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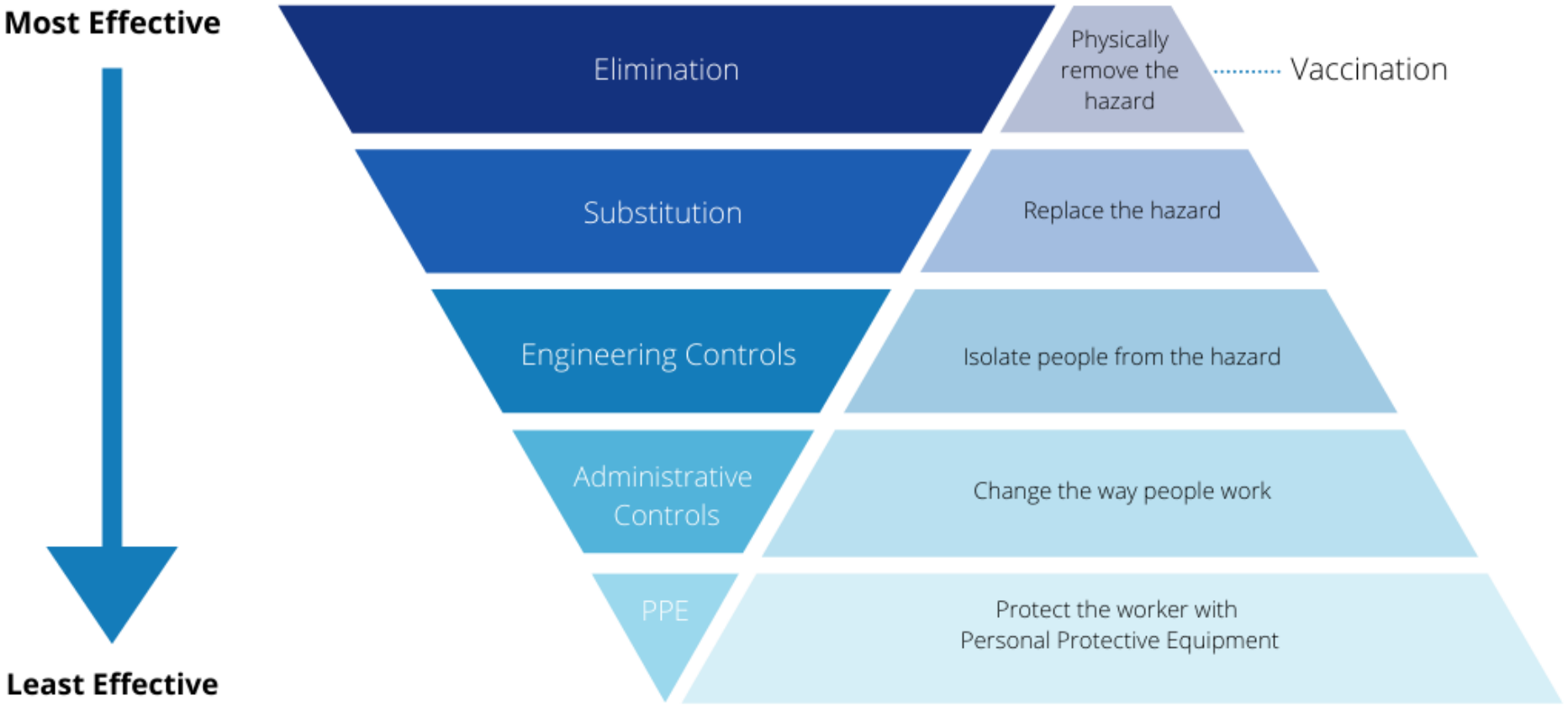
Appendices: COVID-19 Vaccination as a Condition of Employment for Healthcare Personnel

Contents

Figure 1. Hierarchy of Controls



This graphic is adapted from the National Institute for Occupational Safety and Health (NIOSH) "Hierarchy of Controls" (1). As explained by NIOSH, the control methods that fall into the highest tier of the graphic are potentially more effective and protective than those that are lower. Following this hierarchy normally leads to the implementation of inherently safer systems, with reduction of illness and injury in workplaces.

Vaccines are an elimination method in the top tier and thus are highly effective at reducing risk of hazard to HCP.

