

Do Declination Statements Increase Health Care Worker Influenza Vaccination Rates?

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In response to health care worker influenza vaccination rates that are below desired targets, strategies designed to stimulate vaccination have been proposed, including the use of declination statements for those refusing vaccination. The impact of these statements has not been thoroughly investigated and may be affected by their specific language and context. This review examines the available data on the use and impact of declination statements to increase health care worker vaccination rates and notes some potential pitfalls and issues that may arise with their use.

Because health care workers (HCWs) play an important role in the transmission of influenza to patients, influenza vaccination of HCWs has been recommended for several decades [1]. Often serving as the nidus for health care-associated influenza outbreaks, healthy HCWs can shed influenza virus with little or no symptoms and may work while ill [2]. Vaccination of HCWs against influenza reduces the morbidity and mortality rates of patients in long-term care facilities [3–5], and vaccination of target populations reduces medically attended acute respiratory infections in their close contacts [6]. Unfortunately, influenza vaccine coverage of HCWs in the United States has languished at ~40% [7], leading many groups to call for new measures to improve vaccination rates of HCWs [2, 8–12]. Numerous tools have been used to enhance HCW influenza vaccination coverage, including provision of vaccine free of charge, off-hours vaccination, mobile vaccination carts, administrative emphasis and support, enhanced education, and incentives [1, 2, 7, 11]. Despite these techniques, few institutions have achieved vaccination rates of >80%.

A common component of the HCW hepatitis B vaccination programs [13], the use of a signed informed declination statement for those refusing vaccination, has recently been recommended as a tool to improve HCW influenza vaccination rates [2, 7, 9, 14]. The intent of a declination statement is to

ensure that HCWs are appropriately informed of the rationale for influenza vaccination, to promote the message of patient safety, and to dispel commonly held misconceptions regarding influenza and influenza vaccination. This review examines the use and impact of declination statements on vaccination rates to illuminate the current debate surrounding the use of such statements as a part of HCW influenza vaccination programs.

HCW HEPATITIS B VACCINATION AND THE USE OF DECLINATION STATEMENTS

Signed declinations have been used as a tool to increase HCW hepatitis B vaccination rates for several decades. In 1991, the Occupational Safety and Health Administration enacted the Federal Bloodborne Pathogens Standard [15] in response to increasing concerns regarding the occupational risk of bloodborne pathogen transmission. This standard requires the provision of personal protective equipment, proper waste disposal, postexposure follow-up plans, and work practice controls. In addition, employers must offer the hepatitis B vaccine to employees with the potential for blood and body fluid exposure. Those who refuse vaccination must sign a declination form indicating that they understand the rationale for offering the vaccine and the risks involved with refusal [13].

It is difficult to determine the precise impact of the use of declination statements on hepatitis B vaccination rates from that due to other vaccination program components. Although prestandard vaccination coverage was not recorded, a survey in 1994 of 138 hospitals found that 66.5% of eligible HCWs had received 3 doses of hepatitis B vaccine. Vaccination coverage was higher among hospitals who notified supervisors or imposed sanctions for HCWs who refused vaccination and

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hospitals that required vaccination for employment [16]. The incidence of hepatitis B among HCWs also decreased by 95% from 1983 to 1995. Although this decrease preceded the passage of the standard, one of the greatest decreases in incidence over that time occurred soon after its enactment from 1992 to 1993 [16]. Passage of the standard was noted to result in increased HCW awareness of the importance of hepatitis B as a pathogen, reduced fear regarding vaccination adverse events, and greater vaccine acceptance [17]. Similar surveys have noted an increase in hepatitis B vaccination coverage among HCWs since the standard's passage from 51% in 1992 to 75% in 2002–2003 [17, 18]. In the 2004 National Health Interview Survey, 80.5% of surveyed HCWs aged 18–49 years had received the hepatitis B vaccine [19]. These data suggest that the use of declination statements in a comprehensive program has favorably affected hepatitis B vaccination rates and the incidence of occupationally acquired disease. However, other aspects of hepatitis B vaccination programs that have evolved from the initial emphasis by the standard, such as provision of free vaccine, vaccination as a part of admission to nursing and medical schools, and evolution of perceptions in which vaccination against hepatitis B is a core expectation for HCWs, must be acknowledged as having contributed to these positive outcomes.

The impact of the standard on institutions is also important to examine. Increased resources and efforts were required for HCW education, the determination of which HCWs were covered by the standard, and tracking of HCW vaccination and immune status [20]. In one survey, nearly 25% of vaccination program directors noted inadequate staff to support the standard's requirements, reflecting in part a potential burden related to the collection, recording, and filing of declination statements [17].

