Published in final edited form as:

Infect Control Hosp Epidemiol. 2006 April ; 27(4): 383–387. doi:10.1086/503179.

Impact of the 2004-2005 Influenza Vaccine Shortage on Immunization Practices in Long-Term Care Facilities

Lona Mody, MD, Kenneth M. Langa, MD, PhD, and Preeti N. Malani, MD

Drs. Mody and Malani are from the Geriatric Research Education and Clinical Center and Dr. Langa is from the Health Services Research and Development Center of Excellence, Ann Arbor Veterans Affairs Healthcare System, Ann Arbor, Michigan. Drs. Mody and Malani are from the Division of Geriatric Medicine, Dr. Langa is from the Division of General Internal Medicine, Dr. Malani is from the Division of Infectious Diseases, and Dr. Mody is also from the SGIM-Hartford Collaborative Center for Research and Education in the Care of Older Adults, Department of Internal Medicine, University of Michigan Health System, Ann Arbor

Abstract

Objective—To assess the response of long-term care facilities (LTCFs) to the 2004-2005 influenza vaccine shortage and the impact on resident and healthcare worker (HCW) immunization rates.

Methods—A 12-item questionnaire was sent to 824 randomly selected LTCFs in December 2004. The following 2 open-ended questions were also asked: “How did you cope with the vaccine shortage?” and “Who helped you get your supply?” Immunization rates reported by LTCF administrators for 2003-2003 and 2003-2004 were compared with those for 2004-2005. Immunization rates were defined as the proportion of all eligible residents and HCWs who received influenza vaccine.

Results—Responses were received from 380 LTCFs (46.3%), which had a total of 38,447 beds. Resident mean influenza immunization rates ($\pm$ SD) decreased from $85\% \pm 15.3\%$ in 2002-2003 and $85.1\% \pm 15.3\%$ in 2003-2004 to $81.9\% \pm 19.4\%$ in the 2004-2005 influenza season ($P = .025$). The immunization rates among HCWs also decreased from 51% in 2002-2003 and 2003-2004 to 38.4% in 2004-2005 ($P < .001$). In response to one of the open-ended questions, 96 facilities (25.3%) reported that they obtained vaccine from 2 or more sources. Eight percent commented on specific intensified infection control efforts, and only 2.3% commented on emergency preparedness.

Conclusions—The influenza vaccine shortage in 2004-2005 impacted immunization practices of LTCFs across the United States, leading to decreases in both resident and HCW vaccination rates. The significant decrease in vaccination rates in LTCFs is of concern and has broad implications for policy makers working on emergency preparedness for a possible pandemic of influenza.

In October 2004, contamination issues at the manufacturing site of one of the two companies licensed to provide influenza vaccine forced withdrawal of their product from the US market. The United States was left with half the amount of vaccine needed for the 2004-2005 vaccination campaign. Although contamination can occur during production of any vaccine, the influenza vaccine supply is particularly at risk, given the unique features of

its production. Influenza vaccine is reformulated annually to reflect the antigenic shifts in hemagglutinin and neuraminidase proteins of the influenza virus.¹

In response to the shortage, the Centers for Disease Control and Prevention (CDC) released recommendations for targeting vaccination to individuals who have the greatest risk of developing complications due to influenza, including individuals aged 65 years or older, long-term care facility (LTCF) residents, patients with chronic medical conditions, pregnant women, and children aged 6-23 months. Healthcare workers (HCWs) providing direct patient care were also considered to be a high-risk group.^{2,3}

Although all LTCF residents were considered to be at high risk, LTCFs scrambled to acquire an adequate number of vaccine doses, which forced a quick adjustment of their vaccination policies. The main objective of this investigation was to measure the difference in vaccination rates among LTCF residents and HCWs between the 2004-2005 influenza season and the 2002-2003 and 2003-2004 influenza seasons. We also sought to understand how LTCFs in different regions addressed the vaccine shortage, how facilities eventually acquired their vaccine supply, and whether there was a resultant decrease in vaccination rates.

