

Health Economics of Vaccines; conventional approaches and broader impacts illustrated with respiratory infection

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CURRENT MEMBER JCVI (UK)

PROF POSTMA RECEIVED GRANTS AND HONORARIA FROM PHARMACEUTICAL COMPANIES DEVELOPING, PRODUCING AND MARKETING VACCINES, BOTH WITHIN AND OUTSIDE EU-PROJECTS (E.G., VITAL AND RESCUE)

Respiratory syncytial virus (RSV) immunisation programme: JCVI advice, 7 June 2023

Published 22 June 2023

JCVI recognises that there is a significant burden of [respiratory syncytial virus \(RSV\)](#) illness in the UK population and unmet public health need which has a considerable impact on NHS services during the winter months. JCVI is issuing a short statement of its advice on an RSV immunisation programme which has been shared with the Department of Health and Social Care (DHSC) to consider developing policy on RSV interventions and to allow sufficient lead in time for the necessary planning for a potential RSV immunisation programme.

JCVI has been monitoring products in development for several years and since January has been actively reviewing the latest evidence on immunisation products in late stages of development or newly licensed which could protect both neonates (newborns) and infants, and older adults against RSV infection and disease. A series of meetings of the JCVI RSV subcommittee have taken place in 2023. JCVI has reviewed evidence from manufacturers on the efficacy, safety and duration of protection of these immunisation products alongside clinical and epidemiological data on the burden of RSV in infants and older adults, and with consideration of programme delivery including ability to deliver high uptake in different population groups and clinical settings. Modelling of the impact and cost effectiveness of potential immunisation strategies by the London School of Hygiene and Tropical Medicine has been used to inform JCVI's advice along with second opinion modelling by other academic groups. Cost effectiveness is a key factor in JCVI's considerations which is used to ensure that the finite resources of the health service are used to maximise the health of the population.

Programme to protect neonates and infants

Sanofi in partnership with AstraZeneca have developed a new long acting monoclonal Beyfortus® (nirsevimab) for passive immunisation against RSV infection and disease. Nirsevimab was licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) on 9 November 2022.

Pfizer have developed a bivalent RSV prefusion F maternal vaccine candidate, RSVpreF which has undergone clinical trials and has a potential licensing timeline in 2023.

Advice

The committee notes a seasonal, seasonal-with-catch-up or year-round passive immunisation (monoclonal antibody) programme for newborns could be cost effective over a range of potential prices that combine the cost of the product and its administration.

The committee notes a seasonal or year-round maternal active immunisation programme could be cost effective over a range of potential prices that combine the cost of the product and its administration.

JCVI advises that both products are suitable for a universal programme to protect neonates and infants from RSV. JCVI does not have a preference for either product and whether a maternal vaccination or a passive immunisation programme should be the programme chosen to protect neonates and infants. Therefore, subject to licensure of the maternal vaccine, both options should be considered for a universal programme.

JCVI advises a preference for a year-round offer for a passive immunisation or maternal immunisation programme to ensure high uptake and for reasons of operational effectiveness because this would be less complex and resource intensive to deliver, compared with running seasonal campaigns.

Programme for older adults

There are currently 3 RSV vaccine products in development from manufacturers (GSK adjuvanted PreF, Pfizer PreF and Moderna mRNA) with potential licensure timelines for 2023 or early 2024. The GSK product was very recently licensed by the European Medicines Agency. A fourth product, a Modified Vaccinia virus Ankara (MVA) vaccine from Bavarian Nordic, is currently in phase 3 trials.

Advice

The committee notes an RSV vaccine programme for adults aged 75 years and above could be cost effective at a potential price that combines the cost of the product and its administration, noting that this would be influenced by multi-year protection from a single dose.

JCVI advises a programme for older adults aged 75 years old and above. JCVI currently favours a one-off campaign as the strategy for this programme with the initial offer covering several age cohorts and then a routine programme for those turning 75 years old, with its delivery and implementation to be determined through further consultation between NHS England, DHSC, UKHSA and the devolved administrations.

