

Supplementary Online Content

Radonovich JE, Simberkoff MS, Bessesen MT, et al. Effect of N95 respirators vs medical masks for preventing laboratory-confirmed influenza among outpatient health care personnel: a randomized clinical trial. *JAMA*. doi:10.1001/jama.2019.11645

Supplement 3. eMethods

eResults

eReferences

This supplementary material has been provided by the authors to give readers additional information about their work.

METHODS

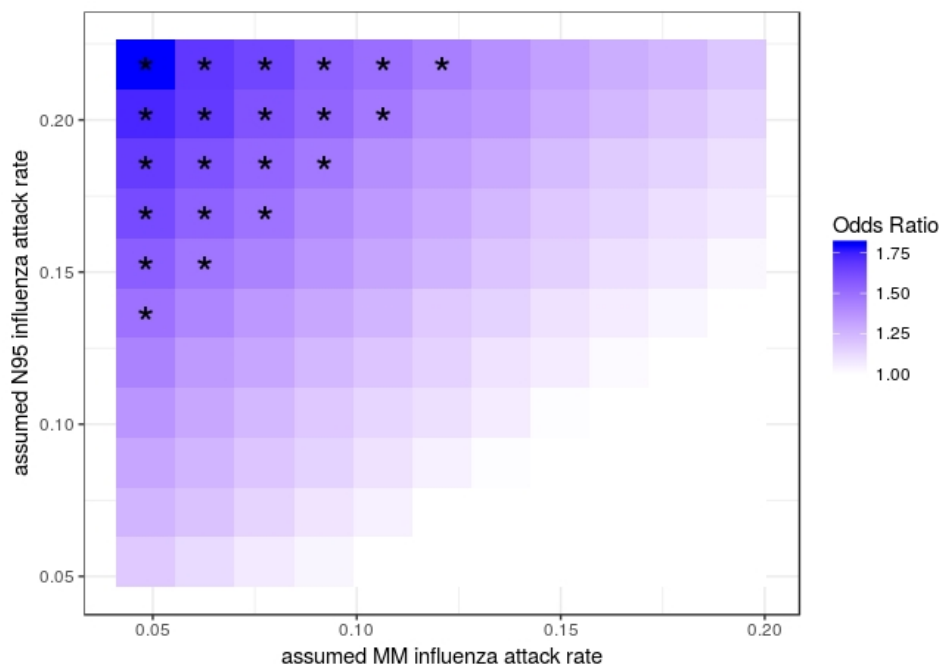
Additional citations³¹⁻³⁵ are available about N95 and medical mask intervention adherence rates.

Sensitivity Analysis.

Our sensitivity analysis was conducted to assess the possible impact the missing outcome data for the LDRI outcome would have on our assessment of the comparative effectiveness of N95 respirators versus MM. We assumed average influenza attack rates for participants who did not complete the study that ranged from half to twice the observed attack rate within each arm. The adjusted odds ratio (averaged across n=50 imputed datasets) was estimated for each pair of arm-specific attack rates. Results demonstrated that a lower-than-observed attack rate in the participants who withdrew in the MM arm would have to be combined with a higher-than-observed attack rate in the participants who withdrew in the N95 arm to achieve a statistically significant result indicating increased effectiveness of MM over N95 masks. Missing symptomatic event reporting in daily and weekly surveys was compared across arms and cohorts. Within a given season, we tabulated whether each participant had reported any symptomatic events. If no data was available for a given participant (*i.e.*, they did not submit any self-reported daily or weekly diaries or never responded to questions about symptomatic events) their outcome was classified as missing. The data show substantially more missing data in the ITT cohort overall due to early withdrawal from the study (ITT cohort: N95 7.5% (189/2512) missing, MM 5.4% (145/2668) missing; PP cohort: N95 0.7% (16/2243) missing, MM 1.1% (28/2446) missing). We fit a generalized linear mixed model to assess whether, when controlling for completion status, there was a significant difference in symptomatic reporting rates. We found that there was no evidence of differential symptomatic event reporting across arms, adjusting for study completion.

