

QUALITY ASSURANCE SAMPLING PLANS IN US STOCKPILES FOR PERSONAL PROTECTIVE EQUIPMENT: A COMPUTER SIMULATION TO EXAMINE DEGRADATION RATES

Mitchell T. Dubaniewicz, Dana R. Rottach, and Patrick L. Yorio

Medical countermeasure stockpiles in the United States are designed to support healthcare workers and the public during public health emergencies; they include supplies of personal protective equipment (PPE). As part of typical PPE manufacturing processes, appropriate test methods are used to ensure that the devices provide adequate protective performance. At the time of manufacture, performance is often measured and weighed against an objective standard of quality, resulting in a pass or fail attribute being assigned to individual PPE items and thence to production lots. Incorporating periodic performance testing for stockpiled PPE can ensure that they maintain their protective qualities and integrity over time while in storage. There is an absence of guidance regarding how to design quality assurance programs for stockpiled PPE. The applicability of the Lot Quality Assurance Sampling (LQAS) approach to stockpiled PPE was examined in a previous study that compared and contrasted different sample sizes in recovering the true percentage of defective units in large lots in the LQAS framework. The current study carries this line of inquiry forward by integrating PPE degradation over time and comparing different sampling time intervals in recovering the true underlying degradation rate. The results suggest that product degradation is more easily detected when tested at shorter time intervals and for higher degradation rates. They further suggest that sampling interval groupings can be made based on the proficiency with which they recover the true underlying degradation rate.

Keywords: Personal protective equipment, Stockpile, Countermeasures

IN THE UNITED STATES, stockpiles of medical supplies and equipment at the federal, state, and local levels were created with funding and initiatives associated with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.¹ Since then, large volumes of personal protective equipment (PPE) have been acquired. PPE such as respirators, surgical gowns, and gloves are intended

to protect healthcare and emergency responders from the hazards of caring for individuals with contagious diseases and contain the spread of such diseases.²⁻⁴ Predictions of the amount of PPE and the rate at which it will be needed during a public health emergency suggest that PPE consumption will exceed the amount of product that manufacturers can produce.^{3,5-14} Therefore, millions of units of

Mitchell T. Dubaniewicz is a student researcher, Department of Bioengineering, Swanson School of Engineering, University of Pittsburgh, and was on assignment with CDC/NIOSH/NPPTL. Dana R. Rottach, PhD, is a Physical Scientist, and Patrick L. Yorio, PhD, is a Health Statistician; both at the National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Pittsburgh, PA.

PPE are stored across the country in readiness for rapid response in facility-level and public health (local, state, federal) stockpiles.

While it is reasonable to assume that PPE provided through the normal supply chains will give the promised protection, component materials may degrade while in a stockpile.¹⁵⁻²² An example is the commonly stockpiled N95 filtering facepiece respirator (FFR), recommended for protection against a variety of hazards that may be faced during public health emergencies. Most N95 FFRs incorporate filtering media embedded with electrostatic charges. The embedded electrostatic charge may dissipate during extended stockpiling, thereby potentially decreasing the filtration efficiency.^{21,23-25} Thus, stockpiled N95 FFRs, as well as other PPE, may degrade to an unacceptable level while in the stockpile, at a rate influenced by variations inherent in varying designs, materials of construction, materials used in packaging, and stockpile storage conditions.

Given the likelihood of long-term storage, the potential for degradation, and the possible lack of control over storage conditions, many PPE manufacturers provide shelf-life and expiration guidelines. However, when stored in a suitable environment, stockpiled products may be effective well beyond their labeled expiration dates, and development of a suitable shelf-life extension program would be beneficial.

Unsubstantiated stockpile testing schemes may prove unnecessarily expensive. In addition to the costs of performing the tests and the PPE used in the testing, over-testing without careful sampling plan design may lead to discarding an excessive number of relatively good lots due to sampling variation.²⁶

In a previous study, we examined the applicability of a Lot Quality Assurance Sampling (LQAS) approach to stockpiled PPE and posited it as a mechanism to manage the quality of stockpiled PPE over time and potentially realize a PPE-specific shelf-life extension program.²⁷ Given the potential stability of PPE when stored in a suitable environment, our previous article compared and contrasted different sample sizes in terms of their ability to accurately estimate a *fixed* true quality level over a restricted number of samples. However, in light of the potential for PPE to degrade over time, true levels of lot quality can be dynamic and a potentially moving target. Identifying stockpiled PPE that are degrading, and accurately identifying the rate of degradation, may be a desirable component to a stockpiled PPE LQAS. For example, degradation of numerous models and lots in a localized area in the stockpile may indicate localized storage conditions that are less than adequate. Additionally, identification of unacceptable levels of degradation in a single model and/or a single lot can allow for targeted recycling, thereby limiting waste.

Therefore, questions remain regarding how often sampling should be done in order to detect degradation processes and to estimate the rate at which the PPE is

degrading. The current study addresses this missing piece by integrating PPE degradation over time and comparing the consistency of different sampling time intervals in recovering the simulated degradation rate. The primary research questions of the current study are:

1. Can repeated performance testing of PPE samples detect degradation in stockpiled PPE?
2. Do the trends seen over repeated sampling accurately reflect the rate of degradation?
3. Do different time intervals of repeated performance testing differ in terms of the proficiency with which they recover the degradation rate?