JCVI currently does not have a preference among the products it has reviewed as efficacy is broadly comparable and there are no head-to-head studies to allow direct comparison, and so subject to licensure, they can be considered equally suitable for an older adult RSV immunisation programme at this time.

Conclusion

In summary, JCVI advises that a RSV immunisation programme, that is cost effective, should be developed for both infants and older adults.

RSV vaccine for older adults approved by UK medicines regulator

Arexvy could help NHS deal with virus that causes about 8,000 deaths among older people in UK each year



📷 The vaccine has already been approved for use in the US and Europe. Photograph: Thomas Peter/Reuters

The UK's medicines regulator has approved the first vaccine against respiratory syncytial virus (RSV) in older adults.

The virus typically causes cold-like symptoms, but is a **leading cause of pneumonia** in infants and elderly people, with infections in older adults accounting for about 8,000 deaths, 14,000 hospitalisations and 175,000 GP appointments in the UK each year - **more than influenza** during a typical winter season.

The Medicines and Healthcare products Regulatory Agency (MHRA) has authorised the vaccine, Arexvy, for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults 60 years and older - the first time an RSV vaccine for older adults has been authorised for use in the UK.

A study of 24,966 older adults published in the **New England Journal of Medicine** in February suggested vaccine efficacy against LRTD was 82.6%, while efficacy against serious disease was 94.1%.

The vaccine was generally well tolerated, with mild to moderate injection site pain, fatigue, muscle and joint aches or pain and headache the most commonly reported side events. The rate of serious adverse effects was similar between those receiving the vaccine or a placebo jab.

The vaccine, produced by **GlaxoSmithKline**, has already been approved for use in the US and Europe. Further adult RSV vaccines from Moderna and Pfizer are expected to be considered in the coming months.

On 22 June, the Joint Committee on Vaccination and Immunisation (JCVI), which advises UK governments on matters of immunisation, issued a **short statement** to the Department of Health and Social Care advising that a cost-effective RSV immunisation programme should be developed for infants and older adults.

The JCVI cited modelling by the London School of Hygiene & Tropical Medicine and other academic groups suggesting that a vaccination programme for older adults could be cost-effective.

It currently favours a “one-off vaccination campaign targeting several age cohorts and then a routine programme for those turning 75 years old”, the statement said.

A final statement to inform a policy decision about potential RSV immunisation programmes is expected later this summer.

Burden of paediatric respiratory syncytial virus disease and potential effect of different immunisation strategies: a modelling and cost-effectiveness analysis for England



Deborah Cromer, Albert Jan van Hoek, Anthony T Newall, Andrew J Pollard, Mark Jit



Summary

Background Vaccines and prophylactic antibodies against respiratory syncytial virus (RSV) are in development and likely to be available in the next 5–10 years. The most efficient way to use these products when they become available is an important consideration for public health decision makers.

Methods We performed a multivariate regression analysis to estimate the burden of RSV in children younger than 5 years in England (UK), a representative high-income temperate country, and used these results to assess the potential effect of different RSV immunisation strategies (targeting vaccination for infants, or pregnant women, or prophylactic antibodies for neonates). We did a cost-effectiveness analysis for these strategies, implemented either separately or concurrently, and assessed the effect of restricting vaccination to certain months of the year.

Findings We estimated that RSV is responsible for 12 primary care consultations (95% CI 11·9–12·1) and 0·9 admissions to hospital annually per 100 children younger than 5 years (95% CI 0·89–0·90), with the major burden occurring in infants younger than 6 months. The most cost-effective strategy was to selectively immunise all children born before the start of the RSV season (maximum price of £220 [95% uncertainty interval (UI) 208–232] per vaccine, for an incremental cost-effectiveness ratio of £20 000 per quality-adjusted life-year). The maximum price per fully protected person that should be paid for the infant, newborn, and maternal strategies without seasonal restrictions was £192 (95% UI 168–219), £81 (76–86), and £54 (51–57), respectively.

Interpretation Nearly double the number of primary care consultations, and nearly five times the number of admissions to hospital occurred with RSV compared with influenza. RSV vaccine and antibody strategies are likely to be cost-effective if they can be priced below around £200 per fully protected person. A seasonal vaccination strategy is likely to provide the most direct benefits. Herd effects might render a year-round infant vaccination strategy more appealing, although it is currently unclear whether such a programme would induce herd effects.

