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Findings, Issues, and Options



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Influenza is an infectious disease that affects the population of the United States to varying degrees almost every year. In some years, influenza occurs in epidemic proportions in all States. In 1957-58, for example, it contributed to approximately 70,000 excess deaths. In other years, such as 1976-77, influenza occurs very infrequently and reportedly produces no excess deaths. During the 7-year period from 1971-72 through 1977-78, there were an estimated 127,000 influenza-related excess deaths reported in the United States, and Americans spent over \$1 billion on influenza treatment.

The preferred method of controlling influenza is its prevention through vaccination. Inactivated influenza vaccines have been marketed in the United States since the 1940's. Because the chemical (antigenic) makeup of prevalent influenza virus(es) changes almost yearly, the composition of influenza vaccine is reevaluated annually and in most years reformulated.

The Federal Government is responsible for conducting influenza surveillance (monitoring influenza occurrence and mortality) and establishing standards for influenza vaccine composition, purity, safety, and efficacy. In one year, 1976-77, the Federal Government supported a nationwide effort to immunize virtually the entire U.S. population against the so-called swine influenza virus. In two subsequent years, the Federal Government gave assistance to State and local health departments to purchase and distribute influenza vaccine.

Influenza vaccine has never enjoyed widespread acceptance or demand by either the public or health professionals. In each of the years from 1971-72 through 1977-78, only about 10 percent of the Nation's population received in-

fluenza vaccine. Further, in any given year, only about 20 percent of the high-risk population (people at greater risk of dying from influenza if they contract the disease) received influenza vaccine. (In 1976-77, however, both of these percentages doubled.)

The effectiveness of influenza vaccination has been examined repeatedly. Its effectiveness can vary from year to year because of changes in the influenza virus. On the basis of data from clinical trials, OTA estimates that the clinical efficacy or effectiveness of influenza vaccine was about 60 percent from 1971-72 through 1977-78 (see app. B).

In 1976-77, swine flu vaccinations were associated with about 500 cases of a rare paralytic condition called Guillain-Barre Syndrome (GBS). As a result, the vaccine's safety was seriously questioned. However, since 1976-77, influenza vaccinations have proven to be quite safe. GBS may have been an adverse reaction (side effect) peculiar to swine flu vaccine (see app. D).

This OTA study evaluates influenza vaccination on the basis of another criterion—cost effectiveness. In this analysis, prevention of influenza by vaccination is compared to treatment of the disease if it occurs. Changes in health effects and medical care costs produced by influenza vaccination from 1971-72 through 1977-78 are estimated. Costs and health effects are viewed primarily from a societal perspective, although a medicare perspective is also included. Using data obtained from selected Government agencies and incorporating certain assumptions, OTA developed a computerized cost-effectiveness model to generate the following findings concerning influenza vaccinations. Details regarding the data and methods used in the cost-effectiveness analysis are described in chapter 2 and appendix E.

¹ Excess deaths occur when the observed number of deaths exceeds the expected number of deaths in a given time period.

FINDINGS

The findings below were generated by OTA's cost-effectiveness model and apply to influenza vaccinations administered from 1971-72 through 1977-78.

General and Productivity Effects

1. The medical care costs associated with influenza vaccination in the United States during this 7-year period totaled \$808 million; for that cost, about 150 million doses of vaccine were given, and those vaccinations yielded approximately 13 million years of healthy life, for a per vaccination cost of \$63 per year of healthy life gained.
2. Medically attended influenza-related illness during this 7-year period accounted for an average of 15 million days of self-reported work loss each year. Productivity loss associated with that work loss totaled \$764 million each year.
3. Influenza vaccination prevented 5 million days of self-reported work loss and saved \$253 million in productivity loss from medically attended influenza-related illness during this 7-year period.
4. Influenza vaccination prevented 3.6 million days of self-reported housekeeping loss with an imputed economic value of \$136 million during this 7-year period.

Cost Effectiveness for the General Population

Vaccination of a population may result in added years of life for some members of the population. These members will, on average, incur typical medical care costs during the added years. Analysis of the costs of a vaccination program, therefore, could include these added medical care costs. Analysts disagree on whether such inclusion is appropriate for a cost-effectiveness analysis. Thus, OTA has calculated the cost effectiveness of vaccination both ways: by excluding such added costs, and by including them.