METHODS

Computer Simulation

The research questions posed were answered through a series of statistical simulations. The study used a computer simulation to “create” batches of stockpiled PPE over the course of their lifetime with known quality levels at each stage in their life cycle. It also allows for the simulated PPE samples to be sampled to determine if the parameters that were “created” can be recovered. This technique makes it possible to vary applicable quality parameters (ie, the actual percent of passing units in a lot and the rate at which that percent declines as degradation occurs over time) and create real-life stockpile contexts. A common desktop mathematical software package, *R* version 3.5.0, was used to conduct the simulation and analyze the results.²⁸ The steps taken in the simulation are briefly summarized in Figure 1.

In order to integrate PPE degradation over time, lots or batches of stockpiled PPE were created and tracked over the course of their lifetime. Lots over time were simulated through the use of sets containing the total number of PPE items out of lots of 100,000 that would pass a performance test. A set for each degradation parameter was generated, containing entries for the true number of passing units every month over a 100-year lifespan. At year zero, all PPE in each lot were considered to have “passed” an applicable performance test (eg, the tests used by NIOSH for respirator certification or the tests designated by the FDA for clearing surgical or isolation gowns). At subsequent times, a proportion of the lot was set to “fail” the performance test. In total, 9 different linear degradation rates were simulated in which a fixed number of additional units become defective each year. These rates were 0.01%, 0.05%, 0.1%, 0.25%, 0.5%, 1.0%, 2.0%, 5.0%, and 10% and corresponded to an additional 10, 50, 100, 250, 500, 1,000, 2,000, 5,000, and 10,000 units becoming defective every year. The choice of using a linear degradation model was made for conceptual simplicity. Exponential degradation was also modeled as a comparison, but other forms of nonlinear degradation could have been selected instead.

1. Generate the true number of passing PPE for every month over 100 years based on a true 0.01% linear degradation rate.
2. Take 32 random samples every month.
3. Perform linear regressions of sample pass percentage vs. time over the first 5, 10, and 15 years to get standardized regression coefficients that approximate the true degradation rate.
4. Repeat steps 2 and 3 for 150 separate trials.
5. Calculate the mean and variance of the standardized regression coefficients for the first 10 years.
6. Calculate the number of trials in which no degradation was detected (i.e. the standardized regression coefficient was ≥ 0) for the first 5 and 15 years.
7. Repeat steps 2-6 using sampling intervals of 3 months, 6 months, 9 months, 1 year, 2 years, 3 years, 4 years, 5 years, and 10 years.
8. Repeat steps 1-7 using 0.05%, 0.1%, 0.25%, 0.5%, 1.0%, 2.0%, 5.0%, and 10% true linear degradation rates.
9. Repeat steps 1-8 using true exponential rates.
10. Statistically compare the variances of the standardized regression coefficients across the 10 different sampling intervals for linear degradation rates of 0.25%, 1.0% and 5.0%.

Figure 1. Simulation Steps

Once these series of sets were created to represent the PPE lots with known degradation rates over the course of their lifetime, it was then possible to collect random samples from them over time. Sampling time intervals of 1 month, 3 months, 6 months, 9 months, 1 year, 2 years, 3 years, 4 years, 5 years, and 10 years were examined. Although some of the time intervals examined are not likely to

be selected for use in actual stockpiles, they were chosen for comparison purposes. A fixed sample size of 32 PPE units was selected to be used for each sample. As such, 32 random numbers from the lot of 100,000 (representing single units of PPE) were selected from each designated time point with replacement. The sample fail rate was then computed according to Equation 1:

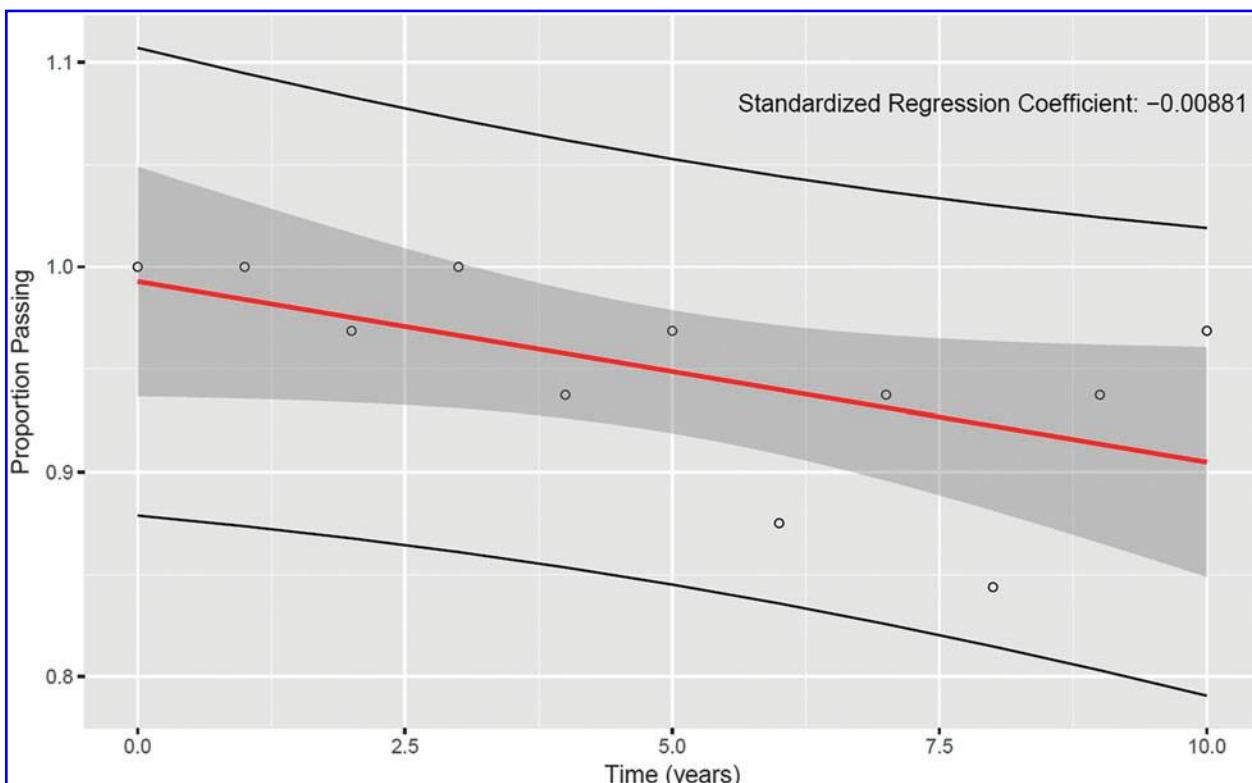


Figure 2. An example linear regression over 10 years for yearly sampling intervals and 1.0% linear degradation rate

$$\hat{p} = \frac{x}{n}, \quad (1)$$

where \hat{p} is the observed sample fail rate, x is the number of PPE items that failed in the sample, and n represents the sample size (ie, the total number of PPE items contained in each sample—in this case, 32). A linear regression of the sample fail rates for each time interval was computed for each simulated lot. This process was iterated 150 times. Thus, 150 distinct trials were conducted for each parameter in the study, and trends across these trials could be used for the analysis designed to answer the research questions.

RESULTS

Detecting and Determining Degree of Degradation

In response to the first research question posed, concerning the utility of periodic testing, the results of the simulation suggest that repeated performance testing of PPE samples can detect degradation in stockpiled PPE, but it depends on the time interval of repeated testing along with the magnitude of the degradation. In order to examine this research question, linear regressions were performed on sample results over a 15-year period. For each individual trial, the percent of PPE passing for each sample was used as the dependent variable, and time was used as the independent variable. The standardized regression coefficients, or slopes of the fitted lines, directly measured the predicted degradation rate. Because each lot was simulated to degrade over time, the measured pass rate would be expected to decrease in consecutive samples, and a negative regression slope should result. A negative regression slope in any given trial of repeated testing, therefore, suggests that the simulated degradation was detected. A slope of zero, or a positive slope, would denote a trial in which there was no detection of any degradation—even though degradation did exist. This does not necessarily mean that no defective units were found, but rather that linear regression did not find a consistent increase in defective units over time. These failures to detect the applied degradation could be considered “false negatives”—in other words, testing did not discern the decrease in the quality of the lot. If the entire lot were tested at each time, the regression slope would recover the degradation rate applied to the lot. For smaller samples, variability due to sampling will affect the accuracy of the recovered slope. Figure 2 provides an illustration of one of the regressions derived from the study in which a negative standardized regression coefficient was found.

Table 1 reports the number of trials out of 150 in which sampling failed to detect degradation for specific sampling intervals, denoted by the rows, and the true linear degradation rate, denoted by the columns. This table clearly shows that degradation is detected more often as the sam-

pling interval gets smaller and the true degradation rate increases.* For the degradation rates of 2% and higher, each of the sampling intervals was able to “see” the lot degradation through sample-to-sample trends in every trial. When degradation was very low, it was undetectable by most sampling intervals. For example, the 0.01% degradation was not detected in some trials for each of the sampling intervals studied. This is partially a symptom of the duration of time examined. The 0.01% annual degradation lot results in an additional 10 failing units every year for the 100,000-item lot. At the end of the regression period—15 years—the 0.01% annual degradation results in only 150 failing items in the entire lot after 15 years, a 0.15% failure or 99.85% pass rate in the lot after aging. Hence, the lack of degradation detection is not automatically concerning for this low degradation rate considering the very small amount of degradation over just 15 years.

*Several variations to the simulation, which are not reported, were performed as robustness checks. In one, an initial stockpile percent passing of 80% was used instead of the assumption that all PPE would pass testing at time zero. Such an assumption is slightly biased toward “detection” through finding a negative slope due to the first sample’s being fixed at 32/32 passes. The heteroscedasticity resulting from the impossibility of sampling higher than 100% passing was mostly avoided by lowering the initial percent passing far enough to allow room for sampling variability above the true pass percent. As expected, the trials in which no degradation was detected were more numerous across the board in this simulation. Also of note, breaking down no degradation detected into standardized regression coefficients of zero and positive values, the 80% initial percent passing simulation resulted in many more positive values, but fewer zero values. However, the same patterns of detection regarding the effect of sampling intervals and degradation rates were still strongly shown.

