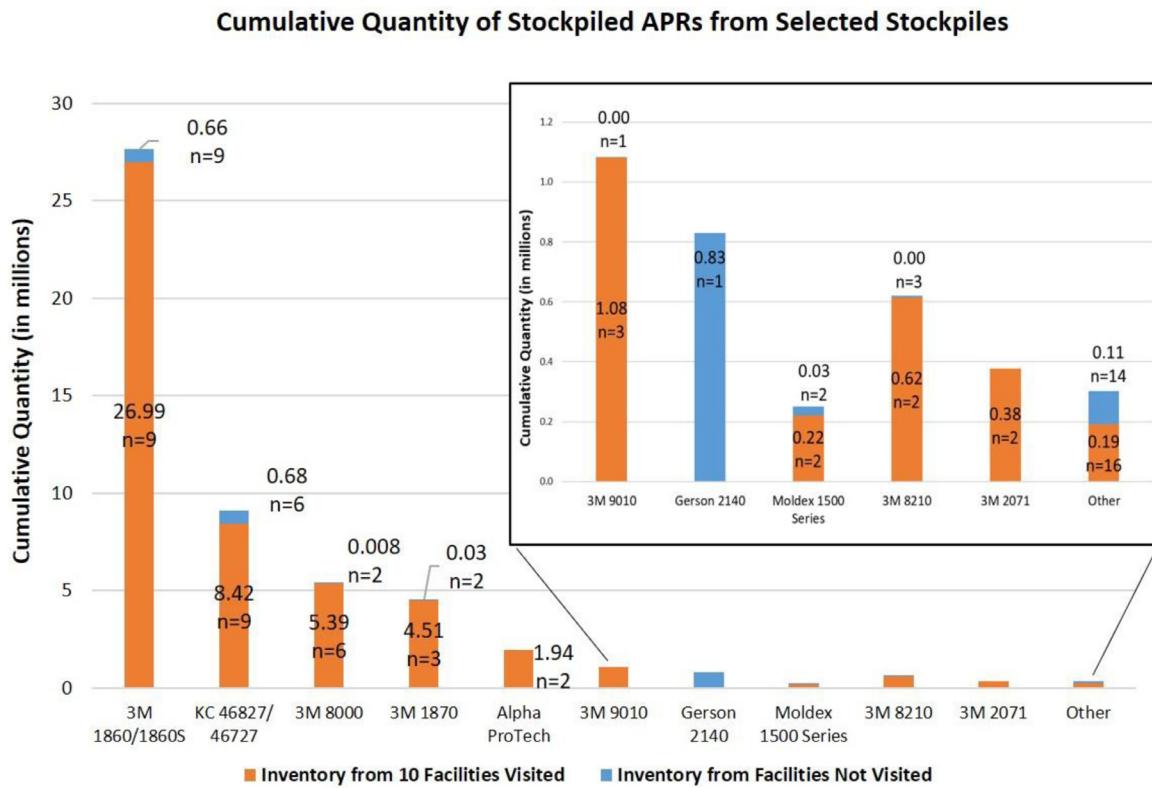


Fig. 4. Cumulative quantities of APRs across 20 stockpiles that provided detailed inventories; on top of bar, n = x refers to the number of stockpile facilities that currently stockpile this model.

specific times of the year. Other stockpile facilities did not have the technology in place to continuously monitor or regulate temperature and %RH and were located in geographic regions likely to experience temperature and humidity extremes. This combination of circumstances resulted in frequent deviations from ideal storage conditions over time. Where facilities did not actively monitor temperature and humidity, NIOSH researchers left data loggers to log temperature and humidity values every hour for 1 year.

Stockpiled APR inventory information

When selecting the stockpile sites for inclusion in the next phase of this study (ie, testing sampled APRs and gowns), it was important to identify collaborating sites with disparate conditions and APR and Level 3 and 4 surgical gown inventories that were consistent with the inventories at other sites. General inventory information (eg, manufacturer/model) was provided from stockpile managers representing 29 stockpiles, with thirty-one¹ different APR models stored across these stockpiles. Out of the 31 models, 3 models were elastomeric half facepieces for use with P95 cartridges, one model was a P95 filter cartridge, and the remaining 27 were N95 filtering facepiece respirators. Detailed inventory information was provided for 20 of these 29 stockpiles—for example, years in storage, quantity, and/or expiration date (if applicable).