5. When vaccinations are administered to the general population and the *medical care costs* incurred during additional years of life yielded by vaccination are *excluded*, the age-specific costs of generating a year of healthy life through influenza vaccination are these:

<i>Age in 1971-72</i>	<i>Per vaccination cost/year of healthy life</i>
<3 years	\$258
3-14	196
15-24	181
25-44	64
45-64	23
≥ 65	(cost saving)
All ages	\$63

The cost effectiveness of influenza vaccination improves with increasing age of the vaccinee at the time of vaccination.

6. When *medical care costs* incurred during additional years of life yielded by vaccination are *included*, the age-specific costs of generating a year of healthy life are these:

<i>Age in 1971-72</i>	<i>Per vaccination cost/year of healthy life</i>
<3 years	\$1,745
3-14	1,880
15-24	2,010
25-44	2,027
45-64	2,084
≥ 65	1,782
All ages	\$1,956

Cost Effectiveness for Medically High-Risk Populations Only

7. When vaccinations are administered to the *medically high-risk* population (i. e., those most susceptible to influenza morbidity and mortality), and *medical care costs* during additional years of life yielded by vaccination are *excluded*, the age-specific costs of generating a year of healthy life through influenza vaccination are these:

<i>Age in 1971-72</i>	<i>Per vaccination cost/year of healthy life</i>
15-24 years	\$44
25-44	23
45-64	15
≥ 65	(cost savings)
All ages	\$10

With the assumptions about treatment costs and health effects that are used in this analysis, vaccination of high-risk persons within a given age appears more cost effective than vaccination of the general population (see app. E).

- 8 When estimated *medical care costs* in additional years of life are *included*, however, the costs of generating 1 year of healthy life among *high-risk persons* are these:

<i>Age in 1971-72</i>	<i>Per vaccination cost year of healthy life</i>
15-24 years	\$3,050
25-44	3,620
45-64	4,150
≥ 65	4,040
All ages	\$3,880

Factors That Affect Cost Effectiveness

9. Three factors substantially affect the cost effectiveness of influenza vaccination in both the general and high-risk populations: 1) vaccine efficacy, 2) cost of vaccination, and 3) including medical care expenditures in extended years of life.

Substantial alterations in *vaccine* efficacy produce directly proportional, but smaller, changes in the cost-effectiveness ratio. For example, a 30-percent increase in vaccine efficacy produces about a 17-percent drop in the cost of gaining a year of healthy life for all ages combined.

For the period 1971-72 through 1977-78, the cost of *vaccination* (vaccine cost plus administration fee) substantially affects the cost effectiveness of annual influenza vaccination. For example, at a cost of \$1.55, vaccination of a person 65 years old produces net savings in medical care costs, while at a cost of \$9.39, that same vaccination yields a net cost of \$34 for each year of healthy life gained.

Including *medical care expenditures* in extended years of life substantially increases the cost of gaining a year of healthy life through influenza vaccination. This variable completely overshadows the changes produced by all other variables combined in the sensitivity analysis.

ISSUES

- To what extent, if any, should the Federal Government promote the use of influenza vaccine?
- What mechanisms are available to the Federal Government to promote influenza vaccination?
- For whom should influenza vaccination be promoted?

Prior to 1976-77, the Federal Government had not extensively promoted the use of influenza vaccine. Thus, for example, it did not purchase influenza vaccine for distribution to Federal, State, and local public health clinics (as it did selected vaccines for childhood immunizations). Prior to 1976-77, Federal activities related to influenza vaccine included the following:

- establishing the formula for, and evaluating the safety and efficacy of, each year's

- vaccine (Food and Drug Administration (FDA));
- disseminating to health professionals and medical care institutions the recommendations of the Immunization Practices Advisory Committee (ACIP)—a governmentally financed outside advisory group that establishes nationally recognized standards for the use of all marketed vaccines in the United States (Centers for Disease Control (CDC));
- conducting annual surveillance of influenza virus activity and influenza-related mortality (CDC);
- occasionally mounting public educational programs to encourage the use of influenza vaccine by selected groups identified by ACIP (Public Health Service (PHS)); and
- attempting to develop more effective influenza vaccines (National Institutes of Health (NIH)).