In another variation to the simulation, the sample size taken at any given time point was adjusted (2, 6, 12, 18, 24, 48, 72, 96, 120, and 240) for each sampling interval (1 month, 3 months, 6 months, 9 months, 1 year, 2 years, 3 years, 4 years, 5 years, and 10 years) so that the total number of individual units sampled would be equal over the examined period of time, regardless of sampling interval. In this version, the degradation was still detected more often as the true degradation rate increased, but the relationship between detection and the sampling intervals disappeared. This suggests that the timing of sampling may be less important than the number of samples tested over the period, although more frequent sampling would presumably be better for detecting sudden changes in the overall quality of a lot not seen in the constant linear degradation rates simulated. It should also be considered that changing the individual sampling sizes in this version of the simulation confounds the sampling intervals with the effects of different inherently discrete probability distributions associated with sampling different sizes. For example, when only 2 samples are taken monthly, there are only 3 possible outcomes: 0%, 50%, and 100% pass rate. There are 241 possible outcomes for the corresponding sample size for the 10-year interval in this simulation.

Table 1. Number of times simulation did not detect degradation (the “false negatives” described in the text) in 150 trials over 15 years for various sampling intervals and true linear degradation rates

Sampling Interval	Degradation Rate									
	-0.01%	-0.05%	-0.1%	-0.25%	-0.5%	-1%	-2%	-5%	-10%	
1 month	16	0	0	0	0	0	0	0	0	0
3 months	59	3	0	0	0	0	0	0	0	0
6 months	84	20	6	1	0	0	0	0	0	0
9 months	107	31	10	1	0	0	0	0	0	0
1 year	122	46	16	3	0	0	0	0	0	0
2 years	133	72	46	17	0	0	0	0	0	0
3 years	136	84	49	14	2	0	0	0	0	0
4 years	134	113	90	32	6	1	0	0	0	0
5 years	142	103	74	16	5	0	0	0	0	0
10 years	144	127	110	73	35	5	0	0	0	0

Worth considering, however, is the potential impact of degradation rates that some sampling intervals effectively recover while others do not. For example, a linear annual degradation rate of 0.25% results in an additional 250 PPE items failing each year from the lot. Over the course of the 15-year period, this adds up to 3,750 defective PPE items out of the lot. Depending on the type of PPE and the intended use, this level of degradation can be consequential. Therefore, it may be important to consider that the linear regression on annual sampling detected this level of degradation in 98% of the trials, with only 3 false negatives out of 150 trials, as seen in Table 2. This can be compared to 89% of the trials when samples are taken every 2 years (17 false negatives out of 150 trials) and 79% of the trials when sampling is done every 4 years (with 32 false negatives).

Table 2 presents linear regressions over the first 5 years (instead of 15 as seen in Table 1). As with the 15-year period shown in Table 1, degradation is detected more often with smaller sampling intervals and higher true degradation rates. But with less data gathered over time and higher true pass percentages at the end of the period, it is not surprising that the number of trials in which no degradation was detected generally increased for each sampling

interval considered. Still, a sampling interval of 1 year and a linear degradation rate of 1%, both values in the middle of the ranges examined, resulted in just 6 out of 150 trials failing to detect degradation, or a 96% detection success rate. It should also be noted that degradation cannot be detected on a 5-year period for the 10-year sampling interval, since this interval includes only the initial sample set, with no testing of degraded samples.

Having shown that degradation can be detected through repeated sampling of PPE stockpiles, it follows to examine how well the degradation rates recovered through sample-to-sample trends conform to the specified rates. Table 3 contains the mean standardized regression coefficients for regressions performed over a 10-year period across 150 trials for each sampling interval and linear degradation rate. The values are all close to the true degradation rate simulated for each lot. In practical terms, when using repeated testing as a component of a stockpiled PPE LQAS, this finding suggests that the sample-to-sample trends seen (ie, the difference in the proportion passing from sample to sample) can be used to estimate the underlying degradation rate with some degree of confidence. Higher confidence can be placed in sampling intervals that consistently recovered

Table 2. Number of times simulation failed to detect degradation in 150 trials over 5 years for various sampling intervals and true linear degradation rates

Sampling Interval	Degradation Rate									
	-0.01%	-0.05%	-0.1%	-0.25%	-0.5%	-1%	-2%	-5%	-10%	
1 month	105	33	9	0	0	0	0	0	0	0
3 months	132	80	54	9	3	1	0	0	0	0
6 months	139	103	75	31	13	1	0	0	0	0
9 months	146	122	105	62	44	6	4	0	0	0
1 year	146	125	100	56	23	6	0	0	0	0
2 years	147	139	121	95	53	23	3	0	0	0
3 years	149	141	137	118	104	61	21	1	0	0
4 years	149	143	132	112	77	32	12	1	0	0
5 years	146	134	123	100	62	29	7	0	0	0
10 years	150	150	150	150	150	150	150	150	150	150

Table 3. Mean standardized regression coefficients in 150 trials over 10 years for various sampling intervals and true linear degradation rates

