HHS Public Access
Author manuscript
Clin Infect Dis. Author manuscript; available in PMC 2024 September 03.

Published in final edited form as:
Clin Infect Dis. 2021 October 20; 73(8): 1424–1430. doi:10.1093/cid/ciab442.

Rotavirus Vaccination Likely to Be Cost Saving to Society in the United States

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Abstract

Background: Following the introduction of rotavirus immunization in 2006 in the United States, there were substantial declines in the domestic rotavirus disease burden. In this study, we assess the value for money achieved by the program in the decade following vaccine introduction.

Methods: We applied an age-specific, static, multicohort compartmental model to examine the impact and cost-effectiveness of the US rotavirus immunization program in children <5 years of age using healthcare utilization data from 2001 to 2015 inclusive. We calculated the incremental cost-effectiveness ratio (ICER) per quality-adjusted life year (QALY) gained from both a healthcare system and societal perspective.

Results: Declines in healthcare use associated with the rotavirus and acute gastroenteritis occurred from 2006 and continued to grow before stabilizing from 2010 through 2011. From 2011 to 2015, an estimated annual average of approximately 118 000 hospitalizations, 86 000 emergency department presentations, and 460 000 outpatient and physician office visits were prevented. From a societal perspective during this same period, the program was estimated to be cost saving in the base case model and in >90% of probabilistic sensitivity analysis simulations

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Supplementary Data
Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

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Potential conflicts of interest. The authors: No reported conflicts of interest. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest.

and from a healthcare system perspective >98% of simulations found an ICER below $100 000 per QALY gained.

Conclusions: After the program stabilized, we found the rotavirus immunization in the United States was likely to have been cost saving to society. The greater than expected healthcare and productivity savings reflect the success of the rotavirus immunization program in the United States.

Keywords

acute gastroenteritis; cost; cost-effectiveness; Rotavirus; rotavirus vaccine

The United States was one of the first countries in the world to introduce national rotavirus immunization. Two rotavirus vaccines are currently recommended for use in the United States by the Advisory Committee on Immunization Practices: RotaTeq introduced in 2006 and Rotarix in 2008 [1]. Before the introduction of the infant rotavirus immunization program in the United States, rotavirus infections were estimated to be responsible for between 55 000 and 70 000 hospitalizations annually [2], with a total annual healthcare cost estimated at more than $300 million [3].

Shortly after introduction, rotavirus vaccination in the United States resulted in substantial declines in rotavirus disease and related healthcare use in children [4–7]. These large declines in rotavirus disease burden have been sustained in the following decade and a half since the vaccination was introduced. Alongside the declines observed in rotavirus disease in vaccinated infant cohorts, there is evidence of indirect herd protection to others within the population, including to unvaccinated children [8]. A low risk of intussusception, a form of bowel obstruction, has also been documented to occur with both rotavirus vaccines in children in the United States [9, 10]. This risk has been assessed to be outweighed by the health benefits of rotavirus vaccination and has not led to any change to vaccine recommendations [11].

An assessment of cost-effectiveness of vaccination is 1 of several factors considered by the Advisory Committee on Immunization Practices when making recommendations for changes to the vaccination schedule in the United States. The cost-effectiveness of rotavirus vaccination in the United States was assessed before introduction of the program [3]. This initial model-based analysis by Widdowson et al predicted that rotavirus vaccination may be cost-effective but was unlikely to be cost saving in the United States [3].

The new data available on the impact of rotavirus vaccination in the United States provide an important opportunity to assess the value for money achieved by the program in the decade following introduction. This study aims to evaluate the cost-effectiveness of the rotavirus program in children <5 years of age in the United States using postimplementation data on program impact.

METHODS

Study Design and Model

We applied an age-specific, static, multicohort compartmental model to examine the impact and cost-effectiveness of the US rotavirus vaccination program implemented in 2006 among children <5 years of age. The model used 1-year age stratifications (<1 year, 1 year, 2 years, 3 years, and 4 years). Model outcomes included rotavirus deaths, rotavirus-coded hospitalizations, all-cause acute gastroenteritis (AGE) hospitalizations, all-cause AGE emergency department (ED) presentations, all-cause AGE outpatient department and physician office visits, symptomatic rotavirus cases not requiring medical care, and hospitalizations for intussusception.