Methods

Study Design and Population

A cross-sectional, observational study was conducted using a nationally representative random sample of LTCFs identified using the Medicare and Medicaid Services' (CMS) Online Survey, Certification, and Reporting (OSCAR) database (available at: <http://www.ahca.org/research/oscar>). Of the 16,480 CMS-certified LTCFs in the database, we randomly sampled 824 (5%). Facilities that are licensed only at the state level or those not participating in CMS are not included in the OSCAR database. The study was approved by the institutional review board at the University of Michigan (Ann Arbor).

Questionnaire

During the second week of December 2004, a brief letter describing the rationale of the study, as well as a 2-page self-administered survey, were sent to each of the 824 LTCFs. All responses were kept anonymous. Reminders were sent to all nonresponders after 4 weeks. The questionnaire was kept brief to optimize the response rate.

The survey asked for basic descriptive information, including the number of beds and location by state. Other questions specifically addressed influenza and pneumococcal vaccination programs, practices for monitoring immunization rates, and the impact of influenza vaccine shortage on the immunization rates at the facility. The following open-ended questions were asked: "How did you cope with the vaccine shortage?" and "Who helped you get your supply?" These 2 open-ended questions were used to determine the full range of possible responses from a heterogeneous sample of community LTCFs⁴.

Statistical Analysis

Data were analyzed using Stata, version 8 (StataCorp). Student's *t* test and 1-way analysis of variance were used for univariate comparison of immunization rates during the 2002-2003, 2003-2004, and 2004-2005 influenza seasons. Categorical outcomes were compared using the χ^2 test. Because some LTCFs did not respond to some items, the total number of responses for some questions was not equal to the total number of evaluable questionnaires.

Responses to the first open-ended question (“How did you cope with the vaccine shortage?”) from 216 LTCFs were grouped into 7 major categories (Table 1). We calculated the proportion of responders with a comment in each of these 7 categories, using the number of facilities in the category divided by the total number of facilities that provided at least 1 relevant answer. Responses to the second open-ended question (“Who helped you get your supply?”) were coded into 12 major categories (Table 2).

Results

Response Rate and Facility Characteristics

Of the 824 surveys, 4 were returned with a note stating that the facility was no longer a LTCF. Of the remaining 820 surveys, responses were received from 380 (46.3%) LTCFs with a total of 38,447 beds. Two facilities responded twice; however, in both cases, only the first response was included for analysis. Table 3 presents LTCF characteristics and response rates. Responders and nonresponders did not differ with regard to the number of beds or location. However, the response rate among nonprofit facilities was significantly higher (133 [54.6%] of 240) than that among for-profit LTCFs (210 [40.3%] of 521; $P = .002$).

Immunization Programs

Nearly all respondents (374 [98%] of 380) indicated that influenza vaccine was offered to their residents, and 312 (82%) reported monitoring vaccination rates. Only 265 respondents (70%) offered pneumococcal vaccine to their residents, and 252 (66%) reported monitoring vaccination rates. A quarter of the respondents chose not to answer questions about pneumococcal vaccine. A total of 362 respondents (95%) stated that they offered influenza vaccine to their HCWs, and 284 (75%) reported monitoring HCW vaccination rates (Table 4).

Mean immunization rates ($\pm$ SD) for LTCF residents were 85.0% $\pm$ 15.8% for 2002-2003 and 85.1% $\pm$ 15.3% for 2003-2004 but decreased to 81.9% $\pm$ 19.4% in 2004-2005 ($P = .025$, for 2002-2003 vs 2004-2005). HCW immunization rates decreased even more dramatically, from 51.1% $\pm$ 23.9% in 2002 and 51.1% $\pm$ 25.8% in 2003 to 38.4% $\pm$ 27.3% in 2004 ($P < .001$, for 2002-2003 vs 2004-2005). There were no statistically significant regional variations in vaccination rates for LTCF residents and HCWs.

