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Cost-effectiveness of pneumococcal vaccination among patients with chronic heart failure

Aim	To analyze the cost-effectiveness of pneumococcal vaccination in 40- and 65-year-old patients with chronic heart failure (CHF).
Material and Methods	Analysis was performed by Markov modeling from the perspective of the healthcare system. The evaluation was based on Russian epidemiological data taking into account results of international studies. The analyzed schedule of vaccination included one dose of 13-valent pneumococcal conjugate vaccine (PCV13) followed by 23-valent polysaccharide vaccine (PPSV23) after one year and vaccination with only one dose of PCV13. The time horizon of the study was 5 years. Costs and life expectancy were discounted at 3.5% per year.
Results	The cost-effectiveness of vaccination for both 65-year-old and 40-year-old CHF patients is very high: the incremental cost of one additional QALY (Quality-Adjusted Life Year) for PCV13+PPSV23 vaccination is 113.24 thousand rubles, while vaccination with PCV13 entails a reduction in costs by 556.50 rubles per one vaccinated patient. For vaccination of 40-year-old CHF patients with PCV13+PPSV23, the incremental costs per 1 QALY will be 519.72 thousand rubles, while for vaccination with PCV13 it will be 99.33 thousand rubles.
Conclusion	Pneumococcal vaccination of CHF patients reduces the associated morbidity and mortality and is highly cost effective.

Keywords	Pneumonia; chronic heart failure; pneumococcal vaccines; cost effectiveness
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Introduction

Patients with chronic heart failure (CHF) face high risk of pneumococcal infection, especially when the disease is progressing [1–4]. Moreover, the frequency of rehospitalization in CHF patients within a year after suffering pneumonia is statistically significantly higher than in patients who have no history of pneumonia (odds ratio (OR) 1.9; 95% confidence interval (CI) 1.1–3.4; p=0.02) [3].

The risk of death also increases significantly in patients with CHF after experiencing pneumonia [5, 6]. According to the independent ORACLE-RF register, the one-year mortality of patients with decompensated HF and a history of pneumonia increases by 22% (OR 1.22; 95% CI 1.04–1.44; p<0.05) [7]. The EPOCH-D–CHF trial showed that the 30 day mortality of patients with decompensated HF increases more than 10-fold in the case of pneumonia compared to that in patients without confirmed pneumonia (OR 13.5; 95% CI 3.5–18.2; p<0.001) [3]. The findings of randomized trials evaluating the treatment efficacy in CHF patients PARADIGM-HF and PARAGON-HF showed that the presence of pneumonia increases total mortality 4-fold (OR 4.34; 95% CI 3.73–5.05 and OR 3.76; 95% CI 3.09–4.58, respectively) [8].

Vaccination is the main tool for the prevention of pneumococcal infection [9, 10]. Pneumococcal vaccination significantly reduces the risk of

cardiovascular death and rehospitalization in patients at very high risk including those with CHF (OR 0.78; 95% CI 0.73–0.83) [11, 12]. However, such vaccination is cost demanding and requires the assessment of its economic feasibility before expanding the National Vaccination Schedule.

Objective

Assess the clinical and economic effectiveness of pneumococcal vaccination in 40- and 65-year old patients with CHF.

Material and Methods

The analysis was performed using the Markov model, which is one of the most common methods used to assess cost effectiveness of medical interventions [13]. The assessment was carried out from the point of view of the from the health care system perspective.

Incidence of pneumococcal community-acquired pneumonia (CAP)

Due to organizational and methodological challenges in acquiring statistical information, which often significantly reduces reliability of data [14, 15], the baseline incidence of CAP in 65-year-old patients corresponded to the mean data of the sample-based Russian trials (1,295 per 100,000 people in this age group) [16, 17]. The results of the US epidemiological study were taken into consideration, that the incidence of pneumococcal CAP in 65-year old patients with CHF was 3.8 times higher than in the general population [18].