We calculated the incremental cost-effectiveness ratio (ICER) per quality-adjusted life year (QALY) gained from both a societal (including productivity costs from caregiver absenteeism) and healthcare system perspective. The cost-effectiveness of the rotavirus immunization program as a whole was evaluated, and we accounted for the estimated proportional market share of each of the 2 brands of rotavirus (RotaTeq and Rotarix) used in the United States as well as differences in vaccine prices and schedules. All costs and consequences were discounted at 3% per annum under the base case model as recommended by the US Public Health Service Panel on Cost-Effectiveness in Health and Medicine [12].

Data Sources for Health Outcomes

The model used healthcare utilization data from 2001 to 2015 inclusive (see Program impact). Hospitalization data were obtained from the Nationwide Inpatient Sample dataset [13] using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes for rotavirus hospitalization (008.61) and for all-cause AGE hospitalization (001–005 [excluding 003.2], 006–007 [excluding 006.3–006.6], 008.0–008.5, 008.6, 008.8, 009.0–009.3, 558.9, and 787.91) to identify hospitalizations associated with the diagnosis code in any 1 of up to 15 discharge diagnoses. We separately modelled coded hospitalizations for rotavirus and all-cause AGE hospitalization (excluding rotavirus coded hospitalizations) and combine these when presenting all-cause AGE hospitalization. Applying the same ICD-9-CM codes used for all-cause AGE hospitalizations, ED presentations, outpatient department visits, and physician office visits for all-cause AGE listed in the first 2 diagnosis fields were obtained from the IBM Marketscan Commercial Claims and Encounters database [14]. Outpatient department and physician visits were combined in the model to estimate ambulatory visits occurring outside of the ED setting.

The base-case model deaths resulting from rotavirus in the prevaccine period followed the cumulative risk as assumed in Widdowson et al [3], with an estimated (death) probability of 7.7×10^{-6} among children <5 years of age, which is equivalent to approximately 30 deaths annually for the United States. For simplicity, we assumed that rotavirus deaths only occurred following rotavirus hospitalization and that 80% of deaths were in children aged <1 year old and 20% in children 1 to 4 years of age [3]. We then calculated a rotavirus hospitalization-fatality rate based on the last 5 years of the prevaccine period (2001–2005) and applied this in the model. The reduction in rotavirus deaths from vaccination were assumed to follow the proportional reduction observed in rotavirus hospitalizations.

The excess rate of intussusception attributable to rotavirus vaccination has been estimated to be approximately 1 to 5 cases per 100 000 vaccinated infants in the United States [9–11]; in the base case model, we assumed 2 cases per 100 000 vaccinated infants. Annual age-specific population counts were obtained from the National Center for Health Statistics Bridged Race population estimates [15, 16]. Single-year remaining life expectancies, averaged across sex, were obtained from the US Actuarial Period Life Table for 2006 [17].

Vaccination

In the United States, RotaTeq is scheduled for 3 doses at ages 2, 4, and 6 months, and Rotarix in 2 doses at ages 2 and 4 months. RotaTeq was used from 2006; Rotarix use began in 2008. Rotavirus vaccine coverage data were obtained from the National Immunization Survey-Child [18] from 2008 to 2016. The survey reports coverage for children aged 19 to 35 months of age (eg, the 2015 sample reflects the uptake in children born between January 2012 and May 2014). In the model, the coverage from the survey from 2008 to 2016 was assigned to cohorts born in 2006 to 2014, respectively, with each year of the survey assumed to represent a single-year age cohort. The uptake in 2015 was assumed to be the same as applied for 2014, which was reasonable because, from 2012, rotavirus coverage levels started to stabilize in the United States. Further details about vaccination uptake and timeliness estimation are provided in the Appendix.

