Preparing for an Influenza Pandemic: Hospital Acceptance Study of Filtering Facepiece Respirator Decontamination Using Ultraviolet Germicidal Irradiation

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Objectives: Predictions estimate supplies of filtering facepiece respirators (FFRs) would be limited in the event of a severe influenza pandemic. Ultraviolet decontamination and reuse (UVDR) is a potential approach to mitigate an FFR shortage. A field study sought to understand healthcare workers' perspectives and potential logistics issues related to implementation of UVDR methods for FFRs in hospitals.

Methods: Data were collected at three hospitals using a structured guide to conduct 19 individual interviews, 103 focus group interviews, and 285 individual surveys. Data were then evaluated using thematic analysis to reveal key themes.

Results: Data revealed noteworthy variation in FFR use across the sample, along with preferences and requirements for the use of UVDR, unit design, and FFR reuse. Based on a scale of 1 (low) to 10 (high), the mean perception of safety in a high mortality pandemic wearing no FFR was 1.25 of 10, wearing an FFR for an extended period without decontamination was 4.20 of 10, and using UVDR was 7.72 of 10.

Conclusions: In addition to technical design and development, preparation and training will be essential to successful implementation of a UVDR program. Ultraviolet decontamination and reuse program design and implementation must account for actual clinical practice, compliance with regulations, and practical financial considerations to be successfully adopted so that it can mitigate potential FFR shortages in a pandemic.

Key Words: patient safety, respiratory protection, influenza, pandemic, filtering face piece respirator, ultraviolet decontamination

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Filtering facepiece respirators (FFRs) are essential to protect health care workers (HCWs) from inhaling aerosols and droplets carrying influenza and other infectious diseases such as severe acute respiratory syndrome and Middle Eastern respiratory syndrome. To prepare for an influenza pandemic, the Occupational Safety and Health Administration recommends use of a particulate respirator that is at least as protective as a National Institute for Occupational Safety and Health (NIOSH)-approved N95 FFRs.[1] The Centers for Disease Control and Prevention (CDC) guidance called for use of N95 respirators to protect HCWs during the initial stages of the 2009 H1N1 pandemic.[2] The threat of a high mortality influenza pandemic is current[3] and an outbreak such as the 1918-19 influenza pandemic can place unsustainable demands on limited FFR supplies. United States acute care hospitals collectively hold an estimated 60 million N95 FFRs, and state holdings vary from 14,000 to 32 million.[4] Assuming 20% to 30% of the U.S. population would become ill with influenza, demand could range from 1.7 to 7.3 billion FFRs.[5] The supply of FFRs can become scarce in even less critical circumstances. For example, various healthcare facilities experienced FFR shortages during the H1N1 outbreak in 2009.[6–8] The CDC has issued guidance for extended use and limited reuse of N95 FFRs in healthcare settings during a pandemic.[9] The threat to public health compels efforts to seek an effective means to mitigate an FFR shortage.

Extensive laboratory research has informed understanding of FFR decontamination and what is needed to ensure their performance afterward.[10–14] A recent laboratory study showed ultraviolet decontamination and reuse (UVDR) significantly reduced (≥3 log) influenza viability in the presence of soiling agents on facepieces from 12 of 15 FFR models and straps from 7 of 15 FFR models.[10,11,15] Filtering facepiece respirator durability evaluations indicated that 10 FFR models did not degrade in fit or filtration efficiency after ten 1-J/cm^2 cycles of UVDR (in preparation). The collective data indicate that there are at least six commercially available FFR models that can withstand the rigors of UVDR.

Two co-authors (B.H., D.H.) led a team to develop the American Society for Testing and Materials method for UV surface decontamination that serves as a baseline for the entire UV industry to use to validate their claims.[16] Laboratory data indicate that UVDR can mitigate potential shortages by extending FFR service life. However, to be successful UVDR, use must also be compatible with HCW operations and logistics.[17,18] We report on a field study at three diverse hospitals that explored the potential for the use of UVDR during a pandemic event to mitigate FFR shortages.

METHODS

The institutional review boards of the U.S. Food and Drug Administration (FDA) and one of the three research sites reviewed and approved the study for human subject research. The other two research sites did not require institutional review board approval. Interviewers had completed the Collaborative Institutional Training Initiative human research curriculum. The Office of Management and Budget approved individual and focus group interviews to collect data.