Given the percentage of pneumonia of pneumococcal origin equal to 69.7% [1], the baseline incidence of pneumococcal pneumonia in 65-year old patients with CHF was set to 3,430 cases per 100,000 people.

In accordance with the Russian epidemiological data, it was assumed that the morbidity was 1.45 times lower in 40-year old patients than in 65-year old patients [2]. It was also taken into consideration that the incidence of pneumococcal pneumonia is 5.1 times higher in 40-year old patients with CHF than in the general population [18]. Thus, the incidence of pneumococcal pneumonia was 3,175 cases per 100,000 people in 40-year old patients with CHF.

The sensitivity analysis also included variants with a 2-fold decrease in morbidity compared to the baseline variant and CAP incidence calculated based on the official rates in persons over working age in the Russian Federation for 2011–2019, which was 359.8 per 100,000 people [2].

CAP hospitalization rate

It was assumed based on the results of expert assessment that 70% of patients with CAP were to be hospitalized.

CAP mortality

The Russian epidemiological data showed that CAP mortality in patients over working age was 7.9% of the total number of cases in 2011–2019, which is comparable with foreign data [19, 20].

It was assumed that CAP mortality in 40-year old patients is 1.2 times lower than in 65-year old patients [2].

The sensitivity analysis also assessed a variant of a 2-fold decrease in mortality compared to the baseline variant.

Death caused by other causes

Mortality from other causes corresponded to the Rosstat data [21].

Vaccination regimens

According to the clinical guideline approved by the Ministry of Health of the Russian Federation, it was assumed that all patients are vaccinated with 13 valent pneumococcal conjugate vaccine (PCV13), and 23 valent pneumococcal polysaccharide vaccine (PPSV23) a year later [22]. The PCV13 vaccination variant was also evaluated in case of underfunding.

Coverage of pneumococcal serotypes

Serotype coverage in PCV13 and PPSV23 CAP was 45.6% and 58.8%, respectively [23].

Patient quality of life (QoL)

Since there are few Russian studies on QoL, foreign data were used in the calculation. The baseline QoL of the patients was set to 0.7542. CAP requiring and not requiring hospitalization was assumed to reduce life expectancy by 0.006 QALYs (Quality-Adjusted Life Years) and 0.004 QALYs, respectively [24].

Time horizon

Time horizon of the study was 5 years.

Vaccine efficacy against CAP induced by vaccine serotypes

The efficacy of PCV13 was assumed to be 48.4% [25]. The efficacy of PPSV23 was set to 20% and 23% in 65-year old and 40-year old patients, respectively [26].

Vaccination costs

Vaccination costs were calculated based of registered prices VAT included (PCV13–1518.63 RUB,

