Pneumococcal Vaccination in the United States and 20 Other Developed Countries, 1981–1996

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This survey describes patterns of pneumococcal polysaccharide vaccine use, vaccine registration, vaccination recommendations, and reimbursement for vaccination in the United States and 20 other developed countries during the period 1981 through 1996. The United States was the only country to use appreciable amounts of the vaccine throughout the study period. Annual vaccine use was stable from 1982 through 1990 but then increased sharply. In the 20 other countries, very little pneumococcal vaccine was used until the 1990s, when new registrations and/or national recommendations were followed by dramatic increases in vaccine use in Iceland (1991), the United Kingdom (1994), Sweden (1995), and Norway, Belgium, and the province of Ontario in Canada (1996). In 1996, pneumococcal vaccine was still not licensed in three and not recommended in four of the 21 countries. Of the seven countries that used the most pneumococcal vaccine, public reimbursement for vaccination was provided in the United States, Canada, and the United Kingdom but not in Iceland, Sweden, Norway, or Belgium.

Pneumococcal infections continue to be an important cause of hospital admission and death in developed countries. Among all occurrences in adults of community-acquired pneumonia requiring hospital admission, Streptococcus pneumoniae ranks first among known microbial causes and accounts for ~30%–50% of such cases [1]. Invasive pneumococcal disease is common among older adults in the United States [2–9]. Recent reports from Denmark [10], Norway [11], Sweden (Å. Örtqvist, personal communication, August 1997), Israel [12], and Canada [13] suggest the incidence in other developed countries may be similar.

In 1977, 14-valent pneumococcal polysaccharide vaccine was registered in the United States and soon thereafter in Canada and several other countries. In 1983 it was replaced by a 23-valent preparation containing the capsular polysaccharides of S. pneumoniae types known to account for ~90% of invasive pneumococcal disease [1]. Five sets of recommendations on the use of pneumococcal vaccine have been published in the United States [1, 14], and a similar number have appeared in Canada [15, 16].

In 1988, a technical advisory group convened by the World Health Organization Regional Office for Europe recommended pneumococcal vaccination for all elderly persons and for persons of any age who are at increased risk of pneumococcal infection [17]. In addition, numerous commentaries have appeared in leading medical journals in North America, Western Europe, and elsewhere. The widespread interest in pneumococcal vaccination is supported by convincing evidence that vaccination is ~50%–70% effective in preventing invasive pneumococcal disease in older adults [1, 14, 18].

In spite of broad interest in pneumococcal vaccination, there is little information on the extent to which the vaccine has actually been used [1, 16]. In contrast, much more is known about the use of influenza vaccine, a vaccine recommended for much the same target population. Recent studies covering the period from 1980 to 1995 document wide variations in influenza vaccination among developed countries [19, 20]. Moreover, national recommendations for influenza vaccination and policies for vaccine reimbursement also vary among countries, and these factors appear to have had substantial impact on levels of vaccine use.

This report describes patterns of pneumococcal vaccine distribution in the United States and 20 other developed countries during the period from 1981 through 1996. It also documents for each country the year in which 14- and 23-valent pneumococcal vaccines were registered, what national recommendations (if any) have been issued regarding their use, and how vaccination expenses are reimbursed.

Methods

Information on the number of doses of 14-valent and 23-valent pneumococcal polysaccharide vaccines distributed in the United States during the period 1981 through 1996 was obtained from the National Immunization Program of the Centers for Disease Control and Prevention and from previously published sources [15]. Similar information on vaccine distribution in 20 other economically developed countries was obtained.

The 21 countries surveyed comprise all but four of the world’s developed market economies, as defined by the United Nations [21]. Annual estimates of the total resident population in each country were obtained from the Office of Epidemiology and Statistical Methodology (1981 through 1992) and the Division of Health Trend Assessment (1993 through 1996) of the World Health Organization, in Geneva [19, 21].

Pneumococcal vaccine use was expressed as the annual number of doses distributed per 10,000 total resident population in each country. Although this is a crude measure of pneumococcal vaccination [19, 20], using another rate such as the number of doses distributed per 10,000 persons ≥65 years of age implies knowing that elderly persons received virtually all of the vaccine used. Such information is not available for any country.

The vaccine manufacturers also provided information on the year in which their products were registered (i.e., licensed) in each country. National recommendations for pneumococcal vaccination issued by government health agencies or ministries and methods of reimbursement for vaccine administration were obtained from official publications [14, 15, 22–26] and/or unpublished information provided by knowledgeable experts in the individual countries and by staff of the vaccine companies.