Of the 380 LTCFs, 157 (41.3%) reported that the influenza vaccine shortage had influenced their immunization program (Table 5). A vast majority of these LTCFs (157 [87.9%]) felt that the shortage would result in a lower immunization rate among their HCWs. Indeed, this concern was reflected by reduced HCW immunization rates (mean $\pm$ SD, 27.7% $\pm$ 28%) among facilities reporting that shortage in the number of vaccine doses would influence HCW immunization rates, compared with immunization rates (mean $\pm$ SD, 46.6% $\pm$ 26.8%) among facilities that felt that vaccine shortage would not influence their programs ($P < .001$). Concern about lower immunization rates among residents was raised by 42 (26.8%) of these 157 LTCFs, which was borne out by lower immunization rates among their residents (mean $\pm$ SD, 78.6% $\pm$ 22.4%), compared with rates among residents at LTCFs without concern about reduced immunization rates (mean $\pm$ SD, 84.3% $\pm$ 16.4%; $P = .015$). Facilities also expressed concern about HCW absenteeism (65% of facilities) and the possibility of an influenza outbreak (53%).

Vaccine Sources

A total of 216 facilities (56.8%) detailed their efforts to obtain an adequate number of vaccine doses in the open-ended questions (Table 1). Ninety-six LTCFs obtained influenza vaccine from 2 or more sources. These sources were diverse and included health

departments, the CDC, acute care hospitals, pharmacies, local clinics and physicians, and home care agencies (Table 2). Efforts to pool resources from different sources were described by 96 (44%) of the 216 respondents. A total of 46 LTCFs (21.3%) reported making multiple phone calls to health authorities. Eleven percent responded that they used a risk stratification model proposed by the CDC.² Only 17 (7.9%) specified that they intensified specific infection control efforts, and even fewer (5 [2.3%]) commented on emergency preparedness in the event of an outbreak of influenza. Twenty-three facilities detailed timely acquisition of their supply because of a coordinated response to the shortage at the county or city level in their area.

Discussion

The unanticipated shortage of influenza vaccine in 2004-2005 left many LTCFs without a sufficient supply for their residents and HCWs. Results from our survey of 380 LTCFs serving 38,447 older adults demonstrated a significant decrease in both resident and HCW vaccination rates for 2004-2005, compared with the 2 previous influenza seasons. Extrapolating our findings to the 2 million residents residing in LTCFs nationally, an estimated 72,800 vulnerable LTCF residents were not immunized against influenza because of this shortage.

Influenza vaccine distribution has previously faced supply and demand issues. For example, during the 2000-2001 influenza season, production problems delayed initiation of the annual immunization campaigns.⁵ However, this shortage did not appear to influence vaccine coverage among community-dwelling seniors.⁶ These seniors can access vaccines at various venues, including senior centers, community organizations, and retail businesses, and from their primary care physicians. LTCF residents, however, are dependent on their facility to provide their vaccine.

This study demonstrates that LTCFs faced numerous challenges to obtaining influenza vaccine in 2004-2005, often needing to rely on more than one source. These sources varied from county and state health departments, the CDC, and community medical practices to local hospitals, schools, prisons, and public transportation authorities. Facilities reported the need to make multiple phone calls to these sources, with a quarter of LTCFs meeting their needs by pooling supplies from 2 or more sources. We suggest investigating alternate options to reallocate vaccine in a more formal, organized process, perhaps by setting up a central system for distribution with a specific plan to reach all LTCFs.

Somewhat surprisingly, only 17 facilities commented on intensified infection control measures in response to the vaccine shortage, and only 5 facilities were proactive in instituting additional prevention and intervention measures, such as ordering additional diagnostic swabs and stocking antiviral drugs. Because of the frequent delays in distribution of this vaccine, it is important that LTCFs receive clear direction on the appropriate response to any vaccine shortage, with respect to acquiring vaccine, monitoring immunization rates, performing infection control measures, and taking steps to prepare for an outbreak of influenza.

Annual influenza vaccination campaigns for HCWs play a central role in deterring and preventing nosocomial transmission of the influenza virus, particularly because recent evidence shows that the effectiveness of influenza vaccine is modest in older adults.⁷ Not only is the vaccine effective in preventing influenza and reducing absenteeism among HCWs, it has also been associated with a decrease in influenza mortality among patients.⁸⁻¹¹ However, vaccination rates for LTCF HCWs were impacted more dramatically than vaccination rates for LTCF residents. Several facilities could not offer influenza vaccines to

their employees as a result of this shortage. Although some of these HCWs could receive vaccine elsewhere, policies should be established to ensure that LTCFs can obtain an adequate supply for both their residents and employees. In addition, LTCFs should develop clear guidelines to prevent introduction of influenza virus from the community, via both HCWs and visitors.