In 1976-77, the Federal Government mounted the National Influenza Immunization Program, the so-called swine flu immunization program. For that initiative, the Federal Government took the following actions to help ensure that virtually every person in the United States received the swine flu vaccine:

- purchased almost the total 1976-77 influenza vaccine production from vaccine manufacturers;
- indemnified vaccine manufacturers from selected types of product liability (86,88);
- launched massive public education programs to encourage the use of influenza vaccine by most of the U.S. population; and
- strongly encouraged State and local public health departments to participate in the National Influenza Immunization Program.

The swine flu immunization program received much derogatory press coverage, primarily for the following reasons:

- the targeted influenza virus—A/New Jersey/76 (Hsw1N1)—never occurred in epidemic proportions; and
- vaccination was associated with GBS.

In spite of its problems, the swine flu program demonstrated a Federal capability to increase the rate of influenza vaccination throughout the United States. During the 1976-77 season, influenza vaccination rates for all age groups combined were twice the rates from previous years.

Since 1976-77, Federal activities related to the promotion and distribution of influenza vaccine have been sporadic. During the years 1977-80, the Department of Health, Education, and Welfare (HEW), now the Department of Health and Human Services (DHHS), sponsored a series of at least eight conferences in which the Nation's leading experts on several aspects of influenza (e.g., surveillance, diagnosis, prevention, and treatment) discussed how the Federal Government could best use its resources to detect and control influenza (97-104). In addition, in 1978-79 and 1979-80, the Federal Government either: 1) purchased influenza vaccine directly from manufacturers at a fixed nationwide price and distributed it to State and local public health

departments, or 2) provided financial assistance to State and local health departments (for the purchase of influenza vaccine. There was no such Federal support in 1977-78 or 1980-81. In 1978, former HEW Secretary Joseph Califano unsuccessfully attempted to persuade Congress to finance a continuing federally sponsored influenza vaccination program.

At present, there is no federally financed program to influence the use of influenza vaccine. Existing Federal policy regarding influenza vaccination appears to be laissez-faire. In the absence of Federal support, the use of influenza vaccine is primarily determined by private sector physicians, State and local health departments, employers, and self-initiated public demand.

The results of this OTA study indicate that influenza vaccination is a low-cost preventive medicine intervention that yields health benefits among all age groups. Influenza vaccination appears to be most cost effective among high-risk populations.

In addition to generating the costs and savings included in the cost-effectiveness calculations, influenza vaccination improves productivity in the economy. Using historical rates of vaccination from 1971-72 through 1977-78, OTA calculated the value of work loss prevented by influenza vaccination to be \$253 million and the value of housekeeping loss prevented to be \$136 million during that 7-year period.

These results relate to decisions regarding which groups in the population should be targeted to receive the vaccine. If work loss and housekeeping loss are taken into account, the benefits to be gained from vaccinating adults age 17 to 64 increase. When the economic gains from reductions in work loss are included, and the medical care costs incurred during extended years of life are excluded, the cost of gaining a year of healthy life falls to \$134 for ages 17 to 24, \$32 for ages 25 to 44, and \$11 for ages 45 to 64.

Present ACIP recommendations for recipients of influenza vaccination do not explicitly include healthy working-age adults in the general population. Some employers, including Federal

agencies, provide voluntary annual influenza vaccination, usually at low cost. Vaccination rates for working age groups are low, i.e., about 10 percent, as one would expect in light of current ACIP recommendations.

It appears that without strong Federal support, the use of influenza vaccine remains at a level too low for society to fully reap the potential benefits—in terms of health benefits and prevention of productivity losses—of the vaccine.

OPTIONS

The information contained in the findings and issues presented above has certain implications for the future of influenza vaccination and the Federal role related to it. Based on the findings and issues, the following discussions lay out some of the implications that may follow from various Federal actions.

If the Federal Government decides to retain its *laissez-faire* approach to influenza vaccination, then neither Congress nor DHHS would need to enact any new programs. If funding for the Bureau of Biologics (BOB) and CDC remains at current levels, adjusted for inflation, then the following Federal influenza activities would likely remain intact. Influenza investigators within DHHS could continue to meet once or twice yearly to: 1) assess which strains of influenza virus(es)—if any—are likely to invade the United States and 2) formulate the subsequent year's vaccine makeup. BOB would continue to evaluate the safety and efficacy of each year's vaccine formulation, CDC could continue its surveillance of influenza occurrence and mortality. The availability of Federal funds to purchase, distribute, and promote the use of influenza vaccine would be quite limited unless Congress were to specifically appropriate funds for this use. Reductions in funding for these two agencies could easily jeopardize current Federal influenza-related activities.