Program Impact

The general approach to determine the impact of the rotavirus vaccination program was to evaluate changes in the outcomes based directly on routinely collected administrative datasets detailed previously. We established a “with-program” scenario using age-specific observational data, estimating result for 2 scenarios: (1) the period after the program coverage stabilized (2011–2015) to better represent the ongoing impact of the mature rotavirus vaccination program; and (2) the period since the commencement of rotavirus vaccination (2006–2015), including the initial years with lower vaccine coverage (results presented in Appendix Tables 2 and 3). The hypothetical “no-program” scenario was estimated based on the average age-specific outcome rates over the past 5-year data before the program was introduced (2001–2005). The impact of the program was calculated as the difference between the outcomes under the 2 scenarios in children aged younger than 5 years.

Estimates of rotavirus cases not requiring medical care were not available from routinely collected US data. The approach to calculating the reduction in rotavirus cases not requiring medical care was the same as in Reyes et al [19]. This is described in detail in the Appendix, but in summary, we used a traditional cost-effectiveness modelling approach applying a vaccine efficacy [14] against estimated rates of all symptomatic rotavirus cases [20]. This was the only instance that a vaccine efficacy estimate was applied in the model with all other estimates of program impact being established by observed changes in administrative datasets.

Costs and Quality of Life

Following the approach used in preimplementation economic evaluations, costs applied in the model were based on the year the program was introduced, in this case 2006. To estimate costs in each dataset, we used the same ICD-9-CM codes and diagnosis fields described previously. For hospitalizations, we applied age-specific mean cost data from the Nationwide Inpatient Sample for rotavirus or all-cause AGE respectively (see Appendix Table 1). For ED presentations, we applied the age-specific mean charge for all-cause AGE from the Nationwide Emergency Department Sample. For outpatient and physician office visits, we estimated the combined mean costs based on all-cause AGE charge data from the 2006 IBM Marketscan Commercial Claims and Encounters database. No costs were included for rotavirus cases not requiring medical care.

The price per dose for vaccines was estimated from those listed publicly by the Centers for Disease Control and Prevention. For RotaTeq, the 2006 price was applied (US$52) [21]; however, for Rotarix, the earliest price year available was 2008, the year of introduction (US$82.25) [22]. To be consistent with all other costs from the year 2006, we used an approximated 2006 cost (US$75) estimated by adjusting the 2008 Rotarix cost based on the 10% increase in price of RotaTeq from 2006 to 2008. Vaccine administration cost per dose was assumed to be US$10 [3].

The QALY loss for cases requiring medical care was estimated to be 0.0022 [23] and for cases not requiring medical care assumed to be one-half these estimates, as was assumed in Bilcke et al [20, 24]. For intussusception, we estimated a QALY loss of 0.0037 per case [25]. For simplicity, those not ill were assumed to have a utility weight of 1.

We estimated caregiver work absenteeism caring for children sick with rotavirus primarily based on Widdowson et al [3], assuming 1.3 days of missed work for cases requiring outpatient or physician office visits, 2 days for ED visits, 1 day for episodes not requiring medical care, and 10 days for rotavirus death. We assumed 5 days' absenteeism for hospitalized cases based on an analysis of nonmedical costs for rotavirus hospitalizations in the United States [26]. We valued 1 day of missed work for a caregiver at $126.92 based on the average hours on days worked of 7.6 and the 2006 average earning per hour of $16.70 [27].

Sensitivity Analysis

One-way sensitivity analyses were conducted by setting the varied parameter values to their corresponding 95% lower and upper confidence limits of their distributions (see Appendix Table 1). Probabilistic sensitivity analyses (PSAs) were also conducted with ranges that were derived from data where possible and/or computed based on 95% confidence intervals of the mean. For the PSA, 10 000 parameter sets were sampled using Latin Hypercube sampling from distributions listed in Appendix Table 1.