We assessed the possible impact the missing outcome data for the LDRI outcome would have on our assessment of the comparative effectiveness of N95 respirators versus MM. We assumed average influenza attack rates for participants who did not complete the study that ranged from half to twice the observed attack rate within each arm. The adjusted odds ratio (averaged across n=50 imputed datasets) was estimated for each pair of arm-specific attack rates. Results are shown in the Figure (below), and illustrate that a lower-than-observed attack rate in the participants who withdrew in the MM arm would have to be combined with a higher-than-observed attack rate in the participants who withdrew in the N95 arm to achieve a statistically significant result indicating increased effectiveness of MM over N95 masks. This suggests that the primary analysis reported in the main manuscript is fairly robust to the missing outcome data and supports the finding that neither N95 nor MM was superior in preventing LCI or other VRILI among HCP when worn in a fashion consistent with current U.S. clinical practice.

51
52 **Supplemental Figure ^a**



53
54 ^a Assumed N95 versus MM arm influenza attack rates that were imputed for missing outcome data
55 only. Increasing estimated odds ratio is represented by the colored grid squares. Assumed attack rate
56 combinations that produced a significant p-value (adjusted) are marked with an "*".

57
58 **RESULTS**

59
60 **Adherence to Intervention**

61 Study monitor observed device wearing before entering and after exiting patient rooms was 40.6 % in
62 the N95 arm and 33.5 % in the MM arms ($p = 0.02$), suggesting adherence was larger in the N95 arm.

63
64 **DISCUSSION**

65 **Evaluating Effectiveness in a Pragmatic Trial.** One of the challenges with studies evaluating the
66 effectiveness of protective devices is in capturing the difference in outcomes that are clinically
67 significant. While none of our analyses showed important differences between intervention groups,
68 several of the results reached a pre-specified level of marginal clinical significance of 15 percent ¹⁹. For
69 example, the adjusted per-protocol analysis for LCI had estimated a 19.6% increase in odds of
70 laboratory-confirmed influenza associated with the N95 arm when compared to the MM arm.
71 However, this result did not reach the pre-specified level for statistical significance given the overall
72 low number of observed influenza infections. Specifically, for all analyses whether adjusted,
73 unadjusted, PP, or ITT which looked at ILI as an outcome, the relative risk of developing ILI if wearing
74 an N95 compared to MM was estimated to be between 0.83 and 0.87, but with an odds ratio ranging
75 between 1.13 and 1.20 for LCI.

76

Adherence to interventions in a Pragmatic Trial. We measured intervention adherence using two methods, self-report and direct observation; each has its strengths and biases. Properly wearing respiratory protection is important for efficacy³⁶. To minimize the Hawthorne effect³⁷, we used unannounced visits by research personnel, who periodically changed, to gather adherence data. The discrepancy between observed and self-reported rate of adherence to assigned protective devices in our study is consistent with previous studies of infection prevention measures^{38,39} and should be interpreted with recognition that direct observation was typically *not* possible because of doors and curtains that protect patient privacy and confidentiality⁴⁰. Specifically, participants may have donned and doffed protective devices while doors or curtains were closed, making observed adherence rates artificially low. While self-reported and observed adherence were less than ideal, incomplete adherence among HCP is well recognized²; in other words, this trial is representative of current U.S. health care practices. ResPECT was outpatient-based, while previously published studies comparing respiratory protection effectiveness^{3,4,6,12} were inpatient-based and most were conducted in countries where use of respiratory protection has higher cultural acceptance. Our study is the first to report adherence to respiratory protection in the outpatient setting. The level of adherence in our study is higher than that reported in the residential setting, where masks were shown to protect family members from influenza⁴¹.

TABLES AND FIGURES

Table 2 in the manuscript includes summary information for all study years. In the supplemental table, we provide a larger table that includes information by study year and cohort.

DATA SHARING

The dataset reported in this manuscript contains protected health information under U.S. Federal law, namely The Health Insurance Portability and Accountability Act of 1996, 45 CFR parts 160, 162, and 164 and The Privacy Act of 1974, 5 U.S.C. § 552a. Access to and/or release of data would occur in accordance with pertinent institutional review board approval and applicable local, state, and federal laws and regulations.