If the Federal Government instead decides to consistently promote the use of influenza vaccine for selected target populations, it could take one or more of several actions. Three possible options and their implications follow (the three

For example, in the period from 1971-72 through 1977-78, approximately 70 percent of influenza-related work loss occurred in the 25- to 64-year-old age group; yet, on the average only 10 percent of that age group received influenza vaccine during the 1970's.

Likewise, only about 20 percent of the medically high-risk population in the United States receives influenza vaccine in any given year.

actions are not mutually exclusive; in fact, taking all three simultaneously would maximize the immunization status of the population).

1. **The Public Health Service (PHS), if funded to do so, could mount a continuing national campaign to increase the awareness of practicing health professionals, employers, labor unions, and the public about the benefits and costs associated with influenza vaccination among selected target populations.**

It has long been stated that health care consumers have insufficient knowledge to evaluate the use of medical technologies (4,39). Because of their greater expertise in health matters, physicians are considered to act as patients' agents. Studies in the area of medical technology during recent years have dramatically illustrated that physicians themselves sometimes lack knowledge about appropriate technology use. Moreover, once evaluations of technology have been performed, they are rarely disseminated in an effective way to physicians and other users (87).

This option would promote the dissemination of information concerning the economic and health benefits of influenza vaccination. Potential users of the information include physicians, consumers, employers, labor unions, and third-party payers. Each of these groups would have an interest in knowing the effects of vaccination on health benefits, medical care costs, and productivity losses.

The dissemination of information about medical technologies is a legislated function of the

National Center for Health Care Technology (NCHCT). NCHCT has arranged for certain information to be published in major medical journals. In addition, a subcommittee of its National Advisory Council is considering the generic issue of dissemination of medical technology information.

Other areas of PHS are also concerned with vaccination information. CDC and its ACIP, as well as the Office of Health Promotion and Disease prevention, could undertake special information dissemination efforts.

This option is consistent with the perceived need by providers, consumers, and others for better information about the appropriate use of preventive technologies. Information could be provided to groups within the private sector who could then take whatever action they considered appropriate. This approach does not involve Federal financing of influenza vaccination, although it would be compatible with doing so (see below). An assumption behind the strategy of disseminating information is that potential vaccine users in the private sector have incomplete information about influenza vaccination and will act themselves on better information.

If the private sector does not accept the responsibility of using information about influenza vaccination, then any Federal effort to disseminate information would not by itself be likely to alter existing influenza vaccination rates. A 1979 study commissioned by CDC, for example, illustrated that although most physicians are aware that certain groups of high-risk patients should receive influenza vaccine each year, they do not routinely administer it to such groups (90). In that study, 92 percent of 1,000 participating physicians believed that annual influenza vaccinations are necessary for persons with chronic diseases and the elderly. Yet, those same physicians reportedly administered influenza vaccine to only 54 percent of their elderly patients with chronic disease and to only one-third of their elderly patients without chronic illness. If validated by results from other studies, these data indicate that educational efforts may need to be combined with other incentives to promote influenza vaccinations.

The Federal Government could expand the scope of its traditional influenza vaccination strategies by encouraging vaccination of all persons in the work force, not just those with high-risk medical conditions. OTA estimates that influenza caused a productivity loss of approximately \$764 million *each year* from 1971-72 through 1977-78. The Federal Government could encourage employers to help prevent such productivity losses by creating work site immunization programs, educating employees about the benefits of immunization, or reimbursing employers for incurred costs associated with immunization.

2. Congress could authorize and appropriate Federal support for a continuing (annual) publicly assisted nationwide influenza immunization program analogous to federally supported childhood immunization efforts.