Table 1. Vaccine Efficacy and Real-World Effectiveness

Setting	Outcome(s)	Vaccine Efficacy (95% confidence interval)[a]
Phase-3/4 Clinical Trials Experience		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Polack (2) Multinational randomized placebo-controlled trial • Symptomatic infection ≥7 days after dose 2 in persons ≥16 years of age • No significant difference in VE by age, gender, race/ethnicity, BMI, coexisting conditions • Only one case in vaccinated, 4 cases in placebo group (vaccine efficacy 75% [95% CI -152.6-99.5])	1. Symptomatic Infection 2. Severe Disease, Hospitalization, Death 3. Asymptomatic Infection	1. 95% (90.3-97.6%) 2. 75% (-152.6-99.5%) 3. Not assessed
mRNA-1273 (Moderna)		
Baden (3) US multisite randomized, stratified, placebo-controlled trial • Symptomatic infection ≥14 days after dose 2 in persons age >18 years of age • 30 (including one death) in placebo group, none in vaccine group	1. Symptomatic Infection 2. Severe Disease, Hospitalization, Death 3. Asymptomatic Infection	1. 94.1% (89.3-96.8%) 2. 100% 3. Not assessed
Viral Vector Vaccines		
Ad26.COV2.S (J&J)		

Sadoff (4)
Multinational (US, South Africa, Brazil, Chile, Argentina, Colombia, Peru, Mexico) randomized, placebo-controlled trial
• Symptomatic infection ≥14 days and ≥28 days after dose in persons ≥18 years of age
• Similar efficacy across age, gender, race/ethnicity, comorbidities
• Severe disease, hospitalization, or death ≥14 days after vaccine administration:
  ○ 5 COVID-19-related deaths in placebo group
  ○ None in vaccine group
• Asymptomatic infection:
  ○ Based on subset with SARS-CoV-2 serology results 71 days after vaccination, 0.7% of vaccine recipients had no symptoms of COVID-19 but had documented seroconversion to a non–spike protein compared with 2.8% of placebo recipients.
	1. Symptomatic Infection
	
	2. Severe Disease
	3. Hospitalization
	4. Death
	5. Asymptomatic infection
		1. *Global*: at ≥14 days: 66.9% (59.1-73.4%)
		US: at ≥14 days: 74.4% (65.0-81.6%)
		2. 76.7% (54.6-89.1%)
		3. 93.1% (72.7-99.2%)
		4. 100%
		5. 65.5% (39.9-81.1%)

Real-world Experience / Vaccine Effectiveness Studies		
Healthcare Personnel (HCP)		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Tang (5) US; HCP at St Jude Children's Research Hospital: ≥7 days after dose 2	1. Asymptomatic or Symptomatic[a] 2. Asymptomatic 3. Symptomatic or after known exposure	1. 96% (91-98%) 2. 90% (78-96%) 3. 100% (N/A)
Angel (6) Israel; HCP at a tertiary medical center in Tel Aviv: ≥7 days after dose 2	1. Symptomatic 2. Asymptomatic	1. 98% (93-100%) 2. 91% (75-97%)
Hall (7) England; HCP in publicly funded hospitals: ≥7 days after dose 2.	1. Asymptomatic or Symptomatic	1. 86% (76-97%)
Swift (8) US: HCP at Mayo Clinic Health System: >14 days after dose 2.	1. Asymptomatic or Symptomatic	1. 96.8% (95.3-97.8%)
Keehner (9) US: HCP at University of California, San Diego and the University of California, Los Angeles health systems: >14 days after dose 2.	1. Asymptomatic or Symptomatic	1. Absolute risk of testing positive after vaccination was 1.19%