RESULTS

The impact of the rotavirus program on healthcare outcomes varied by age and outcome (Figure 1). The declines found after the implementation of the program were largest in the youngest children, aged younger than 2 years, and for the severe outcome of hospitalization. However, noticeable declines were observed in all age groups considered for the most severe categories and in younger children for the less severe outcomes of ED presentations and outpatient and physician office visits. The declines associated with the program increased over time before stabilizing from 2010 to 2011, consistent with the rise in vaccine coverage after national introduction. Coverage increased from commencement of the program until 2010 and then stabilized from 2011 with approximately 72% to 74% of each annual infant birth cohort fully vaccinated and approximately 13% to 15% partially vaccinated (Figure 2). We focused the results presented here on the more recent period from 2011 to 2015 after uptake stabilized; however, results for the entire period from 2006 to 2015 are presented in the Appendix.

For all children younger than 5 years of age from 2011 to 2015, the estimated average annual declines were 89% for rotavirus hospitalizations, 63% for all-cause AGE hospitalizations, 25% for all-cause AGE ED presentations, and 17% for AGE outpatient and physician office visits (Table 1). This equated to an estimated annual average of approximately 118 000 hospitalizations, 86 000 ED presentations, and 460 000 outpatient and physician office visits prevented. The annual decline in these outcomes during the period directly after the program commenced from 2006 to 2010, even though coverage was still increasing, were less substantial but increased as coverage increased (see Figure 1). In addition, it was estimated that an annual average of 27 deaths and 448 000 symptomatic infections not requiring medical care were prevented. There was an annual average of 69 additional cases of intussusception estimated to be attributed to the program from 2011 to 2015.

The total discounted program cost from 2011 to 2015 was estimated to be $2728 million or approximately $550 million each year. The estimated total savings from the program including productivity costs more than fully offset the total program cost during this period (Table 2). The total cost of the program was not offset by healthcare saving alone, however; during this period, the base case healthcare savings were estimated to be approximately $2000 million. The largest share of healthcare savings associated with the program resulted from hospitalizations prevented followed by AGE outpatient and physician office visits prevented. The base case total incremental QALYs gained from the program over this period were 11 419. A greater proportion of QALYs gained came from prevention of acute disease requiring medical care rather than rotavirus mortality or infections not requiring medical care. The base case ICER from a healthcare perspective was estimated to be approximately $63 000 per QALY gained; from a societal perspective, the program was estimated to be cost saving.

One-way sensitivity analyses indicated that the estimated administration cost (US$10 in base case) was the most influential variable considered irrespective of the perspective. From a healthcare perspective, other influential variables included the QALY loss per child, the annual probability of symptomatic rotavirus in those <2 years, the estimated rate of waning vaccine protection, and then parameters associated with the rates of healthcare use. From a societal perspective, variables associated with missed workdays were also influential, such as estimated caregiver missed workdays because of outpatient and physician office visits.

From a societal perspective, the PSA found the program was cost saving in more than 90% of simulations (Figure 3). From a healthcare perspective, more than 98% of simulations found that the program was cost-effective at a willingness to pay threshold of $100 000 per QALY gained.

DISCUSSION

We found that the rotavirus vaccination program in the United States has resulted in substantial reduction in healthcare use, with the largest healthcare cost savings estimated to come from prevented hospitalizations. After the impact and coverage of the rotavirus program stabilized from 2011, we found the rotavirus program in the United States is likely to have been cost saving to society when including estimated productivity savings. This finding differs from the initial predictions estimated by Widdowson et al before implementation of the program, which suggested that the program may be cost-effective but is unlikely to be cost saving even when productivity costs were included [3]. When only healthcare costs were considered, we estimated the program was likely to have been cost-effective but not cost saving, with results substantially more favorable than previously predicted [3].