SUPPLEMENTAL CITATIONS

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Supplemental Table: Participant Demographic Characteristics, Risk Factors^a, and Site Enrollment (Per Protocol and Intention to Treat Cohorts)

YEARS (VIRAL RESPIRATORY SEASONS)	2011-2012				2012-2013				2013-2014				2014-2015				TOTALS			
INTERVENTION ARMS	MM		N95		MM		N95		MM		N95		MM		N95		MM		N95	
Cohort	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT
Participant-seasons	337	355	282	307	582	634	493	546	754	825	625	701	773	854	843	958	2446	2668	2243	2512
Mean age (SD)	40 (11.5)	40 (11.5)	41 (10.7)	41 (10.8)	42 (11.4)	41 (11.4)	42 (11.4)	42 (11.6)	43 (11.4)	42 (11.4)	44 (11.6)	44 (11.6)	44 (11.7)	44 (11.7)	43 (11.5)	43 (11.5)	43 (11.6)	43 (11.6)	43 (11.4)	43 (11.5)
GENDER																				
Female (%)	288 (85.5)	304 (85.6)	237 (84)	256 (83.4)	477 (82)	520 (82)	429 (87)	473 (86.6)	647 (85.8)	705 (85.5)	542 (86.7)	592 (84.5)	656 (84.9)	719 (84.2)	727 (86.2)	813 (84.9)	2068 (84.5)	2248 (84.3)	1935 (86.3)	2134 (85)
Male (%)	49 (14.5)	51 (14.4)	45 (16)	51 (16.6)	105 (18)	114 (18)	64 (13)	73 (13.4)	107 (14.2)	120 (14.5)	83 (13.3)	109 (15.5)	117 (15.1)	135 (15.8)	116 (13.8)	145 (15.1)	378 (15.5)	420 (15.7)	308 (13.7)	378 (15)
ETHNICITY																				
Hispanic or Latino (%)	78 (23.1)	81 (22.8)	51 (18.1)	59 (19.2)	82 (14.1)	92 (14.5)	85 (17.2)	92 (16.8)	113 (15)	126 (15.3)	97 (15.5)	109 (15.5)	120 (15.5)	128 (15)	116 (13.8)	137 (14.3)	393 (16.1)	427 (16)	349 (15.6)	397 (15.6)
RACE																				
American Indian or Alaska Native (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (0.7)	5 (0.8)	3 (0.6)	4 (0.7)	4 (0.5)	4 (0.5)	6 (1)	6 (0.9)	3 (0.4)	4 (0.5)	4 (0.5)	4 (0.4)	11 (0.4)	13 (0.5)	13 (0.6)	14 (0.6)
Asian (%)	25 (7.4)	28 (7.9)	17 (6)	17 (5.5)	48 (8.2)	50 (7.9)	38 (7.7)	41 (7.5)	53 (7)	56 (6.8)	54 (8.6)	62 (8.8)	73 (9.4)	76 (8.9)	71 (8.4)	75 (7.8)	199 (8.1)	210 (7.9)	180 (8)	195 (7.8)
Black or African American (%)	78 (23.1)	85 (23.9)	73 (25.9)	78 (25.4)	180 (30.9)	200 (31.5)	131 (26.6)	145 (26.6)	211 (28)	226 (27.4)	193 (30.9)	224 (32)	244 (31.6)	271 (31.7)	245 (29.1)	273 (28.5)	713 (29.1)	782 (29.3)	642 (28.6)	720 (28.7)
Native Hawaiian or Other Pacific Islander (%)	1 (0.3)	1 (0.3)	0 (0)	0 (0)	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	2 (0.3)	2 (0.2)	0 (0)	0 (0)	5 (0.6)	5 (0.6)	2 (0.2)	3 (0.3)	9 (0.4)	9 (0.3)	3 (0.1)	4 (0.2)
White (%)	185 (54.9)	192 (54.1)	157 (55.7)	171 (55.7)	276 (47.4)	296 (46.7)	252 (51.1)	280 (51.3)	401 (53.2)	443 (53.7)	299 (47.8)	323 (46.1)	358 (46.3)	403 (47.2)	437 (51.8)	508 (53)	1220 (49.9)	1334 (50)	1145 (51)	1282 (51)