Lancet Public Health 2017;
2: e367–74

See [Comment](#) page e344

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Exploratory Analysis of the Economically Justifiable Price of a Hypothetical RSV Vaccine for Older Adults in the Netherlands and the United Kingdom

F. Zeevat,¹ J. Luttjeboer,² J. H. J. Paulissen,³ J. van der Schans,¹ P. Beutels,⁴ C. Boersma,¹ and M. J. Postma,¹; the RESCEU Investigators^a

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Table 2 Base case results of the annual estimated number of RSV cases, hospitalizations, and deaths, quality-adjusted life years (QALYs) and life years (LY) lost because of RSV related death, and total discounted costs of the RSV vaccine compared to no vaccination in the United Kingdom.

	Target: RSV F Vaccine	Comparator: No Vaccine	Incremental
Expected health outcomes, population total			
Number of RSV vaccinations	2,283,577		2,283,577
Number of RSV infections	603,888	842,818	-238,930
Number of RSV-related events			
Hospitalizations	11,530	17,807	-6,277
GP visits	166,095	231,330	-65,235
Deaths	5,893	10,212	-4,320
QALYs lost			
Due to non-fatal RSV infections	1,871	2,635	-764
Due to death	41,498	71,921	-30,422
Overall	43,369	74,556	-31,187
LYs lost	68,177	118,157	-49,980

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Table 2. Cost-effectiveness/Pricing

		in the Netherlands and the United Kingdom by Willingness-to-Pay Threshold and RSV Incidence						
		EJP by RSV Incidence, € or £						
Country and WTP Threshold		6%	7%	8%	9%	10%	3.32% ^a	7.13% ^a
EJP for the Netherlands, €								
WTP threshold: €20 000/QALY								
Low VE		30.36	37.43	44.51	51.59	58.66	11.36	...
Base case		39.44	48.03	56.62	65.21	73.80	16.38	...
High VE		48.52	58.62	68.72	78.82	88.93	21.40	...
WTP threshold: €50 000 per QALY								
Low VE		80.97	96.49	112.00	127.51	143.02	39.34	...
Base case		100.33	119.06	137.80	156.54	175.28	50.03	...
High VE		119.68	141.64	163.60	185.57	207.53	60.73	...
EJP for the United Kingdom, £								
WTP threshold: £20 000/QALY								
Low VE		46.90	56.61	66.31	76.02	85.73	...	57.90
Base Case		59.01	70.73	82.45	94.18	105.90	...	72.29
High VE		71.11	84.85	98.60	112.34	126.08	...	86.69
WTP threshold: £30 000/QALY								
Low VE		73.08	87.15	101.22	115.30	129.37	...	89.03
Base case		90.50	107.47	124.44	141.42	158.39	...	109.74
High VE		107.91	127.79	147.66	167.54	187.41	...	130.44



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Capturing the value of vaccination within health technology assessment and health economics: Country analysis and priority value concepts



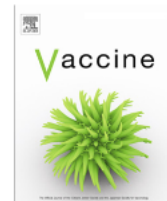
Maarten Postma^{a,b,c,d}, Eliana Biundo^{e,*}, Annie Chicoye^f, Nancy Devlin^g, T. Mark Doherty^e, Antonio J Garcia-Ruiz^h, Patrycja Jarosⁱ, Shazia Sheikh^e, Mondher Toumi^j, Jürgen Wasem^k, Ekkehard Beck^e, David Salisbury^l, Terry Nolan^g

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Capturing the value of vaccination within health technology assessment and health economics: Literature review and novel conceptual framework



Ekkehard Beck^{a,*}, Eliana Biundo^a, Nancy Devlin^b, T. Mark Doherty^a, Antonio J. Garcia-Ruiz^c, Maarten Postma^{d,e,f,g}, Shazia Sheikh^a, Beata Smela^h, Mondher Toumiⁱ, Jürgen Wasem^j, Terry Nolan^b, David Salisbury^k



Fig. 3. Inclusion of VoV concepts in HTA/CEA across countries. a: e.g., herd immunity; b: e.g., disease eradication; c: e.g., decrease in AMR; ACIP: Advisory Committee on Immunization Practices; AMR: antimicrobial resistance; CEA: cost-effectiveness analysis; HTA: health technology assessment; VoV: value of vaccination.