Research Sites

The research team collected data from HCWs, administrators, and support staff at three hospitals to understand clinical and logistical considerations of UVDR use. Gulf Coast Regional Medical Center (GCRMC), a small affiliate of the Hospital Corporation of America, is located in Panama City, Florida, and contains 218 beds, nearly 400 physicians, and a support staff of more than

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900 employees. Stony Brook University Hospital (SBUH), a large suburban facility located in Stony Brook, New York, contains 603 beds, 5777 employees, and 1093 physicians. Stony Brook University Hospital has approximately 32,000 annual inpatient admissions and 96,000 emergency department visits. University of Chicago Medical Center (UCMC), a large metropolitan hospital in Chicago, Illinois, has 617 beds, 8500 employees, and 878 attending physicians. University of Chicago Medical Center has approximately 28,726 annual inpatient admissions and 87,856 emergency department visits.

Sample Recruitment

The sample population was composed of roles that would be affected by extensive FFR use in a pandemic, from frontline HCWs to administrators and support staff. A staff member at each research site invited interview participation by word of mouth and invited survey participation through e-mail. Across all sites, 19 individuals participated in interviews, 103 participated in focus groups, and 287 responded to the survey. General themes were consistent between administrators and clinicians. Table 1 shows participation by roles at each research site. Totals vary because not all respondents completed all sections of the survey.

Research Design

In interviews, participants were given descriptions of the severe health threat in a high mortality pandemic and what UVDR does, then asked for their perception of safety for each of the conditions shown in Figure 1: no respirator (NR), extended use of respirator (R), and reuse of a respirator decontaminated using UV (R/UV).

The survey asked respondents for their perceptions about safety in a pandemic wearing no respirator, wearing a respirator, extended respirator use, and reusing a respirator that had been decontaminated using UVDR.

Data Collection

Individual interviews and focus group interviews followed a guide and lasted approximately 45 minutes. They included an illustration of what a table-top UVDR unit might look like (Fig. 2) and description of how a used FFR would be placed on an open portal (as shown) a slid in for 60 seconds of UV exposure. The port would then be slid out and the FFR retrieved.

Use of cognitive task analysis[19,20] methods revealed participant preferences, experiences, and work procedures at the research sites that are related to FFRs and the prospective UVDR concept. In addition to interviews, a survey captured staff preferences and beliefs to accommodate participants who were unable to participate in face-to-face sessions because of scheduling conflicts. The survey included a rule-out question at the beginning to prevent duplication of interview data.

Data Analysis

Use of thematic analysis[21] detected patterns across all data and identified 20 initial impressions such as "people need assurance that decontamination actually kills the flu virus." Organizing the impressions into 15 themes related to the UVDR approach then made it possible to identify all comments from interviews that corresponded to the themes. Use of descriptive statistics (means, standard deviations, median, mode) described survey data quantitatively.

RESULTS

Participants rated perceptions of safety in each condition on a scale from 1 (unsafe) to 10 (safe) while viewing respiratory protection options during a pandemic as Figure 1 illustrated (Fig. 3). At two sites, some participants emphasized the strength of their aversion to wearing NR during a pandemic by responding "zero" while knowing "1" was the lowest rating. Median ratings among each of the research sites (SBUH, GCRMC, and UCMC) for each of the three conditions were relatively consistent. In the "no FFR" condition, median and first and fourth quartiles values were similar, yielding no "box."

The mean perception of safety wearing an FFR over an extended period without decontamination was higher compared with no protection, but both scenarios were lower than the mean safety perception of using an FFR with UVDR. This is a noteworthy finding, because NIOSH supports extended use of respirators during a pandemic.[22] Although the mean perception of this condition was considered safer than wearing no respirator, there is room for improvement. The range in ratings was fairly large, especially within the extended use category. This might be attributed to respondents' need to speculate about a high mortality disease setting they have not yet experienced, which is termed an "envisioned world" problem.[23]

TABLE 1. Composition of Sample Population From Three Healthcare Research Sites

Site	Method	Admin	RT/PT/OT	Nurse	Physician*	Pharmacist	Academic	Other†	Total
SBUH	Individual interview	5	0	1	2				8
	Focus group	7	11	0	6				24
	Survey	3	0	20	41		14	5	83
GCRMC	Individual interview	6	0	0	0				6
	Focus group	9	2	10	6				27
	Survey	8	7	105	2		3	34	159
UCMC	Individual interview	5	0	0	0				5
	Focus group	10	9	13	8	3	1	8	52
	Survey	3	3	27	1	9			43
	Total	56	32	176	66	12	18	47	407

*"Physician" includes medical students: 4 at GCRMC and 7 at UCMC.