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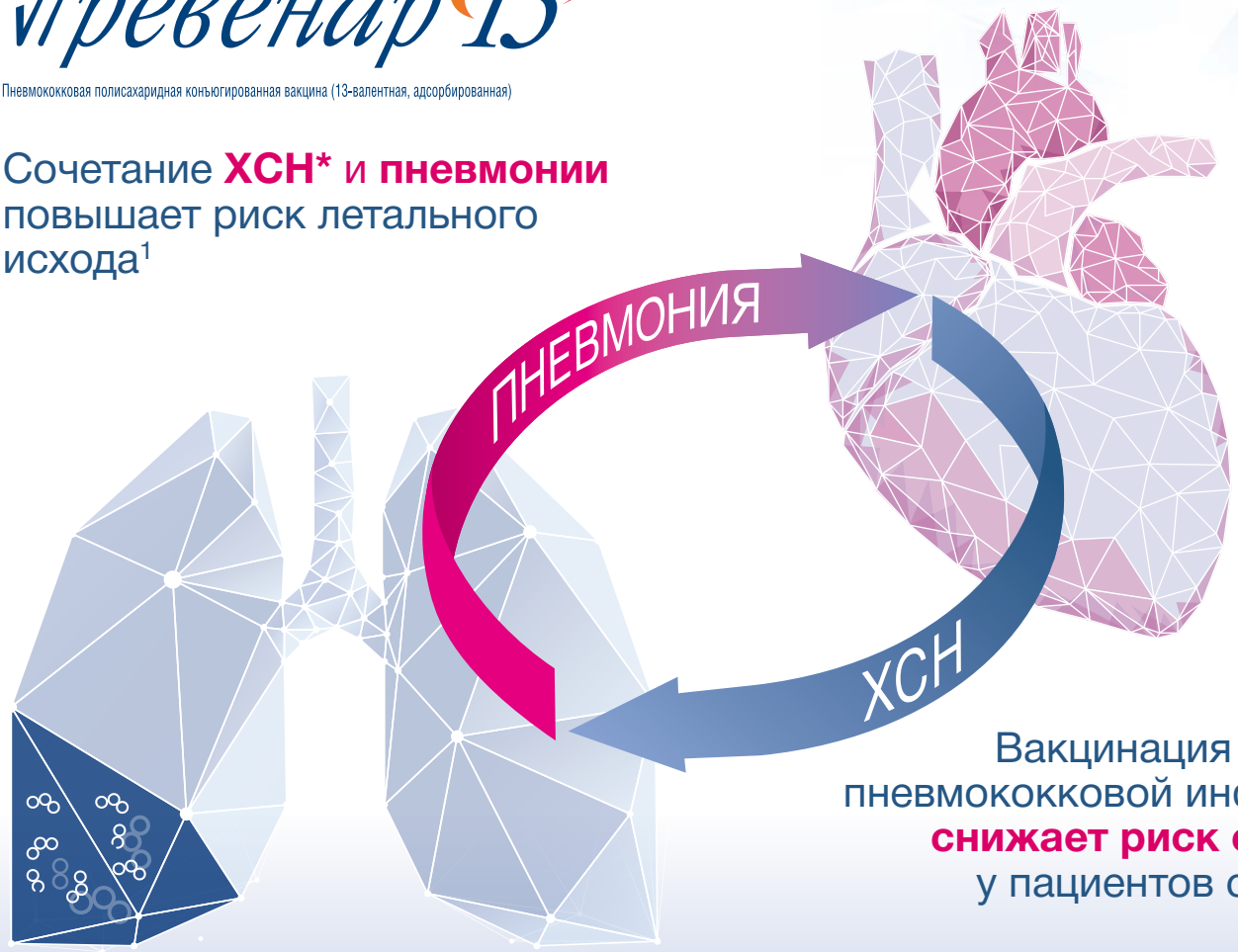
Превенар 13

Пневмококковая полисахаридная конъюгированная вакцина (13-валентная, адсорбированная)

Сочетание **ХСН*** и **пневмонии** повышает риск летального исхода[1]



Вакцинация против пневмококковой инфекции **снижает риск смерти** у пациентов с ХСН[2,3]

КРАТКАЯ ИНСТРУКЦИЯ по применению лекарственного препарата ПРЕВЕНАР® 13

(вакцина пневмококковая полисахаридная конъюгированная адсорбированная, тринадцативалентная)

ЛЕКАРСТВЕННАЯ ФОРМА: суспензия для внутримышечного введения

Вакцина Превенар® 13 представляет собой капсулярные полисахариды 13 серотипов пневмококка: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F и 23F, индивидуально конъюгированные с дифтерийным белком CRM_{197} и адсорбированные на алюминия фосфате.

ОПИСАНИЕ

Гомогенная суспензия белого цвета.

ПОКАЗАНИЯ ДЛЯ ПРИМЕНЕНИЯ

– профилактика пневмококковых инфекций, включая инвазивные (в том числе менингит, бактериемию, сепсис, тяжелые пневмонии) и неинвазивные (внебольничные пневмонии и средние отиты) формы заболеваний, вызываемых *Streptococcus pneumoniae* серотипов 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F и 23F, с 2 месяцев жизни и далее без ограничения по возрасту;
– в рамках национального календаря профилактических прививок;
– у лиц групп повышенного риска развития пневмококковой инфекции.