		among HCP at UCSD and 0.97% among HCP at UCLA
Fabiani (10) Italy: HCP, Treviso province, Veneto region: ≥7 days after dose 2.	1. Asymptomatic or Symptomatic 2. Symptomatic	1. 95.1% (62.4-99.4%) 2. 93.7% (50.8-99.2%)
mRNA-1273 (Moderna)		
Swift (8) US: HCP at Mayo Clinic Health System: >14 days after dose 2.	1. Asymptomatic or Symptomatic	1. 98.6% (90-100%)
Either mRNA Vaccine		
Daniel (11) US: HCP at the University of Texas Southwestern Medical Center: BNT162b2 vaccine ≥7 days after dose 2 or mRNA-1273 ≥14 days after dose 2.	1. Asymptomatic or Symptomatic	1. *Non-vaccinated employees:* (2.61%; 2.29-2.96) *Vaccinated employees*: (0.05%; 0.01-0.13)
Thompson (12) US: HCP, first responders, and other essential and frontline workers in 8 cities: ≥14 days after dose 2.	1. Asymptomatic or Symptomatic	1. 90% (68-97%)
Pilishvili (13) US: HCP in 33 sites (interim analysis): ≥7 days after dose 2.	1. Symptomatic	1. 93.5% (86.5-96.9%)
Population-wide Surveillance		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Haas (14) Israel; national surveillance data in residents of Israel 16 years and older: ≥7 days after dose 2.	1. Asymptomatic or Symptomatic 2. Asymptomatic 3. Symptomatic 4. Hospitalization 5. Severe/Critical Hospitalization 6. Death	1. 95.3% (94.9–95.7%) 2. 91.5% (90.7-92.2%) 3. 97% (96.7-97.2%) 4. 97.2% (96.8–97.5%) 5. 97.5% (97.1–97.8%) 6. 96.7% (96–97.3%)
Dagan (15) Israel; data from subjects 16 years and older from Clalit Health Services, large integrated healthcare organization: ≥7 days after dose 2.	1. Asymptomatic or Symptomatic 2. Symptomatic 3. Hospitalization 4. Severe disease	1. 92% (88–95%) 2. 94% (87–98%) 3. 87% (55–100%) 4. 92% (75–100%)
Chodick (16) Israel; cohort study of members of a large health provider in Israel: 7 to 27 days after dose 2.	1. Asymptomatic or Symptomatic 2. Symptomatic	1. 90% (79-95%) 2. 94% (88-97%)
Viral Vector Vaccines		
Ad26.COV2.S (J&J)		
Corchado-Garcia (17) US; longitudinal data from Mayo Clinic health system: ≥15 days after dose.	1. Asymptomatic or Symptomatic	1. 76.7% (30.3-95.3%)
Elderly Individuals		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Haas (14) Israel; national surveillance data in residents of Israel 65 years and older: ≥7 days after dose 2.	1. Asymptomatic or Symptomatic 2. Asymptomatic 3. Symptomatic 4. Hospitalization 5. Severe/Critical Hospitalization 6. Death	1. 95% (93.9–95.5%) 2. 88.5% (86.4–90.3%) 3. 96.4% (95.9–97%) 4. 96.8% (96.2–97.3%) 5. 97.3% (96.8–97.8%) 6. 96.9% (96–97.6%)
Lopez Bernal (18) Scotland; community surveillance of patients 70 years and older: ≥14 days after dose 2.	1. Symptomatic	1. 80 years and older: 89% (85-93%)
Chodick (16) Israel; cohort study of members of a large health provider in Israel: 7 to 27 days after dose 2.	1. Asymptomatic or Symptomatic	1. *65-74 years*: 82% (63-92%) *75 years and older*: 82% (61-91%)

Either mRNA Vaccine		
Tenforde (19) US; evaluation at 24 hospitals in 14 states of patients 65 years and older: ≥14 days after dose 2.	1. Hospitalization	1. 94% (49-99%)
Nursing Homes – Congregate Settings		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Britton (20) US; residents of 2 skilled nursing facilities in Connecticut: ≥14 days after dose 1 through 14 days after dose 2.	1. Asymptomatic and Symptomatic	1. 60% (33-77%)
Cavanaugh (21) US; residents and workers of skilled nursing facility in Kentucky: ≥14 days after dose 2.	1. Symptomatic	1. Residents 87% (66–95%) Workers 87% (46-97%)
Immunosuppressed Individuals		
mRNA Vaccines		
BNT162b2 (Pfizer)		
Chodick (16) Israel; cohort study of members of a large health provider in Israel: 7 to 27 days after dose 2.	1. Asymptomatic and Symptomatic 2. Symptomatic	1. 71% (37-87%) 2. 75% (44-88%)
Impact of Variant Status on Vaccine Efficacy		
mRNA Vaccines		
BNT162b 2 (Pfizer)		
Alpha (B.1.1.7) Abu-Raddad (22) Qatar; mass immunization campaign in Qatar. VE determined 2 weeks after dose 2.	1. Documented Infection 2. Severe, Critical, or Fatal disease	1. 90% (85.9-92.3%) 2. 100% (81.7–100%)
Alpha (B.1.1.7) Sheikh (23) Scotland; real-world population surveillance from Scotland. VE determined at least 2 weeks after dose 2.	1. Documented infection	1. 92% (90-93%)
Beta (B.1.351) Abu-Raddad (22) Qatar; mass immunization campaign in Qatar. VE determined 2 weeks after dose 2.	1. Documented Infection 2. Severe, Critical, or Fatal disease	1. 75% (70.5-78.9%) 2. 100% (73.7–100%)
Delta (B.1617.2) Sheikh (23) Scotland; real-world population surveillance from Scotland. VE determined at least 2 weeks after dose 2.	1. Documented infection	1. 79% (75-82%)
Viral Vector Vaccines		
Ad26.COV2.S (J&J)		
Beta (B.1.351) Sadoff (4) Multinational; randomized, placebo-controlled trial data from South Africa, 95% cases from Beta (B.1.351) Infection ≥14 days after dose.	1. Symptomatic Infection 2. Severe/Critical Disease	1. 52% (30.3-67.4%) 2. 73% (40–89.4%)
Zeta (P.2) Sadoff (4) Multinational; randomized, placebo-controlled trial data from Brazil, 69% cases from Zeta (P.2) Infection ≥14 days after dose.	1. Symptomatic Infection 2. Severe/Critical Disease	1. 66.2% (51-77.1%) 2. 81.9% (17-98.1%)