USE AND IMPACT OF DECLINATION STATEMENTS IN HCW INFLUENZA PROGRAMS

The signed declination statement, although only a recently proposed tool to improve HCW influenza vaccination rates [7], is increasingly being used in health care facilities. In a survey of 1000 hospitals, 15% of 555 responding hospitals had implemented declination forms during the 2005–2006 influenza vaccination season (J. Bartley, personal communication). A more recent survey of 50 university-associated health care facilities found that 42% tracked formal declinations for those HCWs refusing influenza vaccination with a median declination rate per facility of 14.5% (range, 0.8%–42.0%) [21].

Detailed examination of the impact of declination statements, particularly in the peer-reviewed literature, is limited. In a survey of 418 infectious diseases specialists, 23% noted use of declination statements as a part of their facility's program. Vaccination rates were significantly higher for institutions that required signed declination statements [22]. However, use

of declination statements was not the strongest predictor of higher vaccination rates. Instead, provision of the vaccine free of charge, adequate staffing and resources for the campaign, and education of targeted groups of HCWs were the key attributes of the most successful vaccination campaigns.

In a follow-up survey, which was sent to respondents of the first survey and to respondents of an online query who had noted the use or consideration of declination statements at their institution ($n = 100$) [23], 32 (71%) of 45 respondents indicated that declination statements had been implemented at their facility, with 23 (72%) implementing this strategy for the 2006–2007 season. Of the respondents who reported vaccination rates before and after declination implementation ($n = 22$), vaccination rates significantly increased on average 11.6% (range, –1% to +50%). Eighteen of the institutions concurrently used other strategies to improve HCW vaccination rates. Although mandated at 13 institutions, none of these facilities enacted penalties for failure to sign.

A statewide survey of 108 acute care hospitals and 302 nursing homes in Wisconsin noted use of declination forms as part of HCW influenza vaccination campaigns in 14% [24]. Median rates of vaccination were significantly higher in facilities that required declination forms for HCWs who refused vaccination (65% vs 56% in hospitals; 62% vs 50% in nursing homes). However, the impact of declination forms with adjustment for other facets of vaccination programs was not ascertained. The authors note that declination forms may have been used by more motivated facilities and “may be associated with, but not a cause of, higher rates of employee vaccination” [24, p 1399].

Despite having an extensive influenza campaign, HCW influenza vaccination rates at the Cleveland Clinic remained below institutional goals [25]. For the 2004–2005 influenza season, a program in which HCWs were required to accept vaccination or sign a paper declination form for reasons other than medical contraindications was implemented along with enhanced administrative support, education events, and incentives. The specific penalties for those refusing to sign the statement were not noted. Even with that year's vaccine shortage, vaccination rates increased modestly to 38%. The next year, an Internet-based form was used to capture declination. Vaccination rates increased significantly to 55% (a 9-year high for the institution), whereas 31% declined vaccination. The institution was also able to use the tool to identify specific HCW groups with low adherence for future educational efforts. The specific impact of declination statements could not be determined because of various other added components of the program.

In a quasi-experimental study directly examining the impact of declination statements on vaccination rates [26], influenza vaccine was offered to HCWs at 2 separate hospitals for a baseline period. E-mail messages were then sent to all unvac-

Table 1. Relative Impact of Various Strategies on Health Care Worker Influenza Vaccination Coverage

Intervention and study	Preintervention immunization rate, %	Postintervention immunization rate, %	Overall change in vaccination rate, %	Randomized, controlled trial of intervention	Implemented with other interventions
Declination					
Polgreen et al [23]	54	65	+11	No	Yes
Bertin et al [25]	38	55	+17	No	Yes
Ribner et al [27]	43	65	+22	No	Yes
Mandatory vaccination					
Virginia Mason [37]	30	98	+68	No	Yes
BJC HealthCare [39]	71	99	+28	No	Yes
Education and promotion					
Harbarth et al [31]	13	37	+24	No	Yes
Thomas et al [32]	8	46	+38	No	Yes
Mobile cart					
Sartor et al [29]	7	32	+25	No	Yes
Cooper et al [30]	8	49	+41	No	Yes
Incentives (raffle) [35]	38 ^a	42	NS	Yes	Yes
Educational letter from leadership [35]	38 ^a	39	NS	Yes	Yes
On-site expert education [33]	21 ^a	22	NS	Yes	Yes

NOTE. NS, nonsignificant.

^a Rate from nonintervention arm of concurrent randomized trial of intervention.

cinated HCWs. At one hospital, the alert encouraged vaccination (group A). At the other facility, HCWs were also asked to respond to a formal declination statement in the event they refused vaccination (group B). Whether the declination was mandated, consequences of failure to decline, and other aspects of each facility's vaccination program were not specified. Only 17% of unvaccinated group B HCWs used the tool to decline the vaccine. The frequency of postcommunication vaccination was lower in the declination group (13%, compared with 18% among group A HCWs), although this result did not reach statistical significance. A follow-up survey on reactions to the communication noted a nonsignificantly increased frequency of negative reactions among more respondents in group B versus group A (22.5% vs 13%).