Sampling Interval	Degradation Rate								
	-0.01%	-0.05%	-0.1%	-0.25%	-0.5%	-1%	-2%	-5%	-10%
1 month	-0.01%	-0.05%	-0.10%	-0.26%	-0.49%	-0.99%	-1.99%	-4.98%	-10.00%
3 months	-0.01%	-0.05%	-0.11%	-0.26%	-0.49%	-0.98%	-2.02%	-4.97%	-9.97%
6 months	-0.01%	-0.06%	-0.09%	-0.25%	-0.48%	-1.03%	-2.03%	-4.98%	-10.02%
9 months	-0.01%	-0.05%	-0.11%	-0.25%	-0.49%	-1.04%	-2.02%	-4.97%	-10.03%
1 year	-0.01%	-0.05%	-0.10%	-0.24%	-0.47%	-1.01%	-1.96%	-4.94%	-9.96%
2 years	-0.01%	-0.05%	-0.10%	-0.24%	-0.55%	-1.03%	-2.06%	-5.03%	-10.01%
3 years	-0.01%	-0.05%	-0.10%	-0.23%	-0.52%	-0.89%	-1.94%	-5.09%	-10.07%
4 years	-0.02%	-0.05%	-0.08%	-0.23%	-0.57%	-0.98%	-1.96%	-4.95%	-9.92%
5 years	0.00%	-0.05%	-0.09%	-0.24%	-0.47%	-1.06%	-1.95%	-5.00%	-10.00%
10 years	-0.01%	-0.05%	-0.09%	-0.23%	-0.49%	-0.99%	-2.07%	-4.96%	-10.00%

Table 4. Pairwise comparisons of the regression coefficient variances across 150 trials of different sampling intervals. Groupings of intervals with visually similar features are separated with dashed lines

		P Value from Levene's Test for Difference in Variance Within Regression Coefficients Across 150 Trials							
Degradation Rate	Sampling Interval	1 month	3 months	6 months	9 months	1 year	2 years	3 years	4 years
0.25%	1 month	—	—	—	—	—	—	—	—
	3 months	<0.01	—	—	—	—	—	—	—
	6 months	<0.01	<0.01	—	—	—	—	—	—
	9 months	<0.01	<0.01	0.08	—	—	—	—	—
	1 year	<0.01	<0.01	<0.01	0.35	—	—	—	—
	2 years	<0.01	<0.01	<0.01	<0.01	0.02	—	—	—
	3 years	<0.01	<0.01	<0.01	<0.01	<0.01	0.32	—	—
	4 years	<0.01	<0.01	<0.01	<0.01	<0.01	0.07	0.18	—
	5 years	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.41	0.08
1%	1 month	—	—	—	—	—	—	—	—
	3 months	<0.01	—	—	—	—	—	—	—
	6 months	<0.01	<0.01	—	—	—	—	—	—
	9 months	<0.01	<0.01	0.18	—	—	—	—	—
	1 year	<0.01	<0.01	<0.01	0.81	—	—	—	—
	2 years	<0.01	<0.01	<0.01	<0.01	<0.01	—	—	—
	3 years	<0.01	<0.01	<0.01	<0.01	<0.01	0.40	—	—
	4 years	<0.01	<0.01	<0.01	<0.01	<0.01	0.02	<0.01	—
	5 years	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.24
5%	1 month	—	—	—	—	—	—	—	—
	3 months	<0.01	—	—	—	—	—	—	—
	6 months	<0.01	<0.01	—	—	—	—	—	—
	9 months	<0.01	<0.01	0.65	—	—	—	—	—
	1 year	<0.01	<0.01	<0.01	0.02	—	—	—	—
	2 years	<0.01	<0.01	<0.01	<0.01	<0.01	—	—	—
	3 years	<0.01	<0.01	<0.01	<0.01	<0.01	0.32	—	—
	4 years	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.03	—
	5 years	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.23