CONSIDERATIONS & EXAMPLES



Vaccines are specific and warrant a specific approach that acknowledges their broader impacts



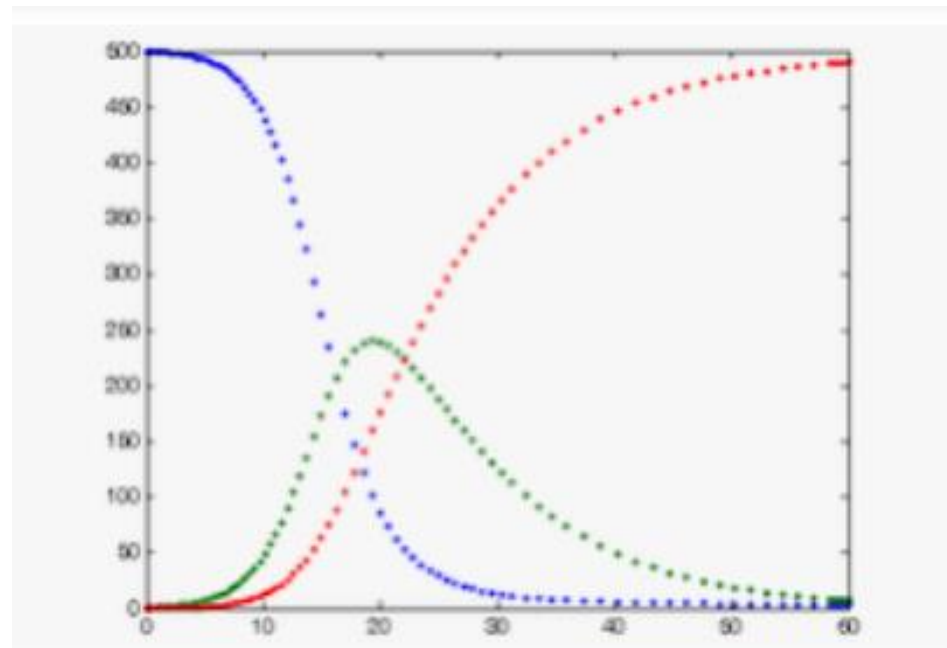
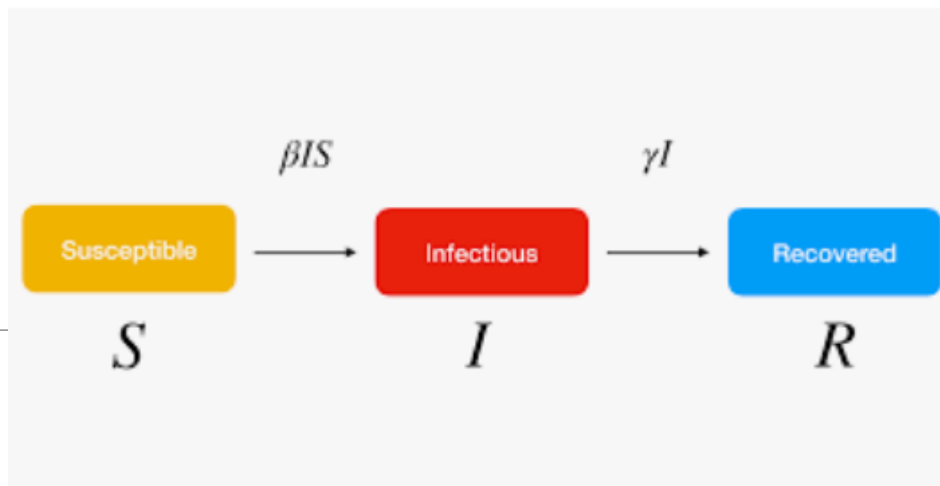
Various broader aspects are increasingly acknowledged