Results

The United States was the only country that used appreciable amounts of pneumococcal vaccine throughout the study period (figure 1). In 1981, 99 doses of vaccine were distributed per 10,000 population, and distribution ranged from 49 to 64 doses per 10,000 population per year during the period from 1982 through 1990. Vaccine distribution began to increase in 1991, reaching 267 doses per 10,000 population in 1996 (R. A. Strikas, personal communication, June 1997).

In contrast with its use in the United States, only small amounts of pneumococcal vaccine were used in Canada, France, Australia, and Switzerland during the 1980s, and little if any was distributed in the other 16 countries (figure 1). From 1990 through 1993, vaccine usage increased slightly in Denmark and the United Kingdom. In Finland, a large clinical trial caused vaccine distribution to rise to 70 doses per 10,000 population in 1992. Remarkably, Iceland purchased 584 doses per 10,000 population in 1991. In the other countries, vaccine use remained at ≤5 doses per 10,000 population until 1994, when a substantial increase was noted in the United Kingdom. Later, similar increases occurred in Sweden (1995) and in Norway, Belgium, and Canada (1996).

The first-generation 14-valent pneumococcal vaccine was registered in only 11 of the 21 countries (table 1). After it was replaced by 23-valent vaccine in 1983, the new vaccine was registered in only 11 countries during the next 3 years. Later, registrations were obtained in the United Kingdom (1989), Italy (1992), Austria and Belgium (1995), and Denmark and Norway (1996). Iceland is the only country that does not require vaccines to be licensed. Pneumococcal vaccine has never been registered in Spain, Portugal, and Greece.

National recommendations for the use of 14-valent pneumococcal vaccine were issued in the United States, Canada, Norway, France, Denmark, and the Netherlands (table 1). Soon after 23-valent vaccine became available, recommendations also appeared in Austria, Australia, and New Zealand. For the 12 remaining countries, initial recommendations were issued much later: in Iceland and Germany, 1991; the United Kingdom, 1992; Belgium, 1993; Sweden, 1994; and Finland, Switzerland, and Ireland, 1996. Nonetheless, by the end of 1996, Italy, Spain, Portugal, and Greece had yet to issue any national recommendations for pneumococcal vaccination.

Recommendations for pneumococcal vaccination have varied widely among the 21 countries. Although Denmark and Norway issued recommendations in 1978 and 1980, respectively, only persons with asplenia were initially targeted for vaccination. Much broader recommendations were not made in these two countries until 1996. Although most of the 21 countries now have national recommendations, substantial differences between countries still exist. All countries with recommendations include asplenia and most include a broad range of conditions associated with immunocompromise, including HIV infection. Most countries also include persons with cardiopulmonary and renal diseases and diabetes mellitus, but heart disease is not mentioned in France and diabetes mellitus and renal diseases are omitted in Austria.

Vaccination is recommended for all elderly persons in 10 countries and for nursing home residents in 6, although only 5 of these countries recommend vaccination for both groups. Italy registered both 14-valent and 23-valent pneumococcal vaccines but has never issued recommendations for their use. In Spain, Portugal, and Greece, pneumococcal vaccine is neither registered nor recommended, although in the autonomous region of Catalonia in Spain recommendations almost identical to those for the United States were issued in 1993 [27].

Methods for providing reimbursement for pneumococcal vaccination of recommended groups also show substantial variation (table 1). Ten countries provide public reimbursement through some form of national or social health insurance. In countries where the vaccine has not been registered and vaccine use is very low (e.g., Spain), public reimbursement has been provided for small numbers of patients, usually those with asplenia, who are vaccinated on a compassionate (i.e., named-
Figure 1. Pneumococcal vaccination in the United States and 20 other developed countries, 1981 through 1996. Vaccine use is shown as the annual number of doses of vaccine distributed per 10,000 population. Rates have been rounded to the nearest whole number.

Discussion

The main finding of this study is that the United States is the only country among the 21 countries surveyed that used appreciable amounts of pneumococcal vaccine throughout the 1981 through 1996 period. Nonetheless, even in the United States, pneumococcal vaccination has not been widespread. The 1994 National Health Interview Survey found that only 30% of elderly persons (≥65 years of age) reported ever having received pneumococcal vaccine [28]. This was slightly more than half the coverage rate (55%) for influenza vaccine in this age group. The 1995 Behavioral Risk Factor Surveillance Study estimated that 35.6% of elderly persons had received "a pneumonia vaccination" [29]. The same year the influenza vaccination rate was 58.1%.

Several reasons have been given for the low level of pneumococcal vaccination in the United States, including lack of understanding by health care professionals and the public of the importance of pneumococcal disease, inconclusive and uninformative results of randomized controlled trials of pneumococcal vaccine in older individuals [1, 14, 18], and ineffective implementation of the Medicare program to reimburse physicians for the cost of pneumococcal vaccine and its administration [30, 31]. In addition, after seeing little return on their marketing efforts in the early 1980s, the two manufacturers in the United States devoted few resources to promoting the vaccine and did not expand their capacities to produce it.