There are several potential reasons for the differences in cost-effectiveness results between those predicted before implementation and our results using data from after introduction of rotavirus vaccination. One major reason is that we estimated a larger number of prevented hospitalizations. This appears to have been primarily because of an underestimation in the preventable hospital burden attributable to rotavirus before introduction of the vaccination program. Before, implementation rotavirus was assumed to be the causative agent in approximately 35% of gastroenteritis hospitalizations in children younger than 5 years [3]. However, we found an observed decline in AGE hospitalization rates in this age group of approximately 60% in the period 2011 to 2015 when compared with the period before introduction, suggesting that rotavirus was responsible for a larger proportion of cases than previously estimated.

The finding of large reductions in AGE hospitalization in children after the introduction of rotavirus vaccination has been found internationally [28] and in other US studies [6, 7]. As in our analysis, these previous US studies also found that declines in AGE hospitalizations increased over time in the years since the rotavirus vaccination program was introduced and were >50% in children under 5 years from 2012 [6, 7]. The reduction in hospitalization is also likely to have been affected by herd protection effects that may have reduced rotavirus-associated hospitalizations in unvaccinated children. These herd effects were not included in the economic analysis conducted before vaccine introduction in the United States [3].

Economic evaluations are usually aimed to help inform future vaccine recommendation decisions; consequently, there has been relatively less focus on assessing the value for money achieved after programs are implemented [29]. However, a study from Australia that assessed the cost-effectiveness of the rotavirus program after introduction also found that the program exceeded the expectation of preimplementation modelling predictions [19]. As in the current study, the Australian analysis estimated that a larger number of rotavirus-associated hospitalizations were prevented in children aged <5 years than were predicted before introduction of the vaccine. The similarities in the findings of these 2 studies from different countries suggest that predictions for other settings may also have underestimated the value of rotavirus vaccination programs. However, the value for money achieved in each setting will be driven by a number of important factors including the declines in health outcomes attributed to rotavirus vaccination and the price negotiated/paid for the vaccine/s in that setting.

Although our analysis has the benefit of being able to incorporate postimplementation data on the impact of the rotavirus program as well as vaccination coverage, it still has limitations. The assessment of the program impact relies primarily on routinely collected healthcare use data. Although this reduces the reliance on modelling to predict program impact, these data are subject to the caveats that come with observational data and can be influenced by other changes outside of the introduction of the vaccination program. These data also rely on diagnoses codes (ICD-9-CM), which, in the case of AGE, are not specific to rotavirus burden and may be influenced by changes in burden of other AGE pathogens. We do not assume that all AGE is due to rotavirus, only that the changes in AGE healthcare use since the introduction of rotavirus immunization program are attributable to the program.

This study provides evidence of the value for money offered by the rotavirus vaccination program in the United States. The greater than expected healthcare and productivity savings reflect the success of the rotavirus program in reducing the associated disease burden in children in the United States.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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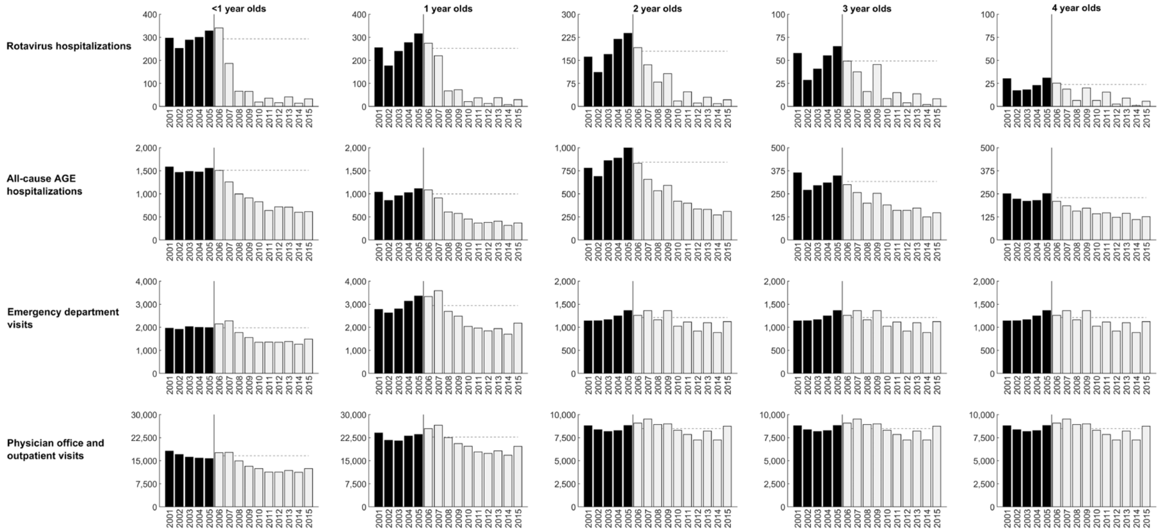