†"Other" represents respondents in roles including social worker, central sterile technician, phlebotomist, electrocardiogram technician, echo technician, and lactation consultant.

OT, occupational therapist; PT, physical therapist; RT, respiratory therapist.

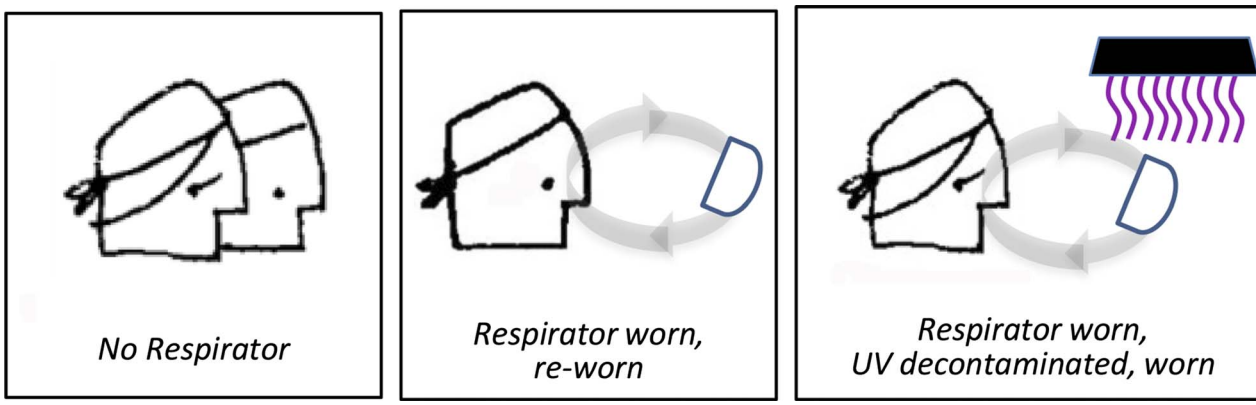

FIGURE 1. Study-defined options for respiratory protection during a pandemic.

Findings

Findings shown in Table 2 are based on themes that summarize coded data.[24]

Surveys

Survey data summarized in Table 3 provided results that were similar in many ways to what we learned from interviews.

DISCUSSION

The novel use of UVDR serves as a hypothesis about the effects of interventions on the cognitive work patterns that individuals and teams perform.[25] Although the UVDR approach does not currently exist, it could and its introduction into the current work context would change it substantially. As an envisioned world problem, interview participants needed to foresee a condition (use of UVDR) that they have not experienced. A design prototype can help make a novel concept easier to envision. A brief description and illustration of what a small UVDR unit might look like (such as Fig. 2) is such a prototype. The figure can be used to elicit responses, grounded in the participants' own experiences, as to how the unit and procedures need to be designed.

Study data show concern over FFR availability (Findings 5, 6). Although all facilities had a buffer supply, all acknowledged that supply was limited and unlikely to be sufficient for any more than a few days of peak demand. Trust in UVDR was a frequently cited barrier to implementation (Findings 10, 11). Although there is a wealth of data in the peer-reviewed literature on UVDR and the ability of FFRs to withstand UVDR, these data must be made easily available for HCWs. Government agencies (e.g., CDC, NIOSH, U.S. FDA) would need to provide their approval for UVDR to be implemented (Finding 10). This is not a trivial process, especially in the preparedness/planning stage. However, for UVDR to be an option, the government must take steps to support the approach. As part of these steps, considerations for availability of UVDR devices during a pandemic must be defined. Hospital