That pneumococcal vaccine use has increased dramatically since 1991 may reflect greater acceptance of retrospective studies showing the clinical effectiveness of vaccination [1, 14, 18] and increased attention to adult immunization by federal agencies [32–34] and professional organizations [35]. Some of the increase might also be explained by revaccination of persons who were first vaccinated in the early 1980s and by wider use of the vaccine among those with HIV infections. However, these factors alone are unlikely to fully account for the recent increase in pneumococcal vaccination. A similar increase in the use of influenza vaccine in the United States began at about the same time, and it too is not fully understood [16, 19, 20].

In the 20 other developed countries included in this report, very little pneumococcal vaccine was distributed throughout the 1980s, and in most the vaccine still remained little-used-
Table 1. Registration, recommendations, and reimbursement for pneumococcal vaccination in the United States and 20 other developed countries.

<table>
<thead>
<tr>
<th>Country</th>
<th>Year (19XX) 14-/23-valent vaccine registered</th>
<th>Year (19XX) national recommendation issued (first/current)</th>
<th>Immunocompromised</th>
<th>Leukemia, Anatomic and functional lymphoma, and myeloma, and Hodgkin’s disease</th>
<th>Cardiopulmonary and renal diseases, diabetes mellitus</th>
<th>Other condition(s)*</th>
<th>Nursing home residents</th>
<th>Age ≥65 y</th>
<th>National or social health insurance</th>
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<td>92/96</td>
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* Other conditions vary among countries and include alcoholism, cirrhosis, solid organ and bone marrow transplantation, CSF leaks, smoking, previous hospital care, celiac syndrome (United Kingdom), and Down syndrome (Sweden).
† Not recommended.
‡ Not registered.
§ Recommended for all persons aged ≥60 years.
‖ A 17-valent vaccine was registered in Belgium from 1982 to 1988.
¶ Does not include heart disease (France) or diabetes mellitus and renal disease (Austria).
** Advisory note only in national vaccination recommendation.
†† Vaccination recommended for any person considered to be at increased risk because of chronic illness.
†‡ No national recommendation has been made.

up through 1996. As a result, vaccination rates among elderly and high-risk persons were certainly much lower than those in the United States. Consider, for example, the 17 countries of Western Europe included in this study. In 1996, the population of persons ≥65 years of age living in these countries was ~57 million. If it is assumed that all the pneumococcal vaccine distributed in these countries during the 5-year period from 1992 through 1996 was given to persons in this age group, and if it is also assumed that none of those who were vaccinated died of any cause, then the 2,761,000 doses of vaccine distributed would have been sufficient to vaccinate <5% of all elderly persons in Western Europe.

In a few of these countries, however, vaccination increased dramatically, and specific policy decisions appear to be largely responsible for these changes. Iceland’s large vaccine purchase in 1991 reflected both the conviction among health authorities that vaccination was useful in preventing invasive pneumococcal disease and heightened concern over the rapid increase in antimicrobial resistance among strains of *S. pneumoniae* [36]. In the United Kingdom, vaccine use increased after the Joint Committee on Vaccination and Immunisation issued its first recommendation on pneumococcal vaccine in 1992 [22]. In Belgium, the first set of recommendations in 1993 [23] was followed by registration in 1995 and an immediate increase in vaccine use. Expanded recommendations in Sweden and Norway (asplenia was the only condition previously mentioned), together with registration in Norway, account for the increase in vaccination noted in these two countries.

The most dramatic increase in pneumococcal vaccine use occurred in Canada in 1996. Since the late 1970s, Canadian recommendations for pneumococcal vaccination have been similar to those in the United States [15]. In spite of these recommendations, however, very little vaccine was used until 1996 [16]. The sudden increase reflected the decision of the
health officials in Ontario to achieve within 3 years a high level of vaccine coverage among recommended groups, including all persons ≥65 years of age.

In 1996, the provincial health department purchased almost 500,000 doses of pneumococcal vaccine for free distribution to physicians and coordinated a public and professional awareness campaign. In addition, the provincial health insurance system reimbursed physicians for administering the vaccine. As a result of this program, the provincial rate for pneumococcal vaccine distribution in 1996 was 402 doses per 10,000 population, and Ontario accounted for 90.5% of the total amount of vaccine distributed throughout Canada. In the remaining provinces and territories, vaccine distribution was only 25 doses per 10,000 population, a level comparable to that in France.