Other (%)	41 (12.2)	42 (11.8)	30 (10.6)	35 (11.4)	55 (9.5)	62 (9.8)	45 (9.1)	49 (9)	59 (7.8)	67 (8.1)	57 (9.1)	68 (9.7)	76 (9.8)	81 (9.5)	69 (8.2)	80 (8.4)	231 (9.4)	252 (9.4)	201 (9)	232 (9.2)
OCCUPATION																				
Administrative/clerical (%)	36 (10.7)	37 (10.4)	39 (13.8)	45 (14.7)	70 (12)	78 (12.3)	65 (13.2)	74 (13.6)	100 (13.3)	115 (13.9)	82 (13.1)	94 (13.4)	96 (12.4)	107 (12.5)	102 (12.1)	119 (12.4)	302 (12.3)	337 (12.6)	288 (12.8)	332 (13.2)
Clinical care support staff (%)	73 (21.7)	76 (21.4)	60 (21.3)	66 (21.5)	119 (20.4)	131 (20.7)	107 (21.7)	123 (22.5)	188 (24.9)	203 (24.6)	129 (20.6)	157 (22.4)	196 (25.4)	217 (25.4)	208 (24.7)	228 (23.8)	576 (23.5)	627 (23.5)	504 (22.5)	574 (22.9)
Environmental services/housekeeping (%)	1 (0.3)	1 (0.3)	1 (0.4)	1 (0.3)	9 (1.5)	12 (1.9)	3 (0.6)	4 (0.7)	4 (0.5)	4 (0.5)	0 (0)	0 (0)	2 (0.3)	2 (0.2)	3 (0.4)	3 (0.3)	16 (0.7)	19 (0.7)	7 (0.3)	8 (0.3)
Physician/APP/physician trainee (%)	37 (11)	39 (11)	35 (12.4)	40 (13)	53 (9.1)	54 (8.5)	48 (9.7)	48 (8.8)	55 (7.3)	59 (7.2)	54 (8.6)	58 (8.3)	80 (10.3)	88 (10.3)	53 (6.3)	61 (6.4)	225 (9.2)	240 (9)	190 (8.5)	207 (8.2)
Nurse/nurse trainee (%)	142 (42.1)	151 (42.5)	120 (42.6)	123 (40.1)	228 (39.2)	244 (38.5)	224 (45.4)	248 (45.4)	307 (40.7)	337 (40.8)	260 (41.6)	284 (40.5)	319 (41.3)	353 (41.3)	337 (40)	394 (41.1)	996 (40.7)	1085 (40.7)	941 (42)	1049 (41.8)
Registration/reception (%)	10 (3)	12 (3.4)	11 (3.9)	12 (3.9)	21 (3.6)	27 (4.3)	22 (4.5)	22 (4)	26 (3.4)	28 (3.4)	25 (4)	29 (4.1)	35 (4.5)	39 (4.6)	29 (3.4)	31 (3.2)	92 (3.8)	106 (4)	87 (3.9)	94 (3.7)
Social worker/pastoral care (%)	0 (0)	0 (0)	1 (0.4)	1 (0.3)	9 (1.5)	9 (1.4)	4 (0.8)	4 (0.7)	8 (1.1)	9 (1.1)	10 (1.6)	10 (1.4)	11 (1.4)	11 (1.3)	19 (2.3)	20 (2.1)	28 (1.1)	29 (1.1)	34 (1.5)	35 (1.4)
Other (%)	38 (11.3)	39 (11)	15 (5.3)	19 (6.2)	73 (12.5)	78 (12.3)	20 (4.1)	23 (4.2)	66 (8.8)	70 (8.5)	65 (10.4)	69 (9.8)	34 (4.4)	37 (4.3)	92 (10.9)	102 (10.6)	211 (8.6)	224 (8.4)	192 (8.6)	213 (8.5)
PATIENT POPULATION SERVED																				
Adult (%)	155 (46)	163 (45.9)	140 (49.6)	152 (49.5)	315 (54.1)	338 (53.3)	264 (53.5)	296 (54.2)	414 (54.9)	455 (55.2)	376 (60.2)	434 (61.9)	482 (62.4)	530 (62.1)	471 (55.9)	527 (55)	1366 (55.8)	1486 (55.7)	1251 (55.8)	1409 (56.1)
Pediatric (%)	112 (33.2)	120 (33.8)	41 (14.5)	43 (14)	154 (26.5)	168 (26.5)	89 (18.1)	97 (17.8)	169 (22.4)	177 (21.5)	127 (20.3)	134 (19.1)	81 (10.5)	92 (10.8)	253 (30)	299 (31.2)	516 (21.1)	557 (20.9)	510 (22.7)	573 (22.8)