[a] Asymptomatic or Symptomatic: encompasses reported outcomes that do not distinguish vaccine efficacy between asymptomatic and symptomatic infections including outcomes labeled as any positive test or documented infection.

Table 2. Summary of COVID-19 Side Effects Reported in Phase 3 Clinical Trials for Pfizer-BioNTech, Moderna, and Johnson & Johnson/Janssen Vaccines

Side Effect	Pfizer-BioNtech (2) %	Moderna (3) %	J&J/Janssen (4) %	Placebo (2-4) %
Local (any)	NR	84-89	38-60	18-20*
Pain	66-83	84-88	32-60	8-18
Erythema	5-7	3-9	4-8	0.4-1
Systemic (any)	NR	55-79	45-60	35-42*
Fever ≥38° C	1-16	1-16	2-10	0-1
Headache	39-52	33-59	32-42	14-34
Fatigue	34-59	37-65	32-42	17-33
Myalgia	14-37	23-58	28-38	5-15
Serious AEs (≥ grade 3)	0.6	1.5	0.4	0.4-1.3

Note: Adverse events were reported slightly differently in each trial; some reported for entire study population, others had reactogenicity subset. Ranges include first versus second doses and/or younger versus older populations. Some data were only presented in graphical format; thus, exact percentages were not available. When available, numbers were rounded. The placebo column represents ranges from all 3 trials.

*reported only for Moderna, J&J.

NR, not reported.

Table 3. Summary of Post-authorization Safety Monitoring Systems in the US for COVID-19 Vaccines

Name of Safety Monitoring System	Type of Safety Surveillance	Population(s) included	Major Strengths	Major Weaknesses
CDC/FDA, Vaccine Adverse Event Reporting System (VAERS)	Passive	Entire US population	Early signal detection	Cannot determine causality
CDC, National Healthcare Safety Network (NHSN)	Passive	17,000 LTCF Includes HCP	Early signal detection Directs VAERS reporting	Aggregate voluntary reporting of doses administered and counts of non-specific AEs; Cannot determine causality
DoD, Vaccine Adverse Event Clinical System (VAECS)	Passive	Military	Early signal detection	Cannot determine causality
VA, Adverse Drug Event Reporting System (ADERS)	Passive	VA HCP 8000 residents/day in VA LTCF	Early signal detection	Cannot determine causality
CDC, Clinical Immunization Safety Assessment (CISA)	Clinical consultation service	General population	Review of high-priority AEs of special interest and clinical questions	Cannot determine causality
CDC, v-safe	Active	All vaccine recipients with smartphones	Early signal detection	Relies on recipients to sign up and complete surveys; recipients without smartphones cannot participate
CDC, Vaccine Safety Datalink (VSD)	Linked database monitoring	>12 million persons/year in 9 integrated health systems	Data refreshed weekly with weekly sequential analyses (RCA)	1 to 2-week data lag (up to 6 weeks for hospitalized)
VA Electronic Health Record & Active Surveillance System	Linked database monitoring	Veterans 8000 residents/day in VA LTCF	Data refreshed weekly with weekly sequential analyses (RCA)	~1 week data lag (up to 4 weeks for hospitalized)
FDA, Biologics Effectiveness and Safety (BEST) System	Linked database monitoring	Commercial & CMS medical/pharmacy databases, >100 million beneficiaries	Multiple partners, variety of healthcare settings	1 to 4-months data lag, depending on source
FDA/CMS, Medicare data	Linked database monitoring	55-60 million (92% of US elderly) Includes ~650K LTCF residents	Data refreshed weekly with weekly sequential analyses (RCA)	CMS data lag ~4 weeks
FDA, Post-licensure Rapid Immunization Safety Monitoring (PRISM) program	Linked database monitoring	>70 million individuals/year, all 50 states represented		
Genesis Healthcare (24)	Linked database monitoring	LTCF residents in 284 Genesis long-term care facilities	Near real-time monitoring of adverse events and safety during rapid vaccine deployment in vulnerable LTCF population	
DoD, Electronic Health Record and Defense Medical Surveillance System	Linked database monitoring	Active duty/ Reserves/Guard personnel		