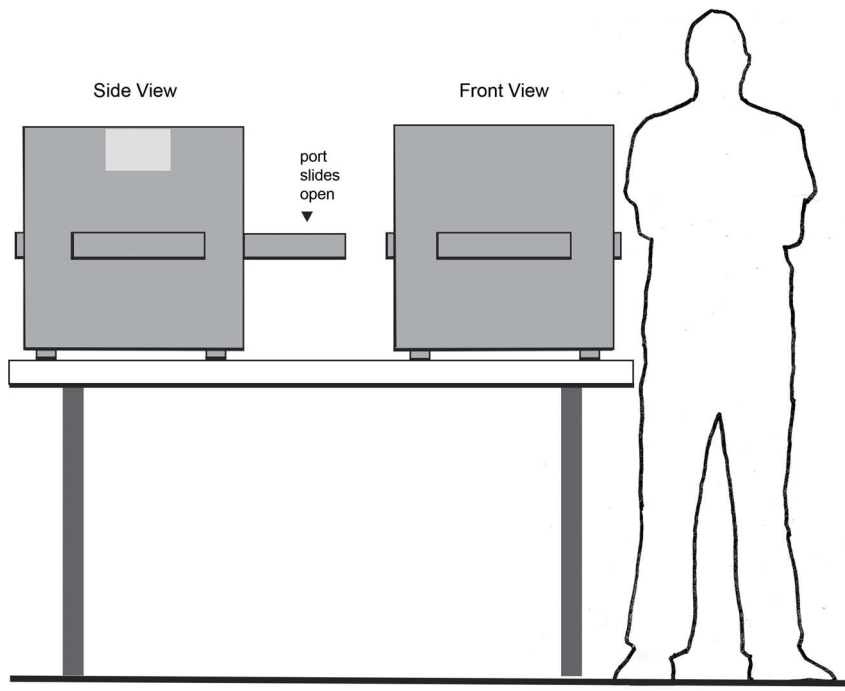

FIGURE 2. UVDR Unit Concept Illustration.

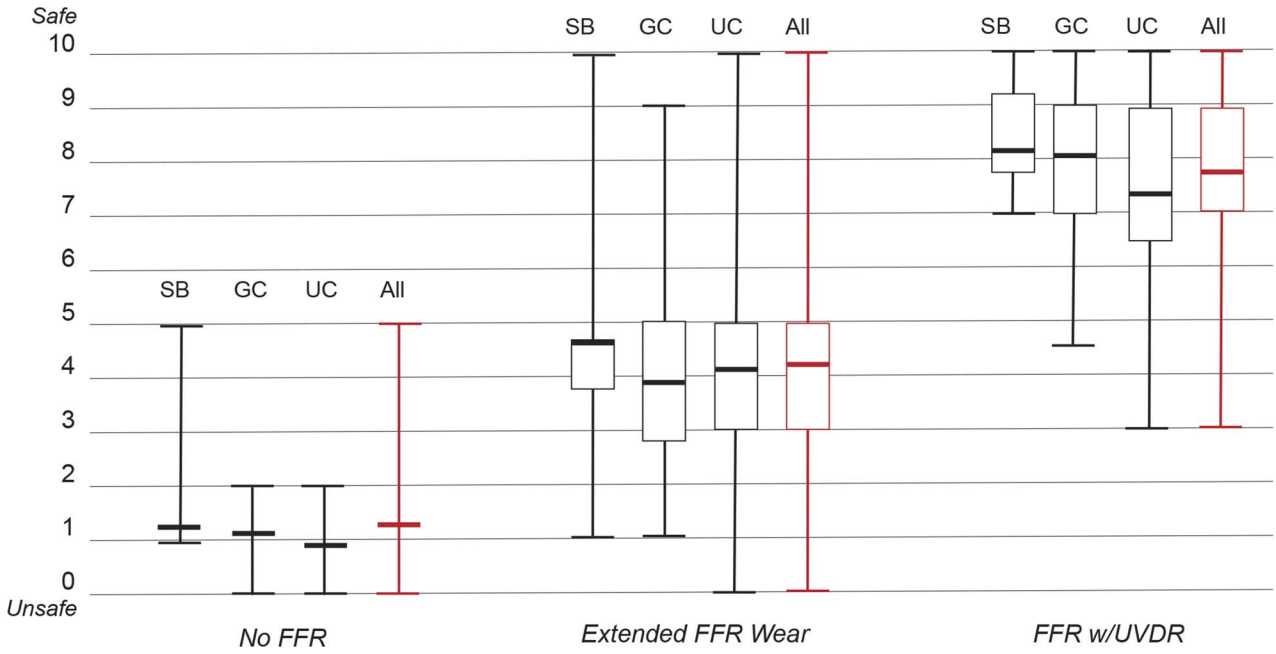

FIGURE 3. Healthcare Worker Respiratory Safety Perceptions for High-Mortality Pandemic Setting (whiskers indicate minimum, maximum ratings; SB-Stony Brook University Hospital, GC-Gulf Coast Regional Medical Center, UC-University of Chicago Medical Center).