No single explanation accounts for the continued lack of use of pneumococcal vaccine in the other 20 countries included in this report. However, the decisions of the vaccine manufacturers have played an important role. Between 1977 and 1981, at least one of the companies registered and marketed its 14-valent vaccine in seven of these countries (table 1). Nonetheless, national recommendations soon followed in only three countries, and in two (France and Norway) they were highly restrictive. Because very few doses of their 14-valent vaccines had been sold, the companies made limited efforts to register their 23-valent products when they became available in 1983 and did little to promote them over the next decade. Moreover, in spite of an increase in the number of vaccine registrations and in the manufacturers’ promotional efforts in the mid-1990s, by the end of 1996 only the United Kingdom, Sweden, and Belgium had registered products from more than one company.

In striking contrast to their use of pneumococcal vaccine, many of these 20 countries have shown substantial increases in influenza vaccination over the past decade [19, 20]. Spain and Italy are the leaders for influenza vaccination in western Europe. Most of the doses of influenza vaccine used are purchased by regional health departments and given to patients free in public clinics. It appears that the unwillingness of regional governments to purchase pneumococcal vaccine is the main reason for its lack of use in these two countries. In France, there is no recommendation for pneumococcal vaccination of all elderly persons [24], nor is public reimbursement provided; this is unlike the policy for influenza vaccination, which is recommended for all persons ≥70 years of age and for which public reimbursement is provided [19]. Not surprisingly, influenza vaccine use in France is high [19, 20], whereas pneumococcal vaccine use remains low.

In four other countries (Switzerland, the Netherlands, Australia, and Germany), national authorities recommend influenza vaccine but not pneumococcal vaccine for persons ≥65 years of age, and appreciable amounts of influenza but not pneumococcal vaccine have been used. It is also worth noting that public reimbursement appears to have been an important factor in raising the level of pneumococcal vaccine use in Ontario and perhaps the United Kingdom, but the same cannot be said for other countries. In Iceland, Sweden, Norway, and Belgium the cost of pneumococcal vaccination is still borne privately, yet the vaccine is being used (table 1). Even in the United States, inadequate reimbursement under Medicare provided few if any financial incentive until recently for physicians to give or patients to receive the vaccine [31].

Among the four countries considered to be developed market economies but not included in this report, Japan is the only one of any size [21]. Data on pneumococcal vaccine use in Japan are unavailable, although very few doses are known to have been distributed and there is neither a national recommendation nor public reimbursement for pneumococcal (or influenza [20]) vaccination. Luxembourg, Monaco, and San Marino are the three remaining countries, and information is available only for vaccination recommendations in Luxembourg. They were issued in 1992 and are identical to those in neighboring Belgium, except for an age recommendation at 55 years [37].

The failure to use pneumococcal vaccine in developed countries over the past 20 years is undeniable. Perhaps no other vaccine that has come to the market over the past 50 years has been so widely ignored by so many countries for so long. Nonetheless, the increases in vaccine use noted in the United States and Iceland (1991), the United Kingdom (1994), Sweden (1995), and Norway, Belgium, and Canada (1996) are soon likely to be followed by similar changes in many other countries. New registrations are expected and will be important: in 1996, pneumococcal vaccine was actively marketed (in addition to being registered) by more than one manufacturer only in Sweden, Belgium, and the United States, and market competition may have contributed to the overall level of vaccine use in these three countries.

New vaccination recommendations are also expected soon in France and the Netherlands and later in other countries. Equally important will be a growing awareness that the incidence of invasive pneumococcal disease is probably similar in most developed countries [2–13] and that for elderly persons vaccination is both clinically effective [1, 14] and highly cost-effective [38] in preventing pneumococcal bacteremia alone.

The continuing spread of antimicrobial resistance among S. pneumoniae [39] and the possibility that pneumococcal conjugate vaccines will be used for priming in adults [40] as well as in children [41] will also contribute to the increased use of pneumococcal polysaccharide vaccine. This increase may not be limited to developed countries. Rapid economic change in developing countries and wider understanding of the importance of S. pneumoniae as probably the leading cause of death due to lower respiratory infections in persons of all ages worldwide [42] should lead to a dramatic growth in pneumococcal vaccination in many countries within the next few years.

Addendum

Since this article was submitted for publication, several changes have occurred (in 1997). Australia now recommends...
vaccination for all persons ≥65 years of age, for Aboriginal and Torres Strait Islander people >50 years of age, and for those with HIV infection [43]. Germany now recommends pneumococcal vaccination for persons with HIV infection and cirrhosis of the liver [44]. In Austria, diabetes mellitus and renal diseases are now included in the recommendations (C. Vlasich, personal communication). In Italy, the region of Emilia Romagna now recommends pneumococcal vaccination for persons with cardiopulmonary diseases, splenectomy, and CSF fistula and for those ≥65 years of age.

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References