Ribner et al [27] noted that the use of a declination form led to a marked increase in vaccination coverage from 43% to 66.5% of the >9000 HCWs within their health care system. More than 20% of HCWs, however, declined vaccination. The declination form was implemented along with visible leadership support, weekly feedback of vaccination rates to supervisors, and an incentive for HCWs receiving the vaccine, so that the precise impact of the form is unknown. The program also did not include physicians.

In a statewide program in which every hospital in Iowa ($n = 115$) voluntarily reported rates of HCW influenza vaccination, the vaccination rates were 12.6% higher at those facilities that used declination statements, compared with those that did not [28]. This significant association was present even after adjustment for urban location and a composite variable indicating the total number of recommended practices iden-

tified to increase HCW vaccination rates (of a total of 15) implemented at each facility. Finally, in another study, HCW influenza vaccination rates did not significantly differ between university-affiliated health care organizations that did and did not use declination forms during the 2007–2008 influenza season (56.4% vs 55.1%) [21].

COMPARISON OF DECLINATION STATEMENTS WITH OTHER STRATEGIES USED TO IMPROVE HCW INFLUENZA VACCINATION RATES

No trials have been published directly comparing the use of declination statements as part of a HCW vaccination program (regardless of the specific vaccine) to other interventions. In addition, published reports of the impact of vaccination strategies involve evaluations of multifaceted programs or interventions. Few have examined the use of a single intervention on HCW vaccination rates. Few published randomized, controlled trials examining a specific intervention designed to improve HCW vaccination rates exist as well. Nonetheless, an examination of the impact of these interventions may provide some measure, albeit limited, of the relative utility of each tool (Table 1).

Tools to improve availability. Lack of access to vaccine has been cited as a common reason for low HCW influenza vaccination rates [2], raising interest in interventions that improve HCW access to vaccination. Sartor et al [29] noted an increase in coverage from 7% before the use of mobile vaccination carts to 32% the year after implementation ($P < .001$). In Australia, use of a “Needles on Wheels” roving vaccination program also

increased vaccination rates from 8% to 49% [30]. In both instances, the mobile vaccination program was coupled with additional strategies, such as provision of free vaccine, education, and promotional campaigns.

Promotional and educational programs. Ensuring that HCWs are aware of a facility's vaccination program and understand the rationale for influenza vaccination is another key focus of interventions used to improve HCW vaccination rates. Focused studies examining the use of such educational or promotional programs, however, are infrequent. The use in high-risk units of educational conferences focusing on reasons why local HCWs refused influenza vaccination and the provision of vaccine on site in these units, E-mail reminders regarding vaccination, and an institutional publicity campaign resulted in a significant increase in HCW influenza vaccination rates from 10% to 26% housewide and from 13% to 37% in the high-risk areas where the formal education occurred [31]. Institution of a formal 1-day vaccination fair in a 300-bed nursing home was associated with a significant increase in vaccination rates (8% to 46%) [32]. Use of a public health nurse who conducted on-site education did not lead to improved vaccination coverage in a randomized, controlled trial in the United Kingdom [33].

Incentives. Providing incentives and rewards to high performers (the so-called carrot approach) has been touted as a method to improve influenza vaccination rates. Although not studied in the HCW population, monetary incentives significantly increased hepatitis B vaccination rates among injection drug users when compared with an outreach program (69% vs 23%) [34]. However, a randomized trial focused on influenza vaccination in which all HCWs received baseline education and then were assigned to 1 of 4 study interventions (no incentive, receipt of a letter emphasizing the importance of HCW vaccination, entry into a raffle for a free vacation, or receipt of both the letter and raffle entry) found no significant differences in influenza vaccination rates in any of the trial arms [35].

Mandatory vaccination. The pioneer in mandating influenza vaccination of HCWs is Virginia Mason Medical Center (VMMC) [36, 37]. In August 2004, prompted by suboptimal vaccination rates and the belief that voluntary programs were not an effective tool to boost vaccine coverage, the VMMC mandated influenza vaccination for all hospital employees and physicians and all non-VMMC employees working at the medical center (eg, community physicians, vendors, students, and volunteers). Signed declinations were not allowed, because administrators believed that such a strategy ran counter to the importance of vaccination in protecting patients [37]. The mandate was implemented in conjunction with visible administrative support, promotional campaigns, drive-through vaccination clinics, and vaccine champions. Vaccination rates for

the >5000 VMMC employees and adjunct personnel have exceeded 98% each of the past 4 years, and several employees were terminated for failure to comply to the new policy [38].