Вакцинация проводится в рамках национального календаря профилактических прививок согласно утвержденным срокам, а также лицам групп риска по развитию пневмококковой инфекции: с иммунодефицитными состояниями, в т.ч. ВИЧ-инфекцией, онкологическими заболеваниями, получающим иммуносупрессивную терапию; с анатомической/функциональной асплений; с установленным кохлеарным имплантом или планирующиеся на эту операцию; пациентам с подтеканием спинномозговой жидкости; с хроническими заболеваниями легких, сердечно-сосудистой системы, печени, почек и сахарным диабетом; больным бронхиальной астмой; недоношенным детям; лицам, находящимся в организованных коллективах (детские дома, интернаты, армейские коллективы); реконвалесцентам острого среднего отита, менингита, пневмонии; длительно и часто болеющим детям; пациентам, инфицированным микобактерией туберкулеза; всем лицам старше 50 лет; табакокурильщикам.

ПРОТИВОПОКАЗАНИЯ

– повышенная чувствительность на предшествующее введение Превенар® 13 или Превенар® (в том числе анафилактический шок, тяжелые генерализованные аллергические реакции);
– повышенная чувствительность к дифтерийному анатоксину и/или вспомогательным веществам;
– острые инфекционные или неинфекционные заболевания, обострения хронических заболеваний. Вакцинацию проводят после выздоровления или в период ремиссии.

СПОСОБ ПРИМЕНЕНИЯ И ДОЗЫ

Способ введения

Вакцину вводят в разовой дозе 0,5 мл внутримышечно. Детям первых лет жизни прививки проводят в верхне-наружную поверхность средней трети бедра, лицам старше 2-х лет – в дельтовидную мышцу плеча.

Перед применением шприц с вакциной Превенар® 13 необходимо хорошо встряхнуть до получения гомогенной суспензии. Не использовать, если при осмотре содержимого шприца выявляются инородные частицы или содержимое выглядит иначе, чем в разделе «Описание» настоящей инструкции.

Не вводить Превенар® 13 внутрисосудисто и внутримышечно в ягодичную область!

Если начата вакцинация Превенар® 13, рекомендуется завершить ее также вакциной Превенар® 13. При вынужденном увеличении интервала между инъекциями любого из приведенных выше курсов вакцинации введение дополнительных доз Превенар® 13 не требуется.

Схема вакцинации

Возраст начала вакцинации	Схема вакцинации	Интервалы и дозировка
2–6 мес.	3+1 или 2+1	Индивидуальная иммунизация: 3 дозы с интервалом не менее 4 нед. между введениями. Первую дозу можно вводить с 2 мес. Ревакцинация однократно в 11–15 мес. Массовая иммунизация детей: 2 дозы с интервалом не менее 8 нед. между введениями. Ревакцинация однократно в 11–15 мес.
7–11 мес.	2+1	2 дозы с интервалом не менее 4 нед. между введениями. Ревакцинация однократно на втором году жизни
12–23 мес.	1+1	2 дозы с интервалом не менее 8 нед. между введениями
2 года и старше	1	Однократно

Дети, ранее вакцинированные Превенар®

Вакцинация против пневмококковой инфекции, начатая 7-валентной вакциной Превенар®, может быть продолжена Превенар® 13 на любом этапе схемы иммунизации.

Лица в возрасте 18 лет и старше

Превенар® 13 вводится однократно. Необходимость ревакцинации Превенар® 13 не установлена. Решение об интервале между введением вакцин Превенар® 13 и ППВ23 следует принимать в соответствии с официальными методическими рекомендациями.

Особые группы пациентов

У пациентов после трансплантации гемопоэтических стволовых клеток рекомендуется серия иммунизации, состоящая из 4 доз препарата Превенар® 13 по 0,5 мл. Первая серия иммунизации состоит из введения трех доз препарата: первая доза вводится с третьего по шестой месяц после трансплантации. Интервал между введениями должен составлять 1 месяц. Ревакцинирующую дозу рекомендуется вводить через 6 месяцев после введения третьей дозы.