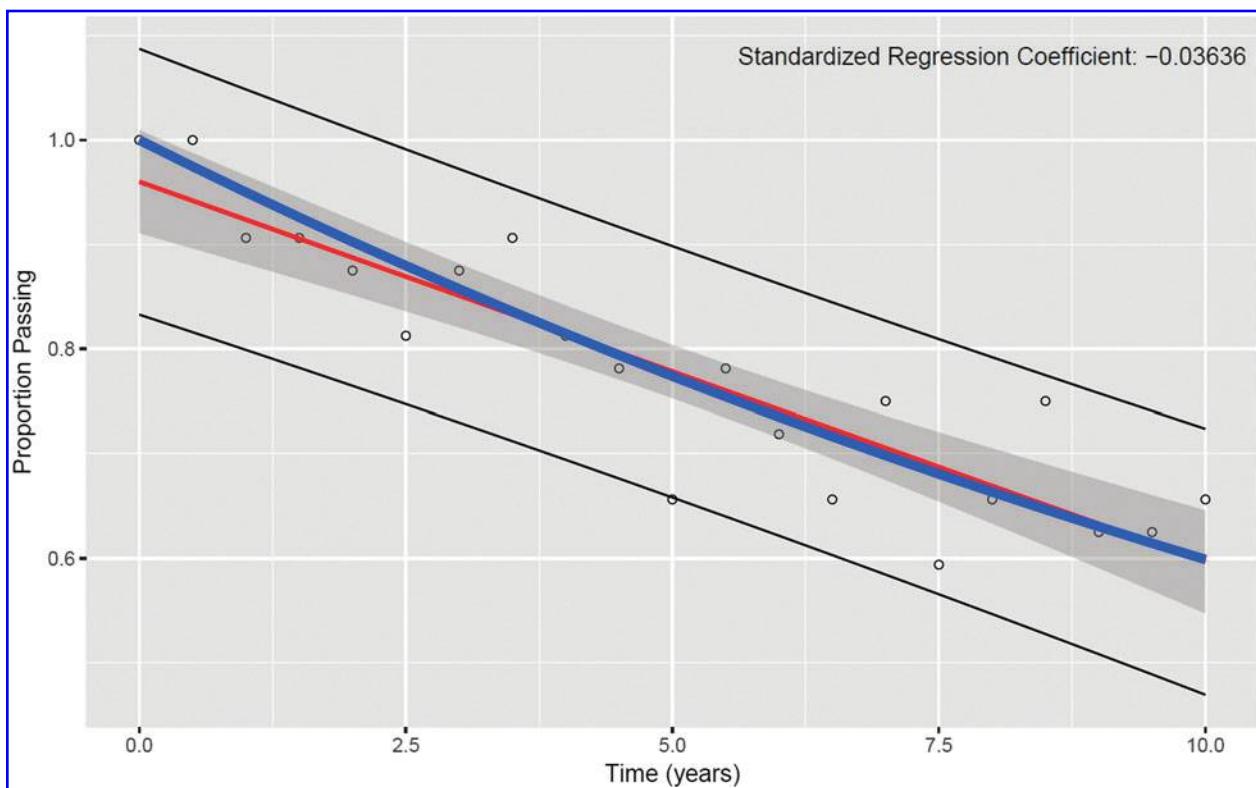


Figure 3. An example linear regression over 10 years for 6-month sampling intervals applied to an underlying exponential rate of 5.0%.

degradation across the simulated degradation rates (shown in Tables 1 and 2).

The third research question posed was whether different time intervals of repeated sampling differ in terms of the consistency with which they recover the true lot degradation rate. The answer to this research question is “yes”: Time intervals did differ in terms of the consistency with which they estimated the degradation rate in the lot. Greater consistency (ie, lower variance in the estimated degradation rate) would imply more confidence in the predicted degradation rate.

Table 4 reports the results of pairwise comparisons of the variances for the standardized regression coefficients taken from regressions over the first 10-year period for 150 trials of each sampling interval and linear degradation rates of 0.25%, 1.0%, and 5.0%. An informal visual inspection of the table suggested that rough groupings of testing time intervals displayed similar characteristics. Based on the pairwise comparisons of the variance in regression coefficients, the following time interval groupings emerged: Group 1: 6 months, 9 months, and 1 year; Group 2: 2 years and 3 years; and Group 3: 4 years and 5 years. These

Table 5. Number of times simulation failed to detect degradation in 150 trials over 15 years for various sampling intervals and true nonlinear degradation rates

Sampling Interval	Degradation Rate									
	-0.01%	-0.05%	-0.1%	-0.25%	-0.5%	-1%	-2%	-5%	-10%	
1 month	20	0	0	0	0	0	0	0	0	0
3 months	48	8	1	1	0	0	0	0	0	0
6 months	86	18	9	1	0	0	0	0	0	0
9 months	109	25	10	2	0	0	0	0	0	0
1 year	116	36	20	4	0	0	0	0	0	0
2 years	131	77	40	11	3	0	0	0	0	0
3 years	131	80	52	20	3	1	0	0	0	0
4 years	140	107	73	30	9	1	0	0	0	0
5 years	138	97	73	23	6	0	0	0	0	0
10 years	146	131	108	67	38	6	0	0	0	0

Table 6. Number of times simulation failed to detect degradation in 150 trials over 5 years for various sampling intervals and true nonlinear degradation rates

Sampling Interval	Degradation Rate								
	-0.01%	-0.05%	-0.1%	-0.25%	-0.5%	-1%	-2%	-5%	-10%
1 month	105	33	10	2	0	0	0	0	0
3 months	135	96	52	11	1	0	0	0	0
6 months	142	106	74	35	17	4	0	0	0
9 months	146	124	100	72	36	3	0	0	0
1 year	144	123	110	63	18	4	0	0	0
2 years	147	137	118	95	56	23	4	0	0
3 years	147	148	137	114	93	57	31	0	0
4 years	148	146	131	116	74	52	10	0	0
5 years	148	140	130	102	73	26	6	0	0
10 years	150	150	150	150	150	150	150	150	150

groupings are more pronounced in the 1.0% and 5.0% degradation rate contexts and suggest that there are similarities in consistency among the time intervals within the same group. They also suggest that some gains in reliability can be expected as the group number decreases. Omitted from the table, the time intervals of 1 month, 3 months, and 10 years produced unique reliability patterns and were not amenable to grouping with other time intervals.