Adult and pediatric (%)	70 (20.8)	72 (20.3)	101 (35.8)	112 (36.5)	113 (19.4)	128 (20.2)	140 (28.4)	153 (28)	171 (22.7)	193 (23.4)	122 (19.5)	133 (19)	210 (27.2)	232 (27.2)	119 (14.1)	132 (13.8)	564 (23.1)	625 (23.4)	482 (21.5)	530 (21.1)
CLINIC TYPE																				
Dental/dialysis (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (1)	6 (0.9)	9 (1.8)	9 (1.6)	6 (0.8)	6 (0.7)	16 (2.6)	16 (2.3)	13 (1.7)	13 (1.5)	6 (0.7)	6 (0.6)	25 (1)	25 (0.9)	31 (1.4)	31 (1.2)
Emergency transport (%)	12 (3.6)	12 (3.4)	0 (0)	0 (0)	18 (3.1)	21 (3.3)	0 (0)	0 (0)	0 (0)	0 (0)	16 (2.6)	17 (2.4)	0 (0)	0 (0)	22 (2.6)	25 (2.6)	30 (1.2)	33 (1.2)	38 (1.7)	42 (1.7)
Emergent/urgent care (%)	82 (24.3)	90 (25.4)	104 (36.9)	114 (37.1)	193 (33.2)	210 (33.1)	87 (17.6)	98 (17.9)	219 (29)	244 (29.6)	143 (22.9)	157 (22.4)	138 (17.9)	156 (18.3)	254 (30.1)	296 (30.9)	632 (25.8)	700 (26.2)	588 (26.2)	665 (26.5)
Primary care (%)	243 (72.1)	253 (71.3)	178 (63.1)	193 (62.9)	363 (62.4)	394 (62.1)	385 (78.1)	427 (78.2)	518 (68.7)	562 (68.1)	435 (69.6)	495 (70.6)	610 (78.9)	672 (78.7)	551 (65.4)	619 (64.6)	1734 (70.9)	1881 (70.5)	1549 (69.1)	1734 (69)
Specialty care (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.3)	3 (0.5)	12 (2.4)	12 (2.2)	11 (1.5)	13 (1.6)	15 (2.4)	16 (2.3)	12 (1.6)	13 (1.5)	10 (1.2)	12 (1.3)	25 (1)	29 (1.1)	37 (1.6)	40 (1.6)
SITE																				
Children's Hospital Colorado (%)	0 (0)	0 (0)	0 (0)	0 (0)	37 (6.4)	39 (6.2)	9 (1.8)	9 (1.6)	82 (10.9)	86 (10.4)	14 (2.2)	14 (2)	28 (3.6)	28 (3.3)	88 (10.4)	105 (11)	147 (6)	153 (5.7)	111 (4.9)	128 (5.1)
Denver Health (%)	100 (29.7)	104 (29.3)	114 (40.4)	127 (41.4)	115 (19.8)	128 (20.2)	138 (28)	147 (26.9)	134 (17.8)	148 (17.9)	114 (18.2)	126 (18)	125 (16.2)	141 (16.5)	115 (13.6)	134 (14)	474 (19.4)	521 (19.5)	481 (21.4)	534 (21.3)
Johns Hopkins University (%)	149 (44.2)	161 (45.4)	106 (37.6)	116 (37.8)	195 (33.5)	219 (34.5)	196 (39.8)	219 (40.1)	224 (29.7)	251 (30.4)	209 (33.4)	229 (32.7)	203 (26.3)	228 (26.7)	281 (33.3)	318 (33.2)	771 (31.5)	859 (32.2)	792 (35.3)	882 (35.1)
The Michael E. DeBakey VA Medical Center (%)	0 (0)	0 (0)	0 (0)	0 (0)	52 (8.9)	54 (8.5)	46 (9.3)	52 (9.5)	95 (12.6)	102 (12.4)	37 (5.9)	57 (8.1)	117 (15.1)	131 (15.3)	107 (12.7)	124 (12.9)	264 (10.8)	287 (10.8)	190 (8.5)	233 (9.3)
VA New York Harbor Healthcare System (%)	88 (26.1)	90 (25.4)	62 (22)	64 (20.8)	89 (15.3)	96 (15.1)	44 (8.9)	53 (9.7)	106 (14.1)	112 (13.6)	115 (18.4)	123 (17.5)	125 (16.2)	135 (15.8)	130 (15.4)	135 (14.1)	408 (16.7)	433 (16.2)	351 (15.6)	375 (14.9)