CDC, Centers for Disease Control and Prevention. CMS, Centers for Medicare and Medicaid Services. DoD, Department of Defense. EMR, electronic medical record. FDA, Food and Drug Administration. LTCF, long-term care facilities. RCA, rapid cycle analysis. VA, Department of Veterans Affairs.

Table 4. Advantages of a Fully Vaccinated Workforce

Domain	Description	References
Reduced Risk of SARS-CoV-2 Transmission and Impact of Exposures on Vulnerable Populations	**Reduce risk of transmission from HCP-to-HCP.** Risk of transmission from HCP-to-HCP has been associated with lack of masking both in healthcare facilities and in social gatherings outside of work.	(25-29)
	Reduce risk of transmission from HCP-to-patient. Risk of transmission from HCP-to-patient has been reported to be low, however, risk can be further reduced through reduction of infection in HCP, especially when patients are unable to mask or may remain at risk of infection despite being vaccinated (i.e., congregate care settings, including post-acute and long-term care, assisted living, and behavioral health settings as well as individuals with impaired response to vaccination due to immunocompromising conditions or to age-related immunosenescence).	(21, 30, 31)
	Reduce risk of patient-to-HCP transmission. Reported risk of exposure from an infected patient leading to HCP infection is low; however, this can be reduced further through vaccination of HCP.	(32)
	Reduce risk of within-household transmission. Risk of transmission in households settings ranges from 10-50% of exposures. HCP who are fully vaccinated are less likely to become infected due to household exposure; they are also, if vaccinated less likely to become infected and transmit within the household.	(30, 32-36)
	Reduce incidence and impact of exposures. For residents of post-acute and long-term care settings, the consequences of unvaccinated HCP extend beyond the risk of infection. Any new case of SARS-CoV-2 infection among HCP represents a potential. The response to an outbreak of SARS-CoV-2 in long-term care facilities includes suspending visitation until the affected unit in the nursing home has had 14 days without a new case of SARS-CoV-2 infection among residents or HCP. Visitation of family and friends for nursing homes residents has only recently resumed. A return to quarantine has profound negative consequences on the emotional well-being, cognitive function, and physical health of nursing home residents. Through vaccination, HCP working in long-term care settings mitigate the risk of both infection and exposure of frail elders who have suffered social isolation during the pandemic.	(37-39)
Promotion of HCP wellness and maintaining a healthy workplace	**Prevention of morbidity and mortality among HCP.** COVID-19 among HCP has followed same trend as general population. HCP are essential workers, and during the pandemic, their role is critical. A reduction in workforce during a pandemic impacts all HCP, resulting in increased stress and increased work load, and decreased capacity to care for patients. Early data suggest decreased number of infections in HCP, beginning soon after the first dose of the two-dose series. Vaccination prevents COVID-19 infection and its long term sequalae.	(6, 7, 9, 11, 40-45)
	Reduce the disruption in workforce. Reduction in HCP infections and exposures can ensure sufficient staffing levels to support patient safety and HCP wellness. In the absence of fully vaccinated workforce, challenges with absenteeism and presenteeism will persist.	(46-50)
	Return to pre-pandemic workplace social and professional interactions. The CDC recently released guidance supporting unmasked and non-distanced interactions between fully vaccinated HCP in breakrooms and meetings however cautioned that if unvaccinated HCP are present, everyone should wear source control and unvaccinated HCP should physically distance from others.	(51)
	Decrease resource burden of exposure investigations and management. A fully vaccinated healthcare workforce will have a reduced number of exposures from HCP-to-patient and thus reduce the resources required to identify exposed HCP and patients, refer for testing, and complete follow up.	(52)
	HCP wellbeing. HCP who are fully vaccinated have reported decreased mental stress after vaccination.	(53)
Maintaining trust in HCP and healthcare institutions	**HCP vaccination can increase overall trust in vaccination.** HCP are trusted messengers and their role modeling of vaccination uptake can reduce vaccine hesitancy among patients.	(54-56)
	Affirmation of patient safety. HCP and institutions that prioritize patient safety recognize vaccinations as important to preventing disease transmission.	(57)
	Recognition of evidenced-based practices. Medical science supports the efficacy and safety of vaccines. HCP who accept vaccines embody the prioritization of evidence-based practices over misinformation.	(58)
	Professional reputation. HCPs may be perceived as representing others in the profession and of their entire institution. Just as professional behavior and appearance reflect well on the entire organization, the professionalism of HCP accepting vaccines may also enhance the positive regard for others in their role, their institution, and healthcare in general.	(59)