The detailed inventory data from these 20 stockpiles, accounting for approximately 53 million APRs, were aggregated. Figure 4 shows these APRs broken down by model and quantity with inventory data from the 10 stockpiles visited by NPPTL researchers noted. Across the entire dataset, the most frequently reported APR models were the 3M 1860/3M 1860S (~52%), Kimberly Clark (KC) 46827/46727

(~17%), and the 3M 8000 (~10%). Ninety-five percent of the APR inventory was captured by 22 product models, all of which were found in at least 1 of the 10 stockpiles visited by NIOSH researchers. Other APR models existed at 14 of the stockpiles and included other 3M and KC models as well as models manufactured by Gerson, Moldex, North², Sperian/Willson, and Cardinal Health.³ Less than 1% of the APR models were elastomeric half facepiece respirators (n = 69,072) and included the 3M 6100, 3M 6200, and the 3M 6300—the corresponding 3M 2071 P95 cartridge filters for these elastomeric half facepiece respirators (n = 377k) were also stockpiled.

Looking at the aggregated dataset, only 12 stockpile managers provided information related to storage time. Of these 12 stockpiles, less than 1% (n = 88.1k) of the cumulative APR inventory were stored ≤ 5 years of storage, 69% (n = 35.8 million) were stored for 5–10 years, and 26% (n = 13.9 million) were stored for ≥ 10 years.

Stockpiled surgical gown inventory information

Limited inventory data was available for surgical gowns. Of the 29 stockpile managers who provided inventory information, only 15 facilities indicated that they stockpiled Level 3 and/or Level 4 surgical gowns but only 10 of these 15 stockpile managers provided detailed quantity and/or storage time information. Five different gown products were represented once model numbers distinguishing different sizes (eg, L or XL) are combined:

- 1) Medline Proxima Aurora Level 3—most frequent (92%; n = 87,074, and 7 stockpiles) with storage times of 0–5 years (one stockpile), 5–10 years (3 stockpiles), and ≥ 10 years (3 stockpiles)

² Currently owned by Honeywell.

³ Not currently a NIOSH-approved respirator manufacturer.

¹ These models are currently NIOSH-approved at time of publishing.

- 2) Cardinal Health Astound Level 3—second most frequent (7.8%, n = 7.4k, and 4 stockpiles) with storage times of 5–10 years (1 stockpiles) and ≥10 years (3 stockpiles)
- 3) Cardinal Health Microcool Level 4—one stockpile with 84 gowns and a storage time of 0–5 years
- 4) KC Ultra Level 3—one stockpile with unknown quantities and for unknown storage times.
- 5) Medline Prevention Plus (no Level claimed by manufacturer)—one stockpile with unknown quantities and a storage time of 0–5 years; manufacturer did not claim an American National Standards Institute/Association for the Advancement of Medical Instrument PB70 Level but claims the gown material passes the American Standards Testing and Material F1671, which is commonly associated with the Level 4 gown classification²⁴

All but the KC Ultra surgical gowns were stored in at least 1 of the 10 stockpiles visited.

DISCUSSION

The performance reliability over time of PPE stockpiled in the United States is a significant health security concern that must be addressed through empirical data that informs the activities and actions of policymakers, product makers, and stockpile managers. However, before obtaining the desired empirical data, NIOSH sought to understand (1) the PPE types that should be a priority for the empirical study, (2) stockpile sites for inclusion in the study such that the study findings support broader policy discussions, (3) common US stockpile environmental conditions, and (4) common US stockpile APR and surgical gown inventories.

Working with a variety of emergency response stakeholders 39 different stockpiles were involved in providing information related to stockpile location, inventory, or environmental conditions. Through its PPE Stockpile Partnership, consisting of representatives from 21 different government and nongovernment entities, NIOSH determined that APR and surgical gowns were the most appropriate PPE types for which inventory and aging viability information was desired.

Additionally, using (1) geographical dispersion, (2) variability in type of stockpile (eg, local, state, or federal), and (3) a 3-level stratified sampling method based on the likelihood that a facility would meet manufacturer-recommended temperature and %RH conditions, NIOSH was able to collect detailed documentation regarding the environmental conditions for a highly diversified convenience sample of 10 stockpiles. Further exploring these 10 stockpiles, NPPTL identified that their respirator and surgical gown inventories (model and storage time) were largely inclusive of the models and storage times observed across the complete sample of stockpiles included in this study that provided inventory information. If an APR has a shelf life, it is commonly 5 years, thus many of the stockpiled respirators identified were past their manufacturer-designated shelf life. In consultation with the NIOSH PPE Stockpile Partnership, it was determined that sampling, testing, and evaluating respirators and surgical gowns from these 10 stockpiles would provide policymakers, product makers, and stockpile managers with empirical data that was actionable.