Additional Analysis

As discussed, the primary research questions were answered using PPE lots that degrade in a linear fashion. Given the possibility that PPE degradation can be nonlinear, an exponential function was also used to set the degradation curve over time, and linear regressions were performed to predict a rate of degradation. Figure 3 depicts the results of this process for a particular trial.

Tables 5 and 6 report the same results as Tables 2 and 3, but with exponential degradation rates. The similar results suggest that degradation can still be detected and that similar patterns in sampling intervals hold for nonlinear degradation.

DISCUSSION

The fundamental purpose of stockpile quality assurance is to detect potential problems with the stored supplies arising from degradation, ideally before users are put at risk. Stockpile quality assurance programs must balance economy with the need for quality assurance. Over-testing can also lead to excessive discarding of relatively good PPE lots due to random sampling variability and, thus, can prove expensive and potentially wasteful, in both the costs of performing the tests and the number of PPE units used in the tests.

By contrast, in a well thought out quality assurance process, the costs associated with the early disposal and frequent

replacement of stockpiled equipment can be balanced against the costs of testing, while providing adequate evidence that stockpiled equipment will provide the expected level of protection when needed. The current study has shown that well-designed periodic testing schemes can detect degrading product in stockpiles before tolerable limits are exceeded, allowing better replacement planning in stockpile management.

With appropriate care, a stockpile quality tracking scheme—incorporating both current and prior testing results—could provide continued assurance of stockpile performance, improving confidence and economy over a single sample of LQAS testing results. The simulation presented here shows the ability of one such evaluation protocol. In many cases, trends observed in quantitative test results could be incorporated into continuing stockpile evaluations. Simulations such as the ones presented here could incorporate observed real-world degradation rates to further refine sampling rates and criteria. For instance, criteria could be developed to identify lots with testing results that significantly differ from the average, potentially allowing identification of poor storage conditions or other issues. A wide variety of PPE would need to be covered by a comprehensive stockpile monitoring protocol, and our work demonstrates that it is possible to develop such guidelines.

CONCLUSIONS

In this article and our previously published article,²⁷ we sought to provide evidence to determine if stockpiled PPE quality can be reasonably estimated by testing a single sample, to determine if repeated sampling can detect degradation, and to provide some initial guidance to stockpile managers in choosing between possible sample sizes and sampling intervals as they consider testing stockpiled PPE. The current study focused on determining the reliability of different time intervals in recovering rates of PPE lot

degradation. It was found that degradation can be seen through trends in repeated sampling over time. Time intervals, other than 1 month, 3 months, and 10 years, were broken into groups in terms of how reliably the actual degradation rates were predicted. Group 1—6 months, 9 months, and 1 year—was comprised of intervals that were similar and had the best reliability in recovering the true degradation rates, while Group 2 had less reliability and Group 3 had the least.

It is recognized that stockpile resource availability, the volume of PPE at individual stockpiles, and the number of lots per manufacturer/model can vary widely, and these parameters may heavily influence the time interval options appropriate for individual stockpiles. As such, the conclusions provided are not recommendations or guidelines, but rather information and tools to help inform stockpile managers when developing plans for testing the quality of their stockpiles. It is also recognized that the administration of an LQAS for stockpiled PPE can be costly and time consuming. However, the alternative—replacing massive amounts of expired, unused, and potentially good quality PPE—will be even more costly in many cases.

ACKNOWLEDGMENTS

The authors would like to acknowledge Dana Grau, Jeff Ballard, Joseph Reppucci, David Balbi, Ron Shaffer, and Mark Nicas for critical reviews of earlier versions of this manuscript. The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention. In addition, citations to websites external to NIOSH do not constitute NIOSH endorsement of the sponsoring organizations or their programs or products. Furthermore, NIOSH is not responsible for the content of these websites. All web addresses referenced in this document were accessible as of the publication date.

