

drafting of our study or manuscript. In addition, during the past 5 years, the following authors have received financial support and maintained affiliations as follows: Dr Lu-Yao has received clinical research funding from the New Jersey Commission on Cancer Research and the Agency for Healthcare Research and Quality and employment with HealthStat; Dr Peter Albertson has received clinical research funding from Sanofi-Aventis and consultation fees from Blue Cross/Blue Shield; and Dr Weichung Shih has received clinical research funding from Myriad. None of these entities contributed funding or played any role whatsoever in the design, interpretation, or drafting of our study or manuscript. We regret any misunderstanding that resulted from the omission of these disclosures.

Grace Lu-Yao, MPH, PhD
Robert Wood Johnson Medical School
New Brunswick, New Jersey

Peter Albertsen, MD
University of Connecticut
Farmington

Weichung Shih, PhD
University of Medicine and Dentistry of New Jersey
Piscataway

Siu-Long Yao, MD
syao@aya.yale.edu
Robert Wood Johnson Medical School
New Brunswick

Financial Disclosures: Dr Siu-Long Yao reported that during the last 5 years he has been employed by Sanofi-Aventis and Schering-Plough in the area of clinical cancer research. Dr Grace Lu-Yao reported having received clinical research funding from the New Jersey Commission on Cancer Research and the Agency for Healthcare Research and Quality and employment with HealthStat. Dr Albertson reported having received clinical research funding from Sanofi-Aventis and consultation fees from Blue Cross/Blue Shield. Dr Shih reported having received clinical research funding from Myriad.

1. Lu-Yao GL, Albertsen PC, Moore DF, et al. Survival following primary androgen deprivation therapy among men with localized prostate cancer. *JAMA*. 2008; 300(2):173-181.

RESEARCH LETTER

Respirator Tolerance in Health Care Workers

To the Editor: Anticipated respirator intolerance and supply shortages during future influenza pandemics prompted the Institute of Medicine to review respirator use in health care workers¹ and consider whether disposable models could be reused or modified for reuse.² One option involves placing a medical mask over a disposable respirator to diminish contamination and attrition.¹ However, little is known about the workplace tolerability of respirators commonly worn by health care workers, who may be called on to wear respiratory protection for the duration of their work shifts for several consecutive weeks during a pandemic.^{3,4} We estimated the length of time health care workers would tolerate wearing commonly used respirators while performing their typical occupational duties.

Methods. Participants were 27 volunteers (mean [SD] age, 48 [11] years; range, 25-65 years; 15 women) among approximately 225 health care workers employed by the local Veterans Health System who were approached. The inclusion criterion was having worn a respirator in the context of duties at least once; all participants were accustomed to wearing N95 respirators (filters $\geq 95\%$ of particles approximately 0.3 μm in size) for brief periods. Exclusion criteria included systemic disease or pregnancy. The sample comprised 16 nurses, 2 nurse practitioners, 4 nurse technicians, 2 telemetry technicians, 2 respiratory therapists, and 1 clerical assistant from the intensive care unit (n=15), emergency department (n=6), and medical/surgical ward (n=6). Each provided written informed consent, underwent a prestudy examination, and was fit-tested for each respirator. The study was approved by the local institutional review board.

In this unblinded multiple crossover study, before each work shift (intersession interval, ≥ 1 day) each participant was randomly assigned a respirator ensemble (TABLE 1) to wear as long as he or she was "willing to tolerate" the effects while performing typical occupational duties, not including interposed break periods (15 minutes at 2 and 6 hours; 30 minutes at 4 hours). Those who experienced intolerance before 8 hours reported up to 3 reasons for premature discontinuation.

Sample size was chosen to achieve power of 0.8 or greater to detect a difference of 2 hours in median tolerance times. Kaplan-Meier estimates of survival were used for descriptive purposes. Tolerance time for the cup-shaped N95 was compared with a medical mask and with the N95 with an exhalation valve. The 2 respirators that had a medical mask placed over the respirator surface to protect against contamination were compared with the same respirators without a mask. An extended Cox model,⁵ which accounted for correlation between repeated measures within participant, was used to compare the time to doff among respirators by controlling for the effects of sex and age. SAS 9.1 (SAS Institute, Cary, North Carolina) was used for the analyses. The Bonferroni step-down method⁶ was used to adjust the *P* values for 2-sided tests to account for multiple tests.

Results. Each participant wore all 8 respirators except 1 who failed the duckbill N95 fit test. No sequence or period effects were found. Tolerance time varied by respirator model (Table 1). Women were significantly more likely than men to experience intolerance before 8 hours (hazard ratio, 1.97; 95% confidence interval, 1.02-3.75; *P* = .04). Participants discontinued wearing the respirator ensembles before 8 hours in 126 of 215 total sessions (59%), reporting a variety of reasons for intolerance, including communication interference (TABLE 2).