administrators expressed concerns about purchasing and stocking UVDR devices that have a single purpose (Finding 17). One potential solution would be to make the UVDR device versatile enough to be used for other applications. Two of the hospital systems were already using UV for disinfection, so it is possible to envision a multiuse UV device that can also be used for UVDR. One of the hospitals considered other options, such as having a third party decontaminate FFRs or relying on municipal or state health authorities maintain a UVDR unit stockpile in case of need.

Simply developing and stockpiling UVDR units is not enough. Hospital systems need time to prepare for a new approach such as UVDR (Finding 9). The hospitals in this study indicated that UVDR implementation would take 4 to 8 weeks. This need for lead time (Finding 7) likely transcends any new technologies or practices that would be developed to deal with a pandemic. Training and implementation must also be addressed (Finding 13), which could also improve HCW appreciation for, and understanding of, the behaviors and procedures that would be essential in a pandemic. Procedures that deviate from clinical practice and

TABLE 2. Findings Based on Coded Themes from Interviews

F1	Personal considerations impose a strong gradient between those who may, and those who would not, be willing to share masks.
F2	Training and management of PPE, including FFRs, vary.
F3	HCW FFR use poses a compliance challenge.
F4	Clinicians strongly favor UVDR unit location near point of care.
F5	Hospital FFR par stocks are based on historical use rates and may not be able to easily ramp up supplies should a pandemic occur.
F6	Hospital contingency FFR supplies vary among sites, making it uncertain whether they would have enough in the event of a pandemic.
F7	Hospitals envision a minimum of 4 to 8 weeks to implement UVDR before need.
F8	Infection Control and Employee Health departments know that coordination among agencies, government organizations will be essential in a pandemic.
F9	Education and training will play a major role in UVDR implementation.
F10	Trust in UVDR relies on proof from authoritative sources such as CDC, NIOSH, U.S. FDA, and indication of effectiveness
F11	Doubts exist about FFR availability durability.
F12	Potential infection by pathogens other than influenza is a concern.
F13	HCWs need thorough training in the nature of actual threat and protection.
F14	UVDR will need to avoid potential conflicts with clinical practice.
F15	HCW preferences can guide UVDR unit design and use.
F16	Practical requirements will need to be worked out, from location, to procedures, to how individuals would manage their FFRs
F17	Hospitals would need sufficient opportunity to evaluate cost and risk.

PPE, personal protective equipment.

TABLE 3. Selected Survey Responses by Research Site

Topic	SBUH	GCRMC	UCMC
Experience	Mean (SD)	Mean (SD)	Mean (SD)
Years in role	11.61 (10.74)	10.65 (10.61)	12.38 (10.29)
Years in healthcare	17.19 (11.69)	10.69 (10.69)	16.14 (12.08)
Used FFRs in an emergency	13.41%	13.0%	24.0%
Received FFR training	79.5%	89%	93.0%
FFR policies, procedures	(1 = easy, 7 = difficult) mean (SD)	(1 = easy, 7 = difficult) mean (SD)	(1 = easy, 7 = difficult) mean (SD)
Ability to get an FFR	3.73 (1.96)	1.89 (1.29)	2.19 (1.47)
Ability to follow FFR procedures	3.00 (1.54)	1.71 (1.17)	1.89 (1.20)
Familiar with use of UV to decontaminate	27.6%	24.0%	36.0%
Perception of safety in a pandemic	(1 = agree, 7 = disagree)	(1 = agree, 7 = disagree)	(1 = agree, 7 = disagree)
Wearing NR is safe	6.61 (1.09)	5.72 (2.32)	5.37 (2.03)
Wearing a respirator is safe	3.91 (1.65)	1.65 (1.48)	2.37 (1.49)
Extended respirator use is safe	5.93 (1.50)	6.03 (2.10)	5.84 (1.52)
Wearing respirator decontaminated with UVDR is safe	4.06 (1.58)	3.31 (2.53)	3.49 (1.93)
Use of UV would mitigate FFR shortage	82.9%	80.0%	87.0%