Several potential limitations of our study should be acknowledged. First, the results could have been influenced by recall bias, with LTCFs that experienced a shortage reporting their influenza immunization rates more accurately than LTCFs that did not experience a shortage. Recall bias could lead to a greater difference in rates between the groups. In addition, although the response rate of 46% was acceptable, nonresponse could also have introduced a bias. It is likely that the nonresponders either had lower immunization rates or were not affected by the shortage. We do know that the nonresponders were more likely to belong to for-profit facilities than the responders. For-profit facilities were more likely to have less than 50% influenza coverage among residents.¹² Thus, the nonresponder bias could underestimate the differences in influenza vaccine rates between the 2004-2005 season and the previous years. Despite these biases, which are inherent to a questionnaire-based study design, the use of a random nationally representative sample remains a major strength of this study.

In conclusion, LTCFs across the United States encountered considerable difficulty in obtaining their vaccine in a timely fashion as a result of the 2004-2005 vaccine shortage, requiring multiple phone calls to a variety of sources. This led to significant decreases in both resident and HCW immunization rates. The decrease in immunization rates in LTCFs is of concern and has broad implications for policy makers working on emergency preparedness for pandemic influenza.

Acknowledgments

We thank Irene Geniac, RN, for her assistance in mailing the questionnaire for this study. Dr. Mody is supported by a career development award from the National Institute on Aging (K23 AG022463). Dr. Langa is supported by a career development award from the National Institute on Aging (K08 AG19180) and by a Paul Beeson physician faculty scholars in aging research award.

References

1. Treanor J. Weathering the influenza vaccine crisis. *N Engl J Med*. 2004; 351:2037–40. [PubMed: 15492296]
2. Centers for Disease Control and Prevention. Updated interim influenza vaccination recommendations—2004-05 influenza season. *MMWR Morb Mortal Wkly Rep*. 2004; 53:1183–1184. [PubMed: 15614237]
3. Cosgrove SE, Fishman NO, Talbot TR, et al. Strategies for use of a limited influenza vaccine supply. *JAMA*. 2005; 293:229–232. [PubMed: 15644550]
4. Smith, PG.; Marrow, RH., editors. *Field Trials of Health Interventions in developing countries: a toolbox*. 2nd. London: Oxford: Macmillan Press; 1996. Questionnaires; p. 184-185.
5. Centers of Disease Control and Prevention. Delayed supply of influenza vaccine and adjunct ACIP influenza vaccine recommendations for the 2000-01 influenza season. *MMWR Morb Mortal Wkly Rep*. 2000; 49:619–622. [PubMed: 10914929]
6. Zimmer RK, Nowalk MP, Santibanez TA, et al. Shortage of influenza vaccine in 2000-2001: did it change patient beliefs? *Am J Prev Med*. 2003; 24:349–53. [PubMed: 12726873]
7. Jefferson T, Rivetti D, Rivetti A, et al. Efficacy and effectiveness of influenza vaccines in elderly people: a systematic review. *Lancet*. 2005; 366:1165–1174. [PubMed: 16198765]
8. Potter J, Stott DJ, Robert MA, et al. Influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. *J Infect Dis*. 1997; 175:1–6. [PubMed: 8985189]

9. Carman WF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomised controlled trial. *Lancet*. 2000; 355:93–97. [PubMed: 10675165]
10. Sartor C, Dupont-Tissot H, Zandotti C, et al. Use of a mobile care influenza program for vaccination of hospital employees. *Infect Control Hosp Epidemiol*. 2004; 25:918–922. [PubMed: 15566024]
11. Nichol KL. First do no harm: ensuring that healthcare workers vaccinate and are vaccinated. *Infect Control Hosp Epidemiol*. 2003; 24:799–800. [PubMed: 14649765]
12. Bardenheier B, Shefer A, McKibben L, et al. Characteristics of long-term care facility residents associated with receipt of influenza and pneumococcal vaccinations. *Infect Control Hosp Epidemiol*. 2004; 25:946–954. [PubMed: 15566029]

Table 1
Responses Among Long-Term Care Facilities (LTCFs) to the Shortage of Influenza Vaccine During the 2004-2005 Influenza Season