Figure 1.

Rates per 100 000 for rotavirus hospitalization and all-cause AGE hospitalizations, emergency department and combined outpatient and physician office visits in children under 5 years of age for each single year of age. Horizontal dashed lines are estimates of "no-program" rates using a simple mean of the prevaccine rates. The vertical line is the start of the vaccination program. Note that the y-axis varies for different age groups. Abbreviation: AGE, acute gastroenteritis.

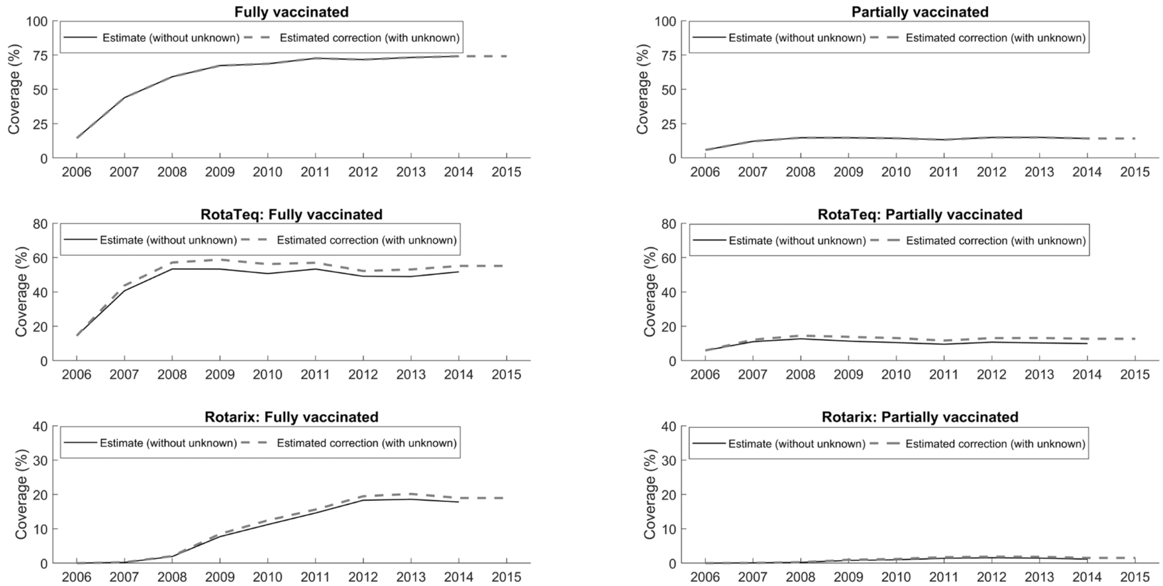

Figure 2.

Estimated vaccine coverage rates used in the model for each cohort for all, by brand, and if fully or partially vaccinated. Dashed lines are the estimated corrected rates used in the model after redistributing proportionally the unknown brands (unknown = where the brand of vaccine was not provided in the data used) and when the uptake in 2015 was assumed to be the same as applied for 2014. Note that all the estimated coverage rates were based on vaccination coverage for children aged 19 to 35 months of age from the National Immunization Survey-Child. The coverage from 2008 to 2016 was assigned to cohorts born in 2006 to 2014 with each year of the survey assumed to represent a single-year age cohort. Please see the Appendix for more detail on coverage estimates used in the model.