traditional training need to be adequately explained and justified (Finding 9). Emergency preparedness must consider logistics, such as where units would be installed, and how they would be calibrated and maintained (Finding 16, 17). Employees need to be trained on the new approach ahead of any emergency (Finding 9, 12). It is impractical to think this training can take place at the outset of a pandemic. There are many ways to handle this ahead of time. For example, training could be included as part of annual fit testing, although this would require resources that are not freely available in health care systems.

Participants typically expressed a preference for keeping an FFR for their own use (Finding 1). In light of this, UVDR protocols that rely on sharing respirators are unlikely to be accepted and batch processing would not likely be well received. This tends to favor the use of multiple smaller UVDR units so that individuals could decontaminate their own FFRs, rather than collect and decontaminate FFRs at a central location. Frontline HCWs strongly favor having decontamination available near point of care (Finding 4), which complements individual FFR decontamination. This conflicts with the legal participants' preference (Finding 19) for a small staff of well-trained individuals to decontaminate FFRs. It may be possible to resolve this conflict through well-designed UVDR equipment that is intuitive to operate (Finding 15). Factors that affect the decision about where to locate UVDR units will need to be considered, including distance to get to a unit without risking cross-contamination while the clinician transports their used mask, time in relation to distance to travel, and space for the UVDR units and storage of FFRs that are waiting decontamination (Finding 12, 16).

Staff members at each research site who are responsible for infection control and employee/occupational health are well-versed in how to engage a large-scale event (Finding 7), including triage of patients into cohorts during a pandemic (Finding 12). They also know that their ability to mount a response relies on collaboration with outside organizations (e.g., federal, state, local government) and HCWs at their facility (Finding 8, 18). More than one site expressed doubts about clinician compliance with UVDR procedures because of causes that range from time pressure caring for those who are critically ill to lack of motivation to be personally accountable (Finding 2, 3). Any additions to the already substantial HCW workload could present a barrier to acceptance (Finding 14).

CONCLUSIONS

Findings supported seven conclusions, and each is shown in Table 4 with the numbers of findings that support them.

Our research revealed four needs for further work. The scope of an influenza pandemic can have far-reaching effects, and a broader study could reveal larger needs. These needs range from training and education, to logistics that would influence UVDR decisions, to relationships among various organizations that will be essential to protect HCWs during a pandemic. New FFR designs should be developed that reflect HCW concerns regarding

TABLE 4. Conclusions and Supporting Findings

	Conclusions	Supporting Findings
C1	UVDR units with expert staff support should be located near patient cohorts in flu wards.	F4
C2	Advanced training in conjunction with CDC on pathogen threat and protection would be essential.	F10,11
C3	Current practice in FFR use may compromise UVDR success.	F1,2,3
C4	Successful UVDR implementation will depend on coordination among hospitals and government agencies and organizations.	F7,8,18,19
C5	Further study is needed to ensure UVDR unit design and procedures complement clinical practice.	F9,12,14,15,16
C6	Further research and development of UV decontamination technologies is warranted, as hospital FFR supplies risk depletion in a pandemic.	F5,6,11
C7	Hospitals will want to explore alternatives before assuming cost and risk burden.	F17,18,19

decontamination, soiling, and durability. Future research can be performed to gain more information from HCWs about practical implementation needs as well as from authoritative sources on UV effectiveness in decontaminating FFRs against multiple pathogens. Learning more from HCWs can provide a basis to move forward with how the UVDR would be conceived, designed, built, tested, fielded, refurbished, upgraded, redesigned, retired, and replaced. Learning how federal, state, and municipal health organizations anticipate and plan for a pandemic would inform understanding of the potential for UVDR.

Although our data showed positive response to the use of UVDR, the technology and its use will have to reflect the clinical, logistic, and regulatory context to succeed. This study revealed action that government agencies and healthcare providers will need to take to avert a potential public health crisis in the event of a high mortality influenza pandemic.

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