Considerable variance was found in relation to stockpile storage conditions. This is not surprising given the lack of clear guidance and limitations in sharing stockpiling practices between facilities. A lack of clear and succinct guidance on best storage practices is likely due to factors such as products designed for routine use and not long-

term storage, no regulations or standards related to long-term storage exist, and there is a lack of empirical evidence that examines the influence of different types of storage conditions on the protective performance of PPE over time. Thus, it is generally unclear how temperature and humidity levels that consistently deviate from manufacturer recommendations within stockpiles influence PPE performance, such as the filtering efficiency of respirators after prolonged storage. An important step in defining best storage practice guidance for stockpile managers is, therefore, completion of an empirical study designed to examine the influence of various storage conditions on PPE performance over time.

CONCLUSIONS AND NEXT STEPS

The 10 facilities visited in this study provide empirical data regarding common PPE inventories and storage conditions that may provide generalizable and important conclusions for policymakers, product makers, and stockpile managers on which to base actions. This is the first study to identify common PPE stockpiled across a variety of levels of oversight, including federal, state, and local governments. The aggregated inventory from 20 stockpiles resulted in information for approximately 53 million respirators, comprised of 38 different APR models. The most common respirator stockpiled within this dataset included the 3M 1860/1860S and the KC 46827/46727. The most common surgical gown stockpiled within this dataset was the Medline Proxima Aurora Level 3. Where storage time information was available, most respirators (69% or 35.8 million) have been stored between 5 and 10 years. Many of the participating stockpile managers were interested in PPE inventory and stockpiling practices of other agencies.

The described effort was the foundation to support the testing and evaluation of stockpiled APRs and Level 3 and 4 surgical gowns sampled from the ten facilities identified in this study. These findings without interpretations can be found on NIOSH's PPE CASE Report website.²³ Detailed analyses between the associations of stockpile environmental conditions and PPE performance will be discussed in future publications that will provide stockpiling policy and practice recommendations to stakeholders and product manufacturers.

DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.ajic.2020.07.010>.

References

1. National Institute for Occupational Safety and Health (NIOSH). *Healthcare Workers*. 2014. Available at: <https://www.cdc.gov/niosh/topics/healthcare/default.html>. Accessed April 29, 2020.
2. Centers for Disease Control and Prevention (CDC). Information on Avian influenza 2016 [updated October 31, 2016]. Available at: <https://www.cdc.gov/flu/avianflu/>. Accessed April 29, 2020.
3. Centers for Disease Control and Prevention (CDC). *Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care facilities*. 1994, [1994/10/02: 54242-303]. Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/00035909.htm>. Accessed April 29, 2020.
4. Lenhart SW, Schafer MP, Singal M, Hajjeh RA. Histoplasmosis – protecting workers at risk. *Center Dis Control Prev*. 2004. Available at: https://www.cdc.gov/niosh/docs/2005-109/pdfs/2005-109.pdf?id=10.26616/NIOSH_PUB_2005109. Accessed April 28, 2020.

