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Health and economic impact of the United States varicella vaccination program, 1996–2020

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Abstract

Objective: To evaluate the health and economic impact of the varicella vaccination program on varicella disease in the United States (U.S.), 1996–2020.

Design: Analysis was conducted using the Centers for Disease Control and Prevention or published annual population-based varicella incidence, and varicella-associated hospitalization, outpatient visit, and mortality rates during 1996–2020 compared to before vaccination (1990–1994). Disease costs were estimated using the societal perspective. Vaccination program costs included costs of vaccine, administration, post-vaccination adverse events, and travel and work time lost to obtain vaccination. All costs were adjusted to 2020 US dollars using a 3% annual discount rate.

Setting: U.S. population aged 0–49 years during 1996–2020 (range: 199.5 million to 214.2 million persons).

Main outcome measures: Number of varicella-associated cases, hospitalizations, hospitalization days, and premature deaths prevented; life-years saved; and net societal savings from the U.S. varicella vaccination program.

Results: Among U.S. persons aged 0–49 years, during 1996 through 2020, it is estimated that more than 91 million varicella cases, 238,000 hospitalizations, 1.1 million hospitalization days, and almost 2000 deaths were prevented, and 118,000 life-years were saved by the varicella vaccination program, at net societal savings of $23.4 billion.

Conclusion: Varicella vaccination has resulted in substantial disease prevention and societal savings for the U.S. over 25 years of program implementation.

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Keywords

varicella disease; varicella vaccine (VAR); cost; benefit

The United States (US) was the first country to introduce the varicella vaccine into the routine childhood vaccination program, starting in 1995 with one dose recommended at age 12–18 months; in 2007 the policy was revised to include two doses routinely for children —a first dose at age 12–15 months and a second dose at 4–6 years [1]. Older children, adolescents, and adults who had neither experienced varicella nor been vaccinated were recommended for catch-up vaccination with 2 doses. Over 25 years of vaccination program implementation in the US, routine varicella vaccination has resulted in dramatic decreases (≥95%) in varicella incidence, hospitalizations, and deaths among persons aged <50 years as varicella vaccination coverage has increased and remained high (≥90% among children aged 19–35 months since 2007) [2–4].

In addition to monitoring the health benefits accrued from the vaccination program, economic assessments are critical for evaluating the impact of vaccine policy. Sizable cost savings have been documented for the 1-dose program [5, 6]. In this paper we summarize the health and economic impact of the US varicella vaccination program on varicella disease during the 25 years since program implementation.

Materials and Methods

Analysis method

For each year of the varicella vaccination program, from 1996 through 2020, we evaluated the impact of vaccination by comparing specific disease burden indicators with those observed from 1990 through 1994 (pre-vaccine period). We calculated varicella-associated cases, hospitalizations, hospitalization days, and premature deaths prevented, years of life saved, and net societal savings by the program. Although the varicella vaccine was licensed in the US in March 1995 and recommended the same year, we started the analysis with 1996 because challenges with storage and handling for this frozen vaccine led to some delays in program initiation. Additionally, we restricted our analysis to persons aged 0–49 years because ≥99% of US persons aged ≥50 years are varicella-zoster virus (VZV) seropositive, indicating immunity and low or no risk for varicella and related complications [7, 8]. The analysis did not consider the potential effect of varicella vaccination on the incidence of herpes zoster (HZ).

Analyses were performed from the societal perspective, which includes both direct and indirect costs. We estimated the net societal savings as the sum of the societal benefits from the prevention of varicella minus the sum of the societal costs of the varicella vaccination program. Direct costs included medical, non-medical, and outbreak response and control costs. Direct medical costs included costs associated with treating varicella and managing complications. Direct non-medical costs included travel expenses to seek care for the patient with varicella. Indirect costs included productivity losses due to premature mortality after varicella, as well as opportunity costs associated with parents or caregivers

who miss work to care for their sick children or with adults who contract varicella and miss work. Benefits of varicella vaccination were quantified as savings in direct and indirect costs that accrue from averting varicella-related morbidity and mortality due to vaccination. The costs associated with the varicella vaccination program included the costs of the vaccine, its administration, post-vaccination adverse events, as well as travel and work time lost to obtain vaccination. All costs were adjusted to 2020 dollars using general and medical Consumer Price Indices [9], and all costs and productivity losses in the future were discounted at a 3% annual rate.

Estimating the burden of disease prevented

The age-specific annual incidence rates of varicella in the US in the pre-vaccine period were estimated from the 1990–1994 National Health Interview Survey self-reported data [6]. For the vaccine period, the national varicella surveillance was not adequate to monitor cases in the early years of the program, therefore we used active surveillance data until the project was discontinued in 2010, and national passive surveillance data thereafter. Specifically, from 1996–2010 we used age-specific incidence from the West Philadelphia area of the Varicella Active Surveillance Project, and from 2011–2019 we used the National Notifiable Diseases Surveillance System [2]. As reported incidence data underestimated the true number of cases because of under-reporting [10], we calculated adjusted incidence rates to estimate the true number of varicella cases by comparing annual varicella outpatient visit rates from an administrative claims database (1994–2019 IBM® MarketScan Research Databases[11][unpublished data]) with the reported incidence data. For the incidence rates during 1996–2010, we calculated an annual adjustment factor by age group based on a ratio of outpatient visit rates to reported incidence rates (2–4 for age 0–9 years, 2–6 for age 10–19 years, and 2–8 for age 20–49 years). For the incidence rates during 2011–2019, since cases were passively reported, we assumed the speed of the decline of the incidence rates was the same as the one for outpatient visit rates and applied these rates of decline to adjust the incidence rates. We increased these adjusted incidence rates by 20% in the sensitivity analyses.

The age-specific annual varicella-associated hospitalization and complication rates were obtained from the 1993–2019 National (Nationwide) Inpatient Sample [3]. We used the average rate for 1993–1995 as the pre-vaccine rate. The age-specific annual varicella mortality rates were obtained from the 1990–2019 National Center for Health Statistics' Mortality Multiple Cause of Death public use records [3]. We used the average mortality rate for 1990–1994 as the pre-vaccine rate. Mortality rates with varicella as the underlying cause were used for the base-case analyses; we included mortality rates with varicella as the contributing cause in the sensitivity analyses.

For all disease burden indicators, we used the 2019 rates to estimate the program impact for 2020. The rates used for disease burden indicators are presented in the Supplementary material for selected years.

Costs associated with disease

Direct costs—Direct costs for outpatient visits, hospitalizations, and varicella outbreak response and control, and travel expenses to seek care for the patient with varicella were included in the analysis. These costs were obtained from published studies [6, 12–14] and unpublished data (2010–2019 IBM MarketScan data) (Table 1). All costs shown are in 2020 dollars.

During the vaccination program, varicella outbreaks continued to occur in the US, though they became smaller and less frequent over time [15]. Responding to these outbreaks, mainly during the 1-dose program, was a heavy burden and costly to local and state health departments. We assumed that the expected cost per case accrued to public health departments for active outbreak management was $14.46 after adjusting by the probability of a case to happen in an outbreak; this is based on a 2004 survey that estimated the average cost to state and local health departments for varicella outbreak response at approximately $6,000 per outbreak [6, 14].

Indirect costs—To estimate productivity losses from varicella morbidity and premature mortality, we used the human capital approach [16]. In this approach, costs for work loss are determined using the number of days of missed work for either the provision of care for a sick child or own illness among adults. The number of days is then multiplied by the daily wage rate associated with the value of lost earning from work or the imputed economic value of housekeeping and home-care activities. We considered that the cost of work loss by parents who served as caregivers when their children had varicella was $396 per case, and the cost of work loss by adults who contracted varicella was $1476 per case [6]. Age-specific lifetime productivity loss resulting from premature death was obtained from a published study [17].

Vaccination costs and adverse events post-vaccination—Two formulations of varicella vaccine are licensed in the US: a single antigen varicella vaccine (VAR) since 1995, and a combination measles-mumps-rubella-varicella vaccine (MMRV) since 2005. Annual varicella vaccine (either VAR or MMRV) purchase data were derived from annual CDC Market Share Report (CDC, unpublished data, 1996–2020). For most years, more than 50% of varicella vaccines were publicly purchased in the US. The 1996–2020 public and private prices for varicella vaccines were obtained from the CDC Vaccine Price List (http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html, accessed June 21, 2021, and unpublished CDC data). The cost (federal excise tax excluded) of VAR has increased from $32.70 and $41.41 in 1996 to $108.51 and $134.98 in 2020 for the public and private sectors, respectively. The cost of MMRV has increased from $71.85 and $114.60 in 2006 to $134.52 and $221.94 in 2020 for the public and private sectors, respectively. For MMRV, we used the cost for the varicella component only, calculated using the price of MMRV multiplied by the price of VAR and the product divided by the sum of prices of MMR and VAR. We assumed that the rate of vaccine wastage (public and private sectors) was 5% [18]. During 1996–2020, more than185 million VAR and 35.5 million MMRV doses were distributed in the US.

The average cost for administering a dose of varicella vaccine was estimated at $30.54 [19]. We assumed that the average travel cost for a caregiver of vaccinated children or an adult to receive a varicella dose was $9.43 and the related indirect costs was $14.65 (accounting for receipt of multiple vaccines at the same visit) [19].

Safety surveillance data during program implementation show that adverse reactions after receiving a dose of varicella vaccine are rare and generally mild, approximately two-thirds being rash, fever, or injection-site reactions [20–22]. We assumed that 1% of vaccinated persons would require a follow-up outpatient visit for minor complications after the first dose, and 0.5% would require such a visit after the second dose [12]. Serious complications due to the vaccine included pneumonia and HZ (vaccine strain) [20, 21]. After weighting the cost estimates by the probability of occurrence, we assumed that average direct (medical and non-medical) and indirect costs per dose for vaccine-related adverse events (not including vaccine-strain deaths) were $1.50 and $0.67, respectively [6]. Additionally, we accounted for the productivity loses of the six vaccine-strain VZV deaths (all in immunocompromised persons) documented in the US [22].

Sensitivity and scenario analyses—We performed various sensitivity and scenario analyses to assess the robustness of our estimates and to estimate the impact of potential changes on the base-case health and economic outcomes accrued by the varicella vaccination program. Specifically, we assessed the effect of varying: 1) mortality rates, by including deaths with varicella as the contributing cause; 2) post-vaccination varicella incidence, hospitalization, outpatient visits, and mortality rates (+20%); 3) direct cost of a varicella case (±20%); 4) indirect cost of a varicella case (±20%); 5) cost of vaccine administration (±20%); and 6) costs of vaccine adverse events (±20%). We also performed worst-case scenario analyses which were combinations of the worst-case values for the input items 2 through 6.

Results

Health impact.

During the first 25 years of the US varicella vaccination program, our analyses estimated that more than 91 million varicella cases, 238,000 hospitalizations, 1.1 million hospitalization days, and almost 2,000 deaths were prevented (Table 2). Additionally, the varicella vaccination program led to 118,000 life-years saved in the US (including years saved beyond 2020, based on life expectancy).

Economic impact.

The societal cost averted by varicella vaccination, by preventing varicella-caused morbidity and mortality, was estimated at $56.9 billion, with 73% ($41.4 billion) due to indirect costs. The overall societal cost for the varicella vaccination program was estimated to be $33.5 billion. Thus, the net societal savings of the US varicella vaccination program for 25 years of program implementation was $23.4 billion. For every dollar spent on varicella vaccination, society saved $1.70 during the first 25 years of the program.

Sensitivity and scenario analyses.

Table 3 shows the deaths prevented and net societal savings from sensitivity and scenario analyses when the values of selected input parameters were varied. There was little change in the number of deaths prevented based on the sensitivity and scenario analyses (−3 to 0% change), except when including deaths with varicella as the contributing cause, which increased the number of deaths prevented by approximately 500 deaths, a 27% increase. There was variability in the estimated net societal savings based on the sensitivity and scenario analyses, ranging from a 61% reduction (worst-case scenario) to a 35% increase (when direct disease costs increased by 20%). Because varicella incidence, hospitalizations, outpatient visits, and mortality rates in the vaccine era may have been underestimated, we performed an analysis with the vaccine era rates 20% higher than what we used in the case-base scenario. In that scenario the net societal savings would be reduced by 8%.

Discussion

Our study documents the substantial health benefits achieved by the US varicella vaccination program, with more than 91 million cases, 238,000 hospitalizations, 1.1 million hospitalization days, and almost 2000 deaths prevented, and 118,000 life-years saved over 25 years since program implementation. Moreover, these benefits were achieved at substantial cost savings for society. We estimated a return on investment of $1.70 for every $1 spent during the first 25 years of the program, moreover, the benefits of the investment will continue to accrue beyond 2020.

The sensitivity and scenario analyses highlight several key aspects of the routine varicella vaccination program. The current level of varicella disease in the US is so low that even 20% hypothetical increases during the vaccine era in varicella incidence, hospitalization, outpatient visit, and mortality rates do not substantially alter the net societal savings. Similarly, the varicella vaccine is safe, and even when we increased the vaccine adverse event rates used in the base case analysis by 20%, the net societal savings also did not change substantially. The current estimate of the net societal savings was most sensitive to increases in direct and indirect costs of varicella disease and administration costs. Data on the probability distributions of variables are unavailable, which prevented us from conducting a Monte Carlo simulation for a multivariate probabilistic sensitivity analysis and estimating confidence intervals. Even with the least favorable worst-case scenario, however, the universal varicella vaccination program in the US was still cost saving at $9.2 billion net saved.

One strength of this study is the use of real-world data rather than model-projected data. We were able to incorporate surveillance data from a range of sources on varicella incidence, hospitalizations, outpatient visits, and deaths with most recent data through 2019 to estimate the annual health and economic impact of varicella on the US population aged 0–49 years. Prior economic evaluations of varicella vaccination that examined universal vaccination in the US employed cost-effectiveness or cost-benefit analysis using vaccine efficacy and vaccination coverage and projected that a varicella vaccination program with 1 dose or 2 doses would result in net savings for society [6, 12]. We took a new approach, based on actual program impact data and also found the program to be cost saving.

Although we followed state-of-art economic evaluation methods and guidelines, our evaluation has several limitations. We used a conservative approach for the parameter estimates, which might have underestimated the full impact of the varicella vaccination program. The remaining limitations mostly related to the availability of and uncertainties in the data. For example, varicella cases may have been missed or under-reported and the fraction missed may have changed over the study period. We attempted to account for under-reporting by weighting the data using outpatient visits, which we considered a more reliable measure of disease burden although this indicator too is prone to underestimation as a proportion of varicella patients do not seek any medical care. During 25 years of varicella vaccine use, reported rates of many adverse events and severe adverse events have decreased. Thus, we might have overestimated the costs for post-vaccination adverse events in the base case analysis. We did not include the costs associated with pain and suffering to family and friends of the patient with varicella due to the complexities in the measurement of caregiver and family effects. In addition, some of the data used to estimate burden of disease may not be generalizable to the US population. For example, for estimating varicella cases during 1996–2010, we relied on data from one active surveillance area, however because varicella was a ubiquitous disease it is likely this site reflects patterns around the country; for estimating outpatient visits, we used an administrative claims database with data primarily from persons with employer-sponsored insurance. Some estimates were based on older data. Lastly, we also restricted our analysis to persons <50 years; this was done to increase the specificity for identifying varicella cases. Throughout this study, our principle was to avoid overestimation of the impacts of the program.

As previously noted, we also did not consider the potential effect of varicella vaccination on HZ. At the launch of the varicella vaccination program there was concern that decreased exposures to varicella following a universal vaccination program would lead to an increase in HZ incidence because of decreased exogenous boosting and that the HZ associated burden would counterbalance the benefits of varicella vaccination in the short and medium term [23]. There was agreement that over the long term (>50 years after childhood vaccination is initiated) a varicella vaccination program is likely to reduce HZ incidence. The predicted impact on HZ incidence was indirect, based on modeling studies to account for community protection after varicella vaccination and uncertainties about the impact of varicella vaccination on HZ incidence. Analyses of real data obtained before and during the US varicella vaccination program and from other countries has not confirmed an increase in HZ incidence attributable to the varicella vaccination program [24–26]. In fact, the risk for HZ in varicella vaccinated children and adolescents is much lower compared with those infected with wild-type VZV. Decreases in HZ incidence among cohorts of varicella vaccinated children through young adults have been reported, which indicates an additional benefit, uncounted in this study [27, 28]. Increasing our understanding of the impact of varicella vaccination on HZ epidemiology, especially whether the lower HZ risk reported among vaccinated children and adolescents is maintained into older ages, would help with refining the estimates of the health and economic impacts of the varicella vaccination program.

Since the start of the varicella vaccination program in the US in 1995, over 25 years of program implementation, dramatic declines in varicella and its severe outcomes have been

documented, including an impressive return on the investment of varicella vaccine with net societal savings. Annually, more than 3.8 million varicella cases, 10,500 hospitalizations, and 100 deaths are prevented each year in the United States. Our data confirm that varicella vaccination is an effective and cost-saving public health intervention, being not only a major public health achievement in terms of disease prevention, but also an efficient public health "buy" in terms of dollars saved. With the US being the first country to implement a routine varicella vaccination, our findings provide useful evidence for countries considering implementation of a universal varicella vaccination program.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

CDC	Centers for Disease Control and Prevention
VAR	varicella vaccine
MMRV	measles-mumps-rubella-varicella vaccine
VZV	varicella-zoster virus
HZ	herpes zoster

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Table 1.

Selected key inputs: costs of varicella hospitalizations without and with complications, hospitalization days, and cost of varicella outpatient visits, by age group[a]

	Mean Cost ($)	Mean hospitalization days
Hospitalization		
Case without complications[b]		
0–9 years	28,273	4.8
10–19 years	23,644	3.8
20–49 years	16,162	3.4
Case with complications[c]		
0–9 years	22,121	4.4
10–19 years	50,203	5.9
20–49 years	24,752	5.4
Outpatient visit		
0–9 years	274	-
10–19 years	214	-
20–49 years	303	-

[a]Estimated using 2010–2019 IBM® MarketScan Research Databases

[b]With an International Classification of Disease, 9th or 10th Revisions, Clinical Modification (ICD-9-CM or ICD-10-CM) codes for uncomplicated varicella (052.9 or B01.9)

[c]With ICD-9-CM or ICD-10-CM codes for varicella, excluding uncomplicated varicella (052.* or B01.*, excluding 052.9 and B01.9)

Table 2.

Estimated cumulative numbers of varicella cases, hospitalizations, and deaths prevented and estimated cumulative varicella vaccination program costs and net costs saved, United States, 1996–2020

Health outcomes prevented	
Varicella cases prevented	91,278,325
Hospitalizations prevented	238,124
Hospitalization days prevented	1,106,580
Deaths prevented *	1,933
Years of life saved *	118,251
Disease costs averted ($, in million)	56,936
Direct costs averted	15,547
Indirect costs averted	41,389
Vaccination program costs ($, in million)	33,497
Vaccine costs	21,578
Administration costs	6,405
Travel costs	1,978
Indirect costs	3,071
Adverse events	465
Net societal savings ($, in million)	23,439

* Varicella as the underlying cause of death

Table 3.

Deaths prevented and net societal savings: univariate sensitivity and scenario analyses (with proportional changes to base-case in parentheses)

	Death Prevented (% change to base-case)	Net Societal Savings (in $Billion) (% change to base-case)
Base case *	1,933	23.4
included mortality rates with varicella as the underlying and contributing cause	2,446 (+27%)	24.3 (+4%)
20% increase of direct costs	1,933 (0%)	26.5 (+13%)
20% reduction of direct costs (1)	1,933 (0%)	20.3 (−13%)
20% increase of indirect costs	1,933 (0%)	31.7 (+35%)
20% reduction of indirect costs (2)	1,933 (0%)	15.2 (−35%)
20% increase of base case administration cost (3)	1,933 (0%)	22.2 (−5%)
20% reduction of base case administration cost	1,933 (0%)	24.7 (+6%)
20% increase of base case adverse events rate (4)	1,933 (0%)	23.3 (0%)
20% reduction of base case adverse events rate	1,933 (0%)	23.5 (0%)
Scenario 1: 20% increase of base case incidence, hospitalization, outpatient visit, and mortality rates after vaccination (5)	1,872 (−3%)	21.6 (−8%)
Scenario 2: Worst-case scenario (combination of 1–5 above)	1,872 (−3%)	9.2 (−61%)

* Varicella as the underlying cause of death