REFERENCES

1. Lister SA. *An Overview of the US Public Health System in the Context of Emergency Preparedness*. Washington, DC: Congressional Research Service; 2005. <https://fas.org/sgp/crs/homesec/RL31719.pdf>. Accessed June 14, 2019.
2. Esbitt D. The Strategic National Stockpile: roles and responsibilities of health care professionals for receiving the stockpile assets. *Disaster Manag Response* 2003;1(3):68-70.
3. Pyrek KM. PPE utilization in a pandemic: more research needed to fuel preparedness. *Infection Control Today* 2014.
4. Institute of Medicine; Board on Health Sciences Policy; Committee on Personal Protective Equipment for Healthcare Personnel to Prevent Transmission of Pandemic Influenza and Other Viral Respiratory Infections: Current Research Issues; Larson EL, Liverman CT, eds. *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel. Update 2010*. Washington, DC: National Academies Press; 2011.
5. Abramovich MN, Hershey JC, Callies B, Adalja AA, Tosh PK, Toner ES. Hospital influenza pandemic stockpiling needs: a computer simulation. *Am J Infect Control* 2017;45(3):272-277.
6. Carias C, Rainisch G, Shankar M, et al. Potential demand for respirators and surgical masks during a hypothetical influenza pandemic in the United States. *Clin Infect Dis* 2015; 60(Suppl 1):S42-S51.
7. Hashikura M, Kizu J. Stockpile of personal protective equipment in hospital settings: preparedness for influenza pandemics. *Am J Infect Control* 2009;37(9):703-707.
8. Jester BJ, Uyeki TM, Patel A, Koonin L, Jernigan DB. 100 years of medical countermeasures and pandemic influenza preparedness. *Am J Public Health* 2018;108(11):1469-1472.
9. Kaji AH, Lewis RJ. Hospital disaster preparedness in Los Angeles County. *Acad Emerg Med* 2006;13(11):1198-1203.
10. Murray M, Grant J, Bryce E, Chilton P, Forrester L. Facial protective equipment, personnel, and pandemics: impact of the pandemic (H1N1) 2009 virus on personnel and use of facial protective equipment. *Infect Control Hosp Epidemiol* 2010;31(10):1011-1016.
11. Radonovich LJ, Magalian PD, Hollingsworth MK, Baracco G. Stockpiling supplies for the next influenza pandemic. *Emerg Infect Dis* 2009;15(6):e1.
12. Reidy M, Ryan F, Hogan D, Lacey S, Buckley C. Preparedness of hospitals in the Republic of Ireland for an influenza pandemic, an infection control perspective. *BMC Public Health* 2015;15(1):847.
13. Rebmann T, McPhee K, Haas GA, et al. Findings from an assessment and inventory of a regional, decentralized stockpile. *Health Secur* 2018;16(2):119-126.
14. World Health Organization. *Avian Influenza, Including Influenza A (H5N1), in Humans: WHO Interim Infection Control Guideline for Healthcare Facilities*. Geneva: World Health Organization; 2006. <http://pandemicflu.utah.gov/docs/HCIInfectionControlAIinhumansWHOInterimGuidelinesfor.pdf>. Accessed June 14, 2019.
15. Rottach D, Fries M, Kilinc-Balci FS, Moore S, Shaffer R. *PPE CASE: Testing of Stockpiled ANSI/AAMI PB70 Level 4 Surgical Gowns*. National Institute for Occupational Safety and Health, NPPTL Report Number P2017-0102. <https://www.cdc.gov/niosh/npptl/pdfs/FINAL-PPE-CASE-7-17-508.pdf>. Accessed June 14, 2019.
16. Kilinc-Balci FS, Fries M, Rottach D, Shaffer R. *PPE CASE: Testing of Stockpiled ANSI/AAMI PB70 Level 3 Surgical Gowns*. National Institute for Occupational Safety and Health, NPPTL Report Number P2018-0104. <https://www.cdc.gov/niosh/npptl/ppecase/pdfs/PPE-CASE-P2018-0104-508.pdf>. Accessed June 14, 2019.
17. Rottach DR, Lei Z. Stockpiled N95 filtering facepiece respirator polyisoprene strap performance. *J Int Soc Respir Prot* 2017;34(2):69-80.
18. El Aidani R, et al. Photochemical aging of an e-PTFE/NOMEX® membrane used in firefighter protective clothing. *Polym Degrad Stab* 2013;98(7):1300-1310.
19. Kim J, Jasper W, Hinestrosa J. Direct probing of solvent-induced charge degradation in polypropylene electret fibres via electrostatic force microscopy. *J Microsc* 2007;225(Pt 1): 72-79.

20. Majchrzycka K, Okrasa M. Effect of temperature, simulated breathing and storage conditions on the filtration efficiency of biodegradable bioactive filters. *Fibres & Textiles in Eastern Europe* 2017;25(1):89-94.

21. Motyl E, Lowkis B. Effect of air humidity on charge decay and lifetime of PP electret nonwovens. *Fibres & Textiles in Eastern Europe* 2006;14(5):59.

22. Viscusi DJ, Bergman M, Sinkule E, Shaffer RE. Evaluation of the filtration performance of 21 N95 filtering face piece respirators after prolonged storage. *Am J Infect Control* 2009; 37(5):381-386.

23. Chen G, Xu Z, Zhang LW. Measurement of the surface potential decay of corona-charged polymer films using the pulsed electroacoustic method. *Meas Sci Technol* 2007;18(5): 1453.

24. Tabti B, Mekideche MR, Plooreanu MC, et al. Corona-charging and charge-decay characteristics of nonwoven filter media. *IEEE Trans Ind Appl* 2010;46(2):634-640.

25. Brown RC. *Air Filtration: An Integrated Approach to the Theory and Applications of Fibrous Filters*. Oxford: Pergamon Press; 1993.

26. Rottach D, Yorio P. Statistical evaluation criteria for stockpiled personal protective equipment. Poster presented at NACCHO Preparedness Summit; April 18, 2018; Atlanta, GA.

27. Yorio P, Rottach D, Dubaniewicz M. Quality assurance sampling plans in U.S. stockpiles for personal protective equipment. *Health Secur* 2019;17(2):140-151.

28. R Core Team. R: A language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing; 2018. <https://www.R-project.org/>. Accessed June 14, 2019.

*Manuscript received March 29, 2019;
revision returned May 6, 2019;
accepted for publication May 7, 2019.*

Address correspondence to:

Dana R. Rottach, PhD

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory

MS 05 626 Cochrans Mill Rd.
Pittsburgh, PA 15236

Email: DRottach@cdc.gov