5. Mills JN, Corneli A, Young JC, Garrison LEG, Khan AS, Ksiazek TGK. Hantavirus pulmonary syndrome—United States: updated recommendations for risk reduction. *MMWR*. 2002;51:1–12.
6. Centers for Disease Control and Prevention (CDC). *Updated Interim Infection Control And Exposure Management Guidance In The Health-Care And Community Setting For Patients With Possible Monkeypox Virus Infection*. Department of Health and Human Services; 2003:1–4.
7. Centers for Disease Control and Prevention (CDC). Monkeypox. Atlanta, GA: CDC; 2015. Available at: <https://www.cdc.gov/poxvirus/monkeypox/>. Accessed April 28, 2020.
8. National Institute for Occupational Safety and Health (NIOSH). *Understanding respiratory protection against SARS: centers for disease control and prevention (CDC)*. 2012. Available at: <https://www.cdc.gov/niosh/nppi/topics/ respirators/factsheets/respsars.html>. Accessed April 28, 2020.
9. Patel A, D'Alessandro MM, Ireland KJ, Burel WG, Wencil EB, Rasmussen SA. Personal protective equipment supply chain: lessons learned from recent public health emergency responses. *Health Security*. 2017;15:244–252.
10. Department of Health and Human Services (DHHS). *An HHS Retrospective on the 2009 H1N1 Influenza Pandemic to Advance All Hazards Preparedness*. Department of Health and Human Services (DHHS); 2012. Available at: <https://phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf>. Accessed April 28, 2020.
11. Beckman S, Materna B, Goldmacher S, et al. Evaluation of respiratory protection programs and practices in California hospitals during the 2009–2010 H1N1 influenza pandemic. *Am J Infect Control*. 2013;41:1024–1031.
12. ASTHO. *Federal Emergency Preparedness Directives and Systems. Emergency Authority and Immunity Toolkit*. Association of State and Territorial Health Officials; 2013. Available at: www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Authority-and-Immunity-Toolkit/Federal-Emergency-Preparedness-Directives-and-Systems-Fact-Sheet/. Accessed April 28, 2020.
13. U.S. Response to Disasters and Public Health Emergencies - Section 3: U.S. Disasters Preparedness and Response Legislation. Available from U.S. National Library of Medicine, National Institutes of Health. Available at: https://disasterinfo.nlm.nih.gov/dimrc/dis_courses/us_response/03-000.html. Accessed April 28, 2020.
14. Lister SA. *An Overview of the US Public Health System in the Context of Emergency Preparedness*. Library of Congress. Washington DC: Congressional Research Service; 2005. Available at: <http://congressionalresearch.com/RL31719/document.php>. Accessed April 28, 2020.
15. Radonovich LJ, Magalian PD, Hollingsworth MK, Baracco G. Stockpiling supplies for the next influenza pandemic. *Emerg Infect Dis*. 2009;15:e1.
16. Rottach DR, Lei Z. Stockpiled N95 filtering facepiece respirator polyisoprene strap performance. *J Int Soc Respir Prot*. 2017;34:69–80.
17. National Institute for Occupational Safety and Health. *PPE case: testing of stockpiled ANSI/AAMI PB70 level 4 surgical gowns*. 2017. Available at: <https://www.cdc.gov/niosh/nppi/pdfs/FINAL-PPE-CASE-7-17-17-508.pdf>. Accessed April 28, 2020.
18. National Institute for Occupational Safety and Health. *PPE case: testing of stockpile ANSI/AAMI PB70 level 3 surgical gowns*. 2018. Available at: <https://www.cdc.gov/niosh/nppi/ppecase/pdfs/PPE-CASE-P2018-0104-508.pdf>. Accessed April 28, 2020.
19. National Academies of Sciences, Engineering, and Medicine. *The Nation's Medical Countermeasure Stockpile: Opportunities to Improve the Efficiency, Effectiveness, and Sustainability of the CDC Strategic National Stockpile: Workshop Summary*. Washington, DC: The National Academies Press; 2016.
20. Pyrek K. PPE utilization in a pandemic: more research needed to fuel preparedness. *Infect Control Today*. 2014;March 2014:1–26.
21. U.S. Food and Drug Administration. *Medical Gowns*. 2018. Available at: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospital-DevicesandSupplies/PersonalProtectiveEquipment/ucm452775.htm>. Accessed April 28, 2020.
22. Effect of stockpiling conditions on the performance of medical N95 respirators and high-level protective surgical gowns. *Federal Register Notice*. 2017;82. Available at: <https://www.cdc.gov/niosh/docket/review/docket297/pdfs/2017-05896.pdf>. Accessed April 27, 2020.
23. Greenawald L, Moore S, Yorio P. *NIOSH PPE CASE Report: Inhalation and Exhalation Resistance and Filtration Performance of Stockpiled Air-Purifying Respirators: Overall Performance of Nearly 4,000 Respirators Sampled from Ten Stockpile Facilities*. Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; 2020. Available at: <https://www.cdc.gov/niosh/nppi/ppecase.html>. Accessed June 30, 2020.
24. NIOSH Personal Protective Equipment Information (PPE-INFO). *ANSI/AAMI PB70-Class 3*. 2019, September 5. Available at: <https://www.cdc.gov/PPEInfo/Standards/Info/ANSI/AAMIPB70Class3>. Accessed April 28, 2020.