Table 5. Strategies to Increase Vaccination Rates

Study	Country	Setting	Ads/ Promo	Educational Materials	Enhanced Access	Incentives	Formal Program and/or Leadership Support	Data	Enforcement and/or Punitive Action	Mandatory Declination	Mandatory Masking	Post-Intervention Annual Immunization Rate (%)
Bennett, 2020 (60)	Australia	Healthcare facilities (hospitals, ambulatory, skilled nursing facilities)						✓				87.7
Drees, 2015 (61)	US (DE)	Academic health system (hospitals, ambulatory, home care)	✓	✓	✓	✓		✓	✓	✓	✓	92.4-93.5
Esolen, 2011 (62)	US (PA)	Academic health system (hospital, ambulatory, surgical center)			✓		✓	✓	✓		✓	92-95
Esolen, 2014 (63)	US (PA)	Academic health system (hospital, ambulatory, surgical center)	✓		✓		✓	✓	✓		✓	95-97
Fricke, 2013 (64)	US (LA)	Hospitals (public, private and academic)	✓		✓					✓	✓	81-91
Frisina, 2019 (65)	US (NJ)	University health center (ambulatory)	✓	✓	✓							91.1
Heinrich-Morrison, 2015 (66)	Australia	Health system (3 hospitals)	✓		✓	✓		✓				80.3
Honda, 2013 (67)	Japan	Academic hospital	✓		✓			✓	✓	✓		96.9
Jiang, 2018 (68)	US (TN)	Pediatric hospital		✓	✓		✓	✓				90
Jung, 2017 (69)	Korea	Academic hospital		✓	✓				✓	✓	✓	94.7
Kim, 2015 (70)	US (RI)	Healthcare facilities (hospitals, skilled nursing facilities, home care)		✓	✓	✓		✓	✓	✓	✓	87.20
Ksienski, 2014 (71)	Canada	Healthcare facilities (hospital, long term care)			✓		✓				✓	74 (hospital), 75 (long-term care)
Marshall, 2019 (72)	Australia	Academic health system (hospital, skilled nursing facility, long term care)	✓		✓		✓	✓		✓		78.6-82.4
McCullers, 2006 (73)	US (TN)	Academic pediatric hospital/research center (oncology)	✓	✓	✓		✓	✓				80 to 96
Modak, 2012 (74)	US (VA)	Academic hospital	✓	✓	✓			✓	✓	✓	✓	85

Palmore, 2009 (75)	US (MD)	Hospital (research center)	✓		✓		✓	✓	✓	✓		88
Perlin, 2013 (76)	US (nat'l)	Health system (hospitals, ambulatory, surgical centers)	✓	✓			✓	✓	✓	✓	✓	90.7 -94.7
Podczervinski, 2015 (77)	US (WA)	Ambulatory (oncology research center)		✓	✓	✓			✓	✓		92 (incentive-based), 96 (penalty-based)

- Examples of enhanced access: Expanded hours of vaccination clinics to all shifts/days, mobile vaccination units, ability to report vaccination obtained outside of work place
- Examples of formal program and leadership support: Unit-based champions; peer vaccinators; institutional vaccination targets; participation of key opinion leaders and/or hospital leadership in vaccination campaign
- Examples of enforcement or punitive action: Badge marking of unvaccinated employees; mandatory education or counseling; disciplinary action; loss of eligibility for annual raises for non-compliance with mandatory masking or declination process
- Examples of mandatory masking: Unvaccinated employees required to mask when face-to-face contact with patient anticipated; during direct clinical care; when in clinical care area; when in facility

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