- Not specific: parents/partners QoL, productivity, strengthening health system
- Some specific: herd immunity, AMR, piece of mind



Examples

- Vaccine effectiveness in the context of dynamic models
- Macro-economic impact
- Peace of mind
- Carer's QoL
- Hospital capacity
- AMR



CORRESPONDENCE

Effect of Vaccination on Household Transmission of SARS-CoV-2 in England

127 Citing Articles

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N Engl J Med 2021; 385:759-760

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TO THE EDITOR:

Table 1. Numbers of Household Contacts and Secondary Cases of Covid-19, According to Vaccination Status of Index Patient, and Adjusted Odds Ratios.*

Vaccination Status of Index Patient	Household Contacts <i>no.</i>	Secondary Cases <i>no. (%)</i>	Adjusted Odds Ratio (95% CI)
Not vaccinated before testing positive	960,765	96,898 (10.1)	Reference
Vaccinated with ChAdOx1 nCoV-19 vaccine ≥21 days before testing positive	3,424	196 (5.7)	0.52 (0.43–0.62)
Vaccinated with BNT162b2 vaccine ≥21 days before testing positive	5,939	371 (6.2)	0.54 (0.47–0.62)

* Odds ratios were adjusted for the age and sex of the index patient and their household contact, geographic region, calendar week of the index case, and an index of multiple deprivation and household type and size. CI denotes confidence interval, and Covid-19 coronavirus disease 2019.

Article

COVID-19 vaccination scenarios: A cost-effectiveness analysis for Turkey

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Table 3. Incremental health outcomes, costs and resulting ICERs for the two vaccination scenarios against the baseline. Health perspective includes the direct health care costs and vaccination costs, and societal perspective also includes the indirect costs of sickness leave and premature death (all costs are in USD and a discount rate of 3% was used for the QALYs).




Scenario	Incremental health outcomes		Incremental direct costs	Incremental indirect cost savings	Total incremental cost savings	ICERs	
	Lives saved	QALYs gained				Health perspective	Societal perspective
Equal effectiveness on transmission and disease (90%)	207,421	1,506,501	770,305,902	6,658,353,668	5,888,047,767	511	Cost saving
Limited effectiveness on transmission (90% on disease and 45% on transmission)	122,550	892,536	932,279,143	3,992,331,439	3,060,052,296	1,045	Cost saving



Article

Estimates of the Global Burden of COVID-19 and the Value of Broad and Equitable Access to COVID-19 Vaccines

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Academic Editor: Zixin Wang

Abstract: The objectives of this research were to produce a macro-level overview of the global COVID-19 burden and estimate the value of access to COVID-19 vaccines. A targeted literature review collated evidence of the burden. Linear modelling and data analysis estimated the health and economic effects of COVID-19 vaccines delivered in 2021, and whether additional value could have been achieved with broader and more equitable access. By 1 December 2020, there had been an estimated 17 million excess deaths due to COVID-19. Low-income countries allocated more than 30% of their healthcare budgets to COVID-19, compared to 8% in high-income countries. All country income groups experienced gross domestic product (GDP) growth lower than predicted in 2020. If all 92 countries eligible for COVAX Advance Market Committee (AMC), access had reached 40% vaccination coverage in 2021, 120% more excess deaths would have been averted, equivalent to USD 5 billion (10⁹) in savings to healthcare systems. Every USD spent by advanced economies on vaccinations for less advanced economies averted USD 28 of economic losses in advanced economies and USD 29 in less advanced economies. The cost to high-income countries when not all countries are vaccinated far outweighs the cost of manufacturing and distributing vaccines globally.

3.1.4. Impact on Macroeconomic Performance

Macroeconomic effects can be produced directly by reducing the productivity of workers infected with COVID-19, and indirectly through lockdowns and other pandemic-related restrictions. However, it is not possible using available data to disaggregate overall effects on GDP into those attributable to direct and indirect causes. There are credible proxy measures of COVID-19's overall impact on macroeconomic performance available in every country, which exist in