Недоношенным детям рекомендуется четырехкратная вакцинация. Первая серия иммунизации состоит из 3 доз. Первую дозу следует вводить в возрасте 2 месяцев независимо от массы тела ребенка, последующие дозы – с интервалом 1 месяц. Введение четвертой (бустерной) дозы рекомендуется в возрасте 12–15 месяцев.

Пожилые пациенты

Иммуногенность и безопасность вакцины Превенар® 13 подтверждены для пожилых пациентов.

Условия хранения и транспортирования

При температуре от 2 до 8 °С. Не замораживать.
Хранить в недоступном для детей месте.
Транспортировать при температуре от 2–25 °С. Не замораживать.
Допускается транспортирование при температуре выше 2–8 °С не более пяти дней.

Срок годности

3 года. Не использовать после истечения срока годности, указанного на упаковке.

Предприятие-производитель

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Претензии потребителей направлять по адресу:

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* ХСН – хроническая сердечная недостаточность.

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PPSV23–1521.99 RUB). The cost of pre-vaccination examination was not considered, as it was assumed that vaccination was performed during a scheduled visit. Variants with a 15% increase and a 15% decrease in vaccination costs were evaluated in the sensitivity analysis.

Costs of treatment of pneumococcal infections

The costs of CAP therapy corresponded to the rates of compulsory medical insurance in St. Petersburg in 2021 (87,361.4 RUB in CAP requiring hospitalization, 3,634.9 RUB in CAP not requiring hospitalization).

Discounting

The costs and life expectancy were discounted by 3.5% per year in the clinical and economic analysis.

Results and Discussion

The study analysis showed that vaccination can significantly reduce the number of CAP incidence and mortality (Table 1).

Table 1 shows that PCV13+PPSV23 vaccination of 100 thousand 65-year old individuals will prevent 3,986 cases of CAP and 315 deaths of CAP over 5 years. Vaccination of 100 thousand 40-year old individuals with PCV13+PPSV23 will prevent 2,461 cases of CAP and 162 deaths due to CAP.

Vaccination of 100 thousand 65-year old individuals with PCV13 will prevent 3,559 cases of CAP and 281 deaths due to CAP. Vaccination of 40-year old individuals with PCV13 will prevent 2,163 cases of CAP and 142 deaths due to CAP per 100 thousand people.

The results of evaluation of the clinical and economic effectiveness are presented in Table 2.

Vaccination of 65-year old patients with CHF is highly economically effective (additional costs per 1 QALY for PCV13+PPSV23 vaccination – 113.24 thousand RUB, and PCV13 vaccination results in a reduction by 556.50 RUB per vaccinated patient).

Vaccination of 40-year old CHF patients with PCV13 and PCV13+PPSV23 results in additional costs of 99.33 thousand RUB and 519.72 thousand RUB per QALY, respectively. (Table 2).

The calculation per QALY is a universal indicator suitable for any medical interventions since each affects either life expectancy or quality of life or both parameters. There is no officially approved threshold of willingness to pay per QALY in the Russian Federation. According to the WHO recommendations, if the additional costs of a medical intervention per QALY do not exceed GDP per capita, it can be considered as highly economically effective, and the additional costs per QALY not exceeding 3-fold GDP per capita are economically acceptable [27]. However, this value may be relatively overestimated. Thus, a systematic survey on the estimation of the willingness to pay per QALY conducted based on data from 17 countries showed that the mean willingness to pay is within 0.5–1.5 GDP per capita [28].

Anyway, given the fact that according to the 2021 data, Russian GDP per capita amounted to 900.1 thousand RUB, vaccination with PCV13 + PPSV23 as well as PCV13 in 40- and 65-year-old patients with CHF is a cost-effective intervention and can be recommended for common clinical use.

The reliability of the results was evaluated in the analysis of sensitivity to changes in model parameters (Table 3).