Comment. A large percentage of participants were unwilling to wear the respirator ensembles for the entire 8-hour work shift, even with interposed break periods. No respirator was ideal: users of disposable models frequently experienced facial heat and pressure, and users of

reusable models frequently experienced communication interference. Wearing a cup-shaped N95 without an exhalation valve was associated with more intolerance than a similar model with a valve. Study limitations

include small sample size, a single study location, and a setting that only simulated a pandemic scenario. However, these findings suggest that new respirator designs may be necessary to improve tolerability.

Table 1. Characteristics and Tolerability of Respiratory Protective Ensembles^a

Ensemble	Manufacturer (Model) ^b	Included Equipment	Cost, \$ ^c	Reusability ^d	Median Tolerance Time (Q75, Q25), h ^e	Probability of Tolerance at 8 h (95% CI) ^f	HR (95% CI) ^g	P Value ^h
Powered air-purifying respirator	3M (BE-12)	Gown, gloves, hood, air hose, filter cartridge, battery pack, and charger	768.20	Yes	7.6 (1.8,8.0)	0.56 (0.35-0.72)		
Cup N95 + exhalation valve	3M (8511)	Gown, gloves, goggles	2.11	No	7.7 (4.1,8.0)	0.55 (0.35-0.72)		
Medical mask (no respirator)	Precept (15320)	Gown, gloves, goggles	1.40	No	7.7 (4.9,8.0)	0.52 (0.32-0.69)		
Duckbill N95	Kimberly-Clark (PFR95170)	Gown, gloves, goggles	1.43	No	6.6 (2.9,8.0)	0.48 (0.29-0.65)		
Half-face elastomeric respirator	North (5500 series)	Gown, gloves, goggles, 2 filter cartridges	20.80	Yes	6.8 (2.1,8.0)	0.41 (0.23-0.58)		
Cup N95 + exhalation valve + medical mask	3M (8511) or Precept (15320)	Gown, gloves, goggles	3.51	No	4.3 (1.9,8.0)	0.41 (0.23-0.58)	1.70 (1.04-2.78) ⁱ	.03
Cup N95	3M (1860)	Gown, gloves, goggles	1.75	No	5.8 (4.1,8.0)	0.33 (0.17-0.51)	1.79 (1.15-2.79) ^j 1.61 (0.97-2.71) ^j	.03 .07
Cup N95 + medical mask	3M (1860) or Precept (15320)	Gown, gloves, goggles	3.15	No	4.1 (1.7,7.2)	0.30 (0.14-0.47)	1.14 (0.72-1.80) ^k	.57

Abbreviations: CI, confidence interval; HR, hazard ratio; N95, filters ≥95% of particles approximately 0.3 μm in size; Q75, tolerance time reached by 75% of participants; Q25, tolerance time reached by 25% of participants.

^aAll respirators were commonly used by the local and national Veterans Health Administration hospitals and were certified by the National Institute for Occupational Safety and Health. Equipment changes between patients were in accordance with airborne transmission-based infection control precautions from the Centers for Disease Control and Prevention² unless the clinical setting required otherwise.

^b3M is located in St Paul, Minnesota; Precept Medical Products, Arden, North Carolina; Kimberly-Clark, Neenah, Wisconsin; and North Safety Products, Cranston, Rhode Island.

^cData from Safety Company (<http://www.safetycompany.com>) and Laboratory Safety supply (<http://www.labsafety.com>) accessed March 24-25, 2008.

^dDesigned to be used for more than 1 patient encounter,¹ as specified by the manufacturer.

^eKaplan-Meier estimates without considering correlation.

^fBased on extended Cox model to account for within-participant correlation.

^gRisk of intolerance (doffing) before 8 h, comparing 2 ensembles.

^hBonferroni step-down method.

ⁱCompared with cup N95 + exhalation valve.

^jCompared with medical mask.

^kCompared with cup N95.

Table 2. Reported Reasons for Discontinuing Respirator Use Before 8 Hours Among 27 Participants^a

Ensemble	No. (%)											
	Terminated <8 hrs (N=27)	Diminished Communication Acuity			Head and Facial Discomfort				Other Somatic Complaints			Complaints per Ensemble ^c
		Visual ^b	Auditory	Vocal	Heat	Pressure or Pain	Burning Eyes	Itching	Nausea	Dizzy or Difficulty Concentrating	Mechanical Interference with Duties	
Powered air-purifying respirator	13 (48)	0	6 (22)	3 (11)	0	0	0	0	0	4 (11)	4 (15)	17 (10)
Cup N95 + exhalation valve	14 (52)	3 (11)	0	0	10 (37)	8 (30)	0	1 (4)	0	2 (7)	0	24 (15)
Medical mask (no respirator)	13 (48)	6 (22)	0	1 (4)	6 (22)	3 (11)	0	0	1 (4)	0	0	17 (10)
Duckbill N95 ^d	16 (62)	2 (8)	0	0	7 (27)	1 (4)	1 (4)	2 (8)	0	4 (15)	0	17 (10)
Half-face elastomeric respirator	17 (63)	0	0	9 (33)	7 (26)	4 (15)	0	1 (4)	1 (4)	3 (11)	0	25 (15)
Cup N95 + exhalation valve + medical mask	16 (59)	1 (4)	0	0	8 (30)	3 (11)	1 (4)	1 (4)	0	1 (4)	0	15 (9)
Cup N95	18 (67)	2 (7)	0	0	10 (37)	3 (11)	7 (26)	1 (4)	0	2 (7)	0	25 (15)
Cup N95 + medical mask	19 (70)	1 (4)	0	0	10 (37)	3 (11)	3 (11)	2 (7)	0	3 (11)	0	22 (14)
Total complaints		15	6	13	58	25	12	8	2	19	4	162 (100)