VA Eastern Colorado Healthcare System (%)	0 (0)	0 (0)	0 (0)	0 (0)	37 (6.4)	40 (6.3)	27 (5.5)	29 (5.3)	55 (7.4)	64 (7.8)	73 (11.7)	79 (11.3)	97 (12.5)	107 (12.5)	59 (7)	69 (7.2)	189 (7.7)	211 (7.9)	159 (7.1)	177 (7.1)
Washington, DC VA Medical Center (%)	0 (0)	0 (0)	0 (0)	0 (0)	57 (9.8)	58 (9.1)	33 (6.7)	37 (6.8)	58 (7.7)	62 (7.5)	63 (10.1)	73 (10.4)	78 (10.1)	84 (9.8)	63 (7.5)	73 (7.6)	193 (7.9)	204 (7.6)	159 (7.1)	183 (7.3)
COMORBID CONDITIONS																				
Asthma (%)	36 (10.7)	39 (11)	35 (12.4)	38 (12.4)	63 (10.8)	71 (11.2)	42 (8.5)	47 (8.6)	80 (10.6)	85 (10.3)	68 (10.9)	79 (11.3)	80 (10.3)	89 (10.4)	70 (8.3)	91 (9.5)	259 (10.6)	284 (10.6)	215 (9.6)	255 (10.2)
Chronic obstructive pulmonary disease (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (0.5)	3 (0.5)	4 (0.8)	4 (0.7)	1 (0.1)	1 (0.1)	2 (0.3)	2 (0.3)	2 (0.3)	2 (0.2)	0 (0)	0 (0)	6 (0.2)	6 (0.2)	6 (0.3)	6 (0.2)
Cardiac disease (%)	2 (0.6)	2 (0.6)	3 (1.1)	3 (1)	13 (2.2)	13 (2.1)	13 (2.6)	15 (2.7)	7 (0.9)	7 (0.8)	9 (1.4)	9 (1.3)	9 (1.2)	12 (1.4)	12 (1.4)	14 (1.5)	31 (1.3)	34 (1.3)	37 (1.6)	41 (1.6)
Other respiratory disease (%)	7 (2.1)	7 (2)	3 (1.1)	3 (1)	7 (1.2)	8 (1.3)	15 (3)	15 (2.7)	11 (1.5)	14 (1.7)	15 (2.4)	17 (2.4)	8 (1)	8 (0.9)	11 (1.3)	14 (1.5)	33 (1.3)	37 (1.4)	44 (2)	49 (2)
Other systemic disease (%)	20 (5.9)	20 (5.6)	12 (4.3)	13 (4.2)	22 (3.8)	23 (3.6)	24 (4.9)	27 (4.9)	39 (5.2)	41 (5)	21 (3.4)	25 (3.6)	34 (4.4)	34 (4)	34 (4)	39 (4.1)	115 (4.7)	118 (4.4)	91 (4.1)	104 (4.1)
ANNUAL INFLUENZA VACCINATION STATUS																				
Not vaccinated (%)	67 (19.9)	70 (19.7)	26 (9.2)	27 (8.8)	91 (15.6)	96 (15.1)	52 (10.5)	61 (11.2)	135 (17.9)	155 (18.8)	113 (18.1)	143 (20.4)	194 (25.1)	229 (26.8)	179 (21.2)	220 (23)	487 (19.9)	550 (20.6)	370 (16.5)	451 (18)
Vaccinated (%)	253 (75.1)	264 (74.4)	249 (88.3)	264 (86)	491 (84.4)	517 (81.5)	439 (89)	469 (88.5)	616 (

^a Clinical Care Support Staff= staff who have direct patient contact such as clinical medical assistant, clinical technician, etc.
APP= Advanced Practice Provider (physician assistant, nurse practitioner)
Occupational Risk based on direct patient contact such as physical examination and/or performance of high risk procedures (intubation, airway suctioning, nebulizer treatments, nasopharyngeal aspiration) for high risk, medium risk for direct patient contact, low risk for no or minimal direct patient contact.