Table 3 shows that the cost effectiveness ratio is sensitive to changes in the model parameters such as CAP incidence and mortality and prices of the vaccines. Of all the variants analyzed PCV13 vaccination is a highly cost-effective intervention. PCV13 + PPSV23 vaccination is also at least economically acceptable in all cases.

Evaluation of the effect on the health system budget carried out without discounting showed that the cost of vaccination of 65-year old CHF patients with one dose of PCV13 will not exceed the reduction in the cost of CAP treatment in the vaccinated patient group over the period of 5 years (i.e., vaccination will not increase the budget burden), and in case of PCV13+PPSV23 vaccination, the reduction of the CAP treatment cost in this patient group will be 82% of the vaccination cost.

In the case of PCV13 and PCV13+PPSV23 vaccination against pneumococcal infection of 40-year old patients with CHF, the 5-year reduction in the cost of CAP therapy will be 83% and 47% of the vaccination cost, respectively.

Conclusion

Vaccination of patients with CHF against pneumococcal infection reduces the associated morbidity and mortality and is highly cost-effective.

Conflict of interest

The publication was prepared using materials of a study supported by OOO Pfizer Innovations. The authors did not receive financial support from OOO Pfizer Innovations related with the preparation of this article. The article reflects the position of the authors, which may differ from the position of OOO Pfizer Innovations.

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Table 1. Number of cases of pneumococcal community-acquired pneumonia (CAP) and related deaths in vaccinated and non-vaccinated patients per 100 thousand people (5-year time horizon)

Parameter	Non-vaccinated patients	PCV13	PCV13+ PPSV23	PCV13 vaccination versus no vaccination	PPCV13+PPSV23 vaccination versus no vaccination	PPCV13+ PPSV23 vaccination versus PCV13 vaccination
65-year old patients						
Community acquired pneumonia	16,198	12,639	12,213	-3559	-3986	-426
Deaths in CAP	1280	999	965	-281	-315	-34
40-year old patients						
Community acquired pneumonia	9,822	7659	7361	-2163	-2461	-298
Deaths in CAP	647	504	485	-142	-162	-20

PCV13, 13 valent pneumococcal conjugate vaccine; PPSV23, 23 valent pneumococcal polysaccharide vaccine.

Table 2. Clinical and economic effectiveness of vaccination against pneumococcal infection (baseline version)

Parameter	Non-vaccinated patients	PCV13	PCV13+ PPSV23	PCV13 vaccination versus no vaccination	PPCV13+ PPSV23 vaccination versus no vaccination	PPCV13+ PPSV23 vaccination versus PCV13 vaccination
65-year old patients						
Life expectancy, years	4.35973	4.36624	4.36702	0.00651	0.00729	0.00078
Life expectancy and quality of life, QALYs	3.27182	3.27703	3.27768	0.00521	0.00586	0.00065
Vaccination costs, RUB	0	1518.63	2987.35	1518.63	2987.35	1468.72
CAP treatment costs, RUB	9441.99	7366.86	7118.31	-2075.13	-2323.68	-248.55
Total direct medical costs, RUB	9441.99	8885.49	10105.66	-556.50	663.67	1220.17
Cost/efficacy, thousand RUB/ extra QALYs	–	–	–	Vaccination* dominates	113.24	1870.50
Cost/efficacy, thousand RUB/ extra year of life	–	–	–	Vaccination* dominates	91.03	1566.15
Cost/efficacy, thousand RUB/ prevented death of pneumococcal infection	–	–	–	Vaccination* dominates	210.77	3622.52
40-year old patients						
Life expectancy, years	4.59904	4.60230	4.60275	0.00326	0.00370	0.00045
Life expectancy and quality of life, QALYs	3.46438	3.46699	3.46737	0.00261	0.00299	0.00038
Vaccination costs, RUB	0	1518.63	2987.35	1518.63	2987.35	1468.72
CAP treatment costs, RUB	5716.65	4457.47	4284.14	-1259.18	-1432.50	-173.32
Total direct medical costs, RUB	5716.65	5976.10	7271.49	259.45	1554.84	1295.39
Cost/efficacy, thousand RUB/ extra QALYs	–	–	–	99.33	519.72	3412.47
Cost/efficacy, thousand RUB/ extra year of life	–	–	–	79.69	419.82	2892.08
Cost/efficacy, thousand RUB/prevented death of pneumococcal infection	–	–	–	182.17	959.62	6607.60