More recently, BJC HealthCare in St. Louis, Missouri, implemented a similar mandatory influenza vaccination program at 14 facilities (11 acute and 3 long-term care facilities). Medical exemptions were allowed, but declination statements were not used. Encompassing all clinical staff, employed physicians, house staff, and volunteers (a population of >25,000), the health care system achieved a remarkable 98.4% vaccination rate. Employment was terminated for 8 employees for failure to comply with the policy [39]. These 2 experiences, although limited, clearly indicate that a mandatory HCW influenza vaccination program is a highly effective intervention, resulting in the highest reported vaccination rates for any intervention designed to improve HCW influenza vaccine coverage.

ASSESSMENT OF DECLINATION STATEMENTS: POTENTIAL PITFALLS

When examining the impact of declination statements, one must consider several important aspects of the form and the vaccination program in which it is implemented. The context of the declination statement must be identified. What other interventions have been put in place to improve vaccination rates? Is the use of the declination statement explicitly and visibly promoted by leadership? Are there penalties for failure to sign? How and when is the declination administered? Declination forms were initially conceived as a tool for face-to-face interaction to allow further education and persuasion regarding vaccination. The use of an online electronic form to improve the efficiency of declination statement collection, unfortunately, could permit an easier "opt out" as opposed to direct interaction with the program champions. Also, whether the declinations are collected concurrently with vaccination programs or at a later date (ie, end of the season) may affect the effectiveness of the tool. In addition, the specific language on the form must be noted. Forms that ask HCWs whether they refuse vaccination or are a simple signature statement may have less impact than those that explicitly outline the ramifications of refusal, including the risk to the patients, colleagues, and family of the HCW. Figure 1 notes examples from 2 declination statements that illustrate this potential variety in statement language that could affect the tool's utility and interfacility comparisons of the effect of such statements.

Another concern regarding the use of declination statements is that collection of these forms may be identified as a primary goal, diverting resources toward statement collection and away from improving availability of vaccine, campaign promotion, and education. Some have proposed that the use of declination statements may actually impede attainment of high vaccination

A

Sample Influenza Vaccine Declination Form

Facility Name: _____

You have given me the opportunity to be vaccinated with the influenza vaccine at no charge to myself.

I have received, read and understand information about the risks and benefits of the vaccine.

However, I decline the influenza vaccine at this time.

Employee's Name (Print)

Employee's Signature

Date

B

III. DECLINATION OF VACCINE - You MUST complete if refusing vaccine

I am eligible to receive the influenza vaccine BUT do not want to take it. I understand that by refusing the vaccine I may be putting my FAMILY, FRIENDS and PATIENTS at risk of getting influenza. I am aware that hospitalized patients are at increased risk of getting serious complications following influenza infection. Please CHECK YOUR REASON(S) for not receiving the influenza vaccine.

<input type="checkbox"/> Afraid of needles	<input type="checkbox"/> Afraid of side effects	<input type="checkbox"/> Fear of getting influenza from the vaccine
<input type="checkbox"/> Don't believe in vaccines	<input type="checkbox"/> Don't think vaccines work	<input type="checkbox"/> I never get the flu
<input type="checkbox"/> Other: _____		

Figure 1. Examples of declination forms used in health care worker influenza vaccination programs. *A*, Example of declination form without language regarding risk to patients by refusing vaccination [41]. *B*, Excerpt of declination form with explicit language regarding risk of vaccine refusal and assessments of rational for refusal [27].

rates. Specifically, authors of a study examining HCW hepatitis B vaccination coverage noted that, with declination rates reaching 45%, declination was 1 factor that potentially “thwart[ed] achievement of full control of this preventable occupational infection” [40, p 423].

The use of declination statements may also prompt facilities to report combined rates of HCW vaccination and declination, often noted as a “program participation rate.” This figure can be misleading because facilities with similar participation rates may have vastly different HCW vaccination coverage (eg, 95% participation at one hospital may include 86% vaccination and 9% declination rates, whereas the same rate at another hospital may refer to a 55% vaccination rate and a 40% declination rate). Because vaccination is the ultimate goal, the vaccination coverage rate of HCWs, which includes persons vaccinated and those with a medical contraindication to vaccination, should be the primary metric used to monitor program effectiveness. In addition, facilities should consider high rates of declination

unacceptable and strive for progressively lower declination rates as a secondary measure of vaccination program success.

CONCLUSIONS

The impact of the use of declination statements on HCW influenza vaccination rates is challenging to elucidate. However, using declination statements in conjunction with other key facets in a de facto vaccine bundle has been associated with increased HCW vaccination coverage and may help reduce misconceptions about the influenza vaccine and emphasize the rationale and importance of vaccination. The downside of declination statements includes the important need for increased resources to track compliance and the risk of negatively affecting the employee-employer relationship. In addition, the ramifications of a HCW refusing to sign the declination must be elucidated. Declination statements, depending on their context and specific language, may lead to a modest increase in

HCW influenza vaccination rates but are not a panacea for low vaccination coverage.

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