There are four potentially beneficial implications of such an influenza immunization program. First, if the Federal Government negotiated a vaccine selling price with manufacturers that applied to public sector sales nationwide (as it did in 1979-80), then vaccination costs would likely be lower than private sector costs. Second, by using participating State and local public health clinics, the Federal Government would have a readily accessible and experienced network for distributing vaccine and information to health professionals. In general, when the Federal Government finances the purchasing and distribution of a vaccine, the rate of use for that vaccine is higher than when its use is determined solely by the private sector. Third, by controlling the public sector distribution of influenza vaccine, the Federal Government could conceivably improve its capability to monitor the occurrence of vaccine side effects. Fourth, supplying the vaccine would probably encourage physicians to provide it to their patients.

There are two possible disadvantages of such a program. First, if public clinics were relied on too heavily for influenza vaccine distribution, such a program could provide disincentives for

private sector physicians to administer influenza vaccine. Private sector physicians could send their patients to public health clinics for their “flu shots” and interrupt their patients’ normal pattern of receiving medical care. Second, the adoption of this program would raise the issue of Federal liability for adverse vaccine reactions under certain conditions.

As to the first disadvantage, CDC believes, as a result of its experiences with childhood immunization programs, that public immunization programs do not significantly disrupt patients’ patterns of health care (26). About 50 percent of all children still receive their immunizations from private physicians.

The second potential disadvantage may be more serious. At present, when the Federal Government purchases and distributes a vaccine, it assumes from the vaccine manufacturers the responsibility of warning potential vaccinees about the inherent risks of vaccination, i.e., rare, unpreventable, adverse reactions. The Federal Government in turn passes this responsibility on to State and local government agencies that accept and administer federally purchased vaccines. The legality of such contractual transfers of responsibility has not been tested in court; as a result, the Federal Government’s liability for adverse reactions that occur in public immunization programs is unclear. This issue has been discussed at length in two prior OTA reports (86,88).

3. Congress could amend the Social Security Act of 1965 to authorize medicare to pay for influenza vaccination.

Until recently, Title XVIII of the Social Security Act explicitly prohibited medicare reimbursement for all preventive vaccinations (42 USC 1395(y)). On December 28, 1980, President Carter signed Public Law 96-611, which authorized medicare payment for vaccinations to prevent pneumococcal pneumonia. At present, medicare pays for the treatment of influenza, but not for its prevention through vaccination.

Adoption of this option by itself would affect only about 45 percent of the population *over* 20 years old that is at high risk of being seriously afflicted by influenza. Approximately 55 per-

cent of this high-risk population is between 20 and 65 years old.

The impact of reimbursement on medicare beneficiaries’ demand for influenza vaccination is difficult to project. The effect of third-party coverage on the use of preventive services is not clear. To date, results of such analyses have been conflicting (41,108). Consumers’ demand for vaccines can also be influenced by their attitudes regarding personal susceptibility to disease, likelihood of disease occurring locally, and vaccine safety and efficacy (86).

It is possible that medicare payment for vaccination would not increase the total number of vaccine recipients among persons over age 65. Payment could simply transfer the cost of vaccination to medicare from those who currently pay for influenza vaccinations among the elderly (e.g., State and local health departments, employers, individual consumers, and in some years, CDC).

In a 1979 study commissioned by CDC, 43 percent of 1,000 participating physicians believed that more patients would receive influenza vaccination if it were covered by medicare or medicaid (90).

Congress could amend the medicare law to permit reimbursement for influenza vaccination by using the same provision regarding pneumococcal vaccination in Public Law 96-611. Alternatively, Congress could approach the reimbursement of influenza vaccination with a broader perspective and could establish criteria for preventive health services to be included in the medicare benefit package. Examples of such criteria include:

- services/ technologies that help prevent disease that particularly affect the elderly; and
- services/technologies that have proven safe and efficacious, and possibly cost effective, when used by individuals 65 years and older.

Special payment mechanisms, for example, waiver of copayment (deductibles and coinsurance) requirements, could be used to encourage beneficiaries’ use of selected preventive health services, especially low-cost items such as vaccinations.

In this analysis, the economics of medicare reimbursement for influenza vaccination would be as follows:

- When the *medical care costs* in extended years of life are *included*, each influenza vaccination administered to a person 65 years or older (in the general population) yields an additional month of healthy life for about \$60.

- When the *medical care costs* in extended years of life are *excluded*, each influenza vaccination administered to a person 65 years or older (in the general population) yields an additional month of healthy life for about \$2.

In either case, influenza vaccination generates a notable health benefit at a reasonably low cost to the medicare program.