QALY, quality-adjusted life year; CAP, community acquired pneumonia; PCV13, 13 valent pneumococcal conjugate vaccine; 23VPS, 23 valent pneumococcal polysaccharide vaccine; * – dominant strategy – medical intervention that reduces costs and improves prognosis versus the comparison variant.

Table 3. Clinical and economic effectiveness of vaccination against pneumococcal infection (sensitivity analysis)

Variant	Cost/efficacy, thousand RUB/ QALY			Cost/efficacy, thousand RUB/ extra year of life			Cost/efficacy, thousand RUB/ prevented death of pneumococcal infection		
	PCV13 vaccination versus no vaccination	PPCV13+ PPSV23 vaccination versus no vaccination	PPCV13+ PPSV23 vaccination versus PCV13 vaccination	PCV13 vaccination versus no vaccination	PPCV13+ PPSV23 vaccination versus no vaccination	PPCV13+ PPSV23 vaccination versus PCV13 vaccination	PCV13 vaccination versus no vaccination	PPCV13+ PPSV23 vaccination versus no vaccination	PPCV13+ PPSV23 vaccination versus PCV13 vaccination
65-year old patients with CHF									
Baseline	Vaccination dominates*	113.24	1870.50	Vaccination dominates*	91.03	1566.15	Vaccination dominates*	210.77	3622.52
Two-fold reduction in CAP incidence	182.56	620.26	4115.60	146.08	498.80	3447.11	336.92	1150.33	7945.77
Morbidity corresponding to the official rates in individuals over working age in the Russian Federation in 2011–2019.	625.47	1411.28	7686.91	500.57	1135.09	6439.31	1152.43	2613.17	14820.29
Two-fold reduction in CAP mortality versus the baseline variant	Vaccination dominates*	221.70	3579.60	Vaccination dominates*	178.87	3127.03	Vaccination dominates*	412.50	7207.96
Vaccine prices are 15% lower than in the baseline variant	Vaccination dominates*	36.78	1532.77	Vaccination dominates*	29.57	1283.37	Vaccination dominates*	68.46	2968.45
Vaccine prices are 15% higher than in the baseline variant	Vaccination dominates*	189.69	2208.23	Vaccination dominates*	152.50	1848.92	Vaccination dominates*	353.08	4276.59
40-year old patients with CHF									
Baseline	99.33	519.72	3412.47	79.69	419.82	2892.08	182.17	959.62	6607.60
Two-fold reduction in CAP incidence	679.18	1516.24	7276.48	545.01	1225.00	6167.90	1243.52	2794.91	14069.14
Calculation of morbidity based on the official rates in individuals over working age in the Russian Federation in 2011–2019.	851.75	1829.78	8561.66	681.47	1473.89	7234.15	1568.107	3391.44	16642.33
Two-fold reduction in CAP mortality versus the baseline variant	196.73	1031.71	6485.77	157.55	837.53	5780.35	359.47	1910.87	13185.11
Vaccine prices are 15% lower than in the baseline variant	12.12	369.94	2832.11	9.72	298.83	2400.23	22.23	683.06	5483.85
Vaccine prices are 15% higher than in the baseline variant	186.53	669.50	3992.83	149.66	540.81	3383.94	342.11	1236.18	7731.36

QALY, quality-adjusted life year; PCV13, 13 valent pneumococcal conjugate vaccine; 23VPS, 23 valent pneumococcal polysaccharide vaccine; CAP, community acquired pneumonia; * – dominant strategy – medical intervention that reduces costs and improves prognosis versus the comparison variant.

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