Abbreviation: N95, filters ≥95% of particles approximately 0.3 μm in size.

^aOne hundred twenty-six of 215 sessions (59%) terminated before 8 h because of intolerance. Participants reported up to 3 reasons for discontinuation for each ensemble; a total of 162 complaints were cited as leading to termination before 8 h.

^bIncluded fogging of eyeglasses or protective goggles.

^cTwenty-six participants; 1 participant failed the duckbill N95 fit test.

Lewis J. Radonovich Jr, MD
 lewis.radonovich@va.gov
 Malcom Randall Veterans Affairs Medical Center
 Gainesville, Florida

Jing Cheng, PhD
 University of Florida College of Medicine
 Gainesville

Brian V. Shenal, PhD
 Veterans Affairs Medical Center
 Salem, Virginia

Michael Hodgson, MD, MPH
 Veterans Health Administration
 Washington, DC

Bradley S. Bender, MD
 Malcom Randall Veterans Affairs Medical Center
 Gainesville

Author Contributions: Dr Radonovich had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Radonovich, Cheng, Shenal, Hodgson, Bender.

Acquisition of data: Radonovich.

Analysis and interpretation of data: Radonovich, Cheng, Hodgson, Bender.

Drafting of the manuscript: Radonovich, Cheng, Hodgson.

Critical revision of the manuscript for important intellectual content: Radonovich, Cheng, Shenal, Hodgson, Bender.

Statistical analysis: Cheng.

Obtained funding: Radonovich, Shenal.

Administrative, technical, or material support: Radonovich.

Study supervision: Radonovich, Bender.

Financial Disclosures: None reported.

Funding/Support: This study was funded by the US Department of Veterans Affairs.

Role of the Sponsor: The sponsor was engaged in the study design but played no role in the conduct of the study; in the collection, management, analysis, and interpretation of the data; or in the preparation, review, and approval of the manuscript.

Disclaimer: The views, opinions, and findings contained in this report are those of the authors and do not necessarily represent the official position or policy of the

North Florida/South Georgia Veterans Health System, the Office of Public Health and Environmental Hazards, the US Department of Veterans Affairs, or the University of Florida or other employers or affiliates.

Additional Contributions: Helen Dunn, MSN, Malcom Randall VA Medical Center, and Elizabeth Franco, RN, Malcom Randall VA Medical Center, coordinated the study and received compensation. Parker Small, MD, University of Florida, provided review and guidance and did not receive compensation.

1. Goldfrank LR, Liverman CT, eds. *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers: Institute of Medicine Report*. Washington, DC: National Academies Press; 2008.
2. *Reusability of Facemasks During an Influenza Pandemic: Facing the Flu: Institute of Medicine Report*. Washington, DC: National Academies Press; 2006.
3. Siegel JD, Rhinehart E, Jackson M, Chiarello L; the Healthcare Infection Control Practices Advisory Committee. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007. <http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf>. Accessed December 1, 2008.
4. Guidance on Preparing Workplaces for an Influenza Pandemic [OSHA 3327-02N 2007]. Occupational Safety and Health Administration. http://www.osha.gov/Publications/influenza_pandemic.html. Accessed December 1, 2008.
5. Lin DY. Cox regression analysis of multivariate failure time data: the marginal approach. *Stat Med*. 1994;13(21):2233-2247.
6. Hochberg YT, Tamhane AC. *Multiple Comparison Procedures*. New York, NY: John Wiley & Sons; 1987.

CORRECTION

Unreported Financial Disclosures: In the Original Contribution titled "Survival Following Primary Androgen Deprivation Therapy Among Men With Localized Prostate Cancer," published in the July 9, 2008, issue of *JAMA* (2008;300[2]:173-181), the authors failed to report financial disclosures on page 180. The financial disclosures should have read, "Dr Siu-Long Yao reported that during the last 5 years he has been employed by Sanofi-Aventis and Schering-Plough in the area of clinical cancer research. Dr Grace Lu-Yao reported having received clinical research funding from the New Jersey Commission on Cancer Research and the Agency for Healthcare Research and Quality and employment with HealthStat. Dr Albertson reported having received clinical research funding from Sanofi-Aventis and consultation fees from Blue Cross/Blue Shield. Dr Shih reported having received clinical research funding from Myriad."