Response	No. (%) of LTCFs (<i>n</i> = 216)
Detailed efforts to pool resources	96 (44.4)
Made multiple calls	46 (21.3)
Used the CDC risk stratification model	23 (10.6)
Had success in obtaining vaccine supply	23 (10.6)
Intensified infection control measures	17 (7.9)
Hand hygiene	6 (2.8)
Restriction of sick visitors	8 (3.7)
Restriction of sick HCWs	7 (3.2)
Educational initiatives	9 (4.2)
Expressed concerns about delayed vaccine supply	10 (4.6)
Expressed concern about emergency preparedness	5 (2.3)

Note. Data are responses to the open-ended question “How did you cope with the vaccine shortage?” and are grouped into 7 major categories for analysis. Several facilities had more than one comment to this question. CDC = Centers for Disease Control and Prevention; HCW = healthcare worker.

Table 2
Sources of Influenza Vaccine for 325 Long-Term Care Facilities (LTCFs)

Source	No. of LTCFs
County health department	138
Pharmacy or other direct supplier	79
State health department	53
Local physicians	49
Local acute care hospital	36
Visiting nurse and home health agencies	14
Nursing home association	10
Centers for Disease Control and Prevention	13
Health maintenance organizations	5
City health department	4
Grocery store	3
Other ^a	10

Note. Data are responses to the open-ended question “Who helped you get your supply?” and are grouped into 12 major categories for analysis.

^aCommunity center (2), veterans hospital (2), local schools (2), prison (1), department of transportation (1), and local businesses (2).

Table 3
Characteristics of Long-Term Care Facilities (LTCFs)

Characteristic	Total No. of LTCFs ^a (n = 16,141)	No. of Sampled LTCFs (n = 824)	No. of Sampled LTCFs That Responded (n = 380)	LTCF Response Rate, %
No. of beds				
0-50 beds	2440	128	62	48.4
51-100 beds	5907	318	160	50.3
101-150 beds	4898	249	100	40.2
150-200 beds	1785	80	38	47.5
>200 beds	1111	49	20	40.8
Type of Ownership				
Nonprofit	4521	240	133	55.4
Government	992	63	37	58.7
For profit	10628	521	210	40.3
US Region				
Northeast	2855	152	68	44.7
South	5405	268	123	45.9
Midwest	5339	270	134	49.6
West	2542	134	55	41.0

^aIn the Medicare and Medicaid Services' Online Survey, Certification, and Reporting (OSCAR) database, with complete data on the number of beds, profit status, and location were available for 16,141 LTCFs.

Table 4
Details of Existing Immunization Programs at the 380 Long-Term Care Facilities (LTCFs) That Responded to the Study Questionnaire

Target Group, Program	Response, No. (%) of LTCFs		
	Yes	No	No Response
Residents			
Influenza vaccination offered	374 (98.4)	3 (0.8)	3 (0.8)
Influenza vaccination rates monitored	312 (82.1)	64 (16.8)	4 (1.1)
Pneumococcal vaccination offered	265 (69.7)	23 (6.1)	92 (24.2)
Pneumococcal rates monitored	252 (66.3)	99 (26.1)	29 (7.6)
Healthcare workers			
Influenza vaccination offered	362 (95.3)	12 (3.2)	6 (1.6)
Influenza vaccination rates monitored	284 (74.7)	87 (22.9)	9 (2.4)

Table 5
Survey Responders' Opinion on the Influence of Influenza Vaccine Shortage on the Immunization Program at Their Long-Term Care Facility (LTCF)

Result of Vaccine Shortage	Response, No. (%) of LTCFs	
	Yes	No
It will lead to a lower immunization rate among residents	42 (26.8)	115 (73.2)
It will lead to a lower immunization rate among HCWs	138 (87.9)	19 (12.1)
It will lead to a higher immunization rate among residents	10 (6.4)	147 (93.6)
It will lead to a higher immunization rate among HCWs	8 (5.1)	149 (94.9)
It will lead to a higher HCW absenteeism	103 (65.6)	54 (34.4)
We may have an influenza outbreak	53 (33.8)	104 (66.2)

Note. Data are survey responses by 157 (41.3%) of 377 LTCFs that responded “yes” to the question “Do you think that the shortage will affect your immunization rates?”