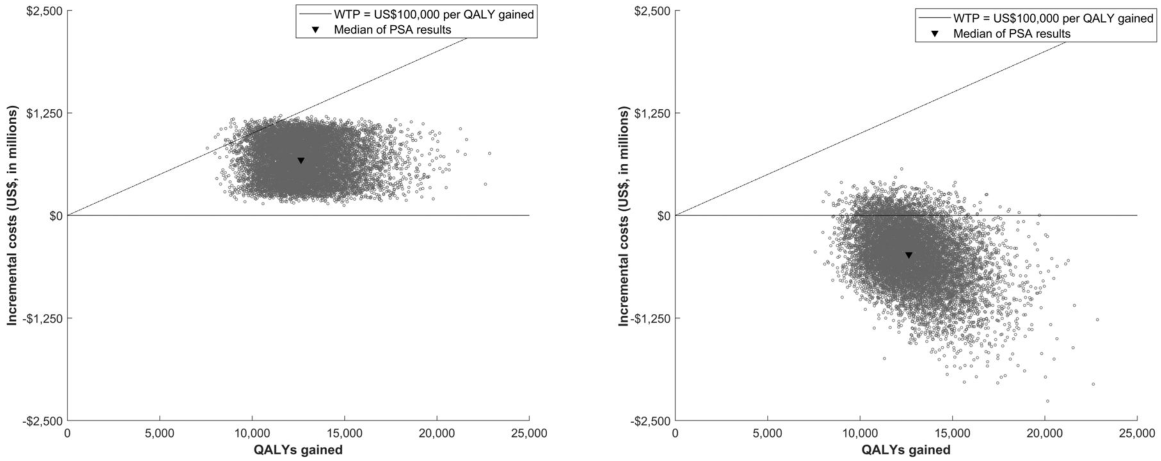

Figure 3.
Results from the probabilistic sensitivity analysis (PSA). Shown are cloud plots representing 10 000 simulations for the years 2011 to 2015 (left: healthcare payer perspective; right: societal perspective). Each dot is a simulation resulting from 1 Latin hypercube sample of the parameters. The filled triangle shows the location of the median. Reference line is used to show the total costs difference (horizontal axis) and total QALYs gained (vertical axis) at willingness-to-pay (WTP) ICER threshold of US$100 000/QALY gained. Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year.

Table 1.

Estimated Total Outcomes and Prevented Outcomes Between 2011 and 2015 (Since the Program Uptake Stabilized), Undiscounted

	Total Outcome (No Program)	Total Outcome (With Program)	Total prevented outcomes (%)	Annual average prevented (%)
Rotavirus deaths	153	17	136 (89)	27 (89)
Rotavirus hospitalizations only	158 000	18 000	140 000 (88)	28 000 (88)
All-cause AGE hospitalizations	932 000	343 000	589 000 (63)	118 000 (63)
All-cause AGE ED presentations	1 701 000	1 271 000	430 000 (25)	86000 (25)
All-cause AGE outpatient and physician office visits	12 880 000	10 582 000	2 298 000 (18)	460 000 (17)
Symptomatic infections not requiring medical care	N/A	N/A	2 242 000 (N/A)	448 000 (N/A)

Abbreviations: AGE, acute gastroenteritis; ED, emergency department; N/A, values could not be calculated in our model.

Table 2.

Base Case Estimated Total QALYs, Total Costs, and ICER Between 2011 and 2015 (Since the Program Uptake Stabilized), Discounted

	Total QALY Losses		Incremental QALYs Gained	Total Costs (Millions)		Incremental Costs (Millions)	ICER ($/QALY)
	No Program	With Program		No Program	With Program[a]		
Healthcare payer perspective	37 010	25 591	11 419	$5034	$5756	$722	$63 228
Societal perspective	37 010	25 591	11 419	$8162	$7900	−$262	Cost-saving

Abbreviations: ICER, incremental cost-effectiveness results; QALY, quality-adjusted life years.

[a]The total discounted program cost over this period was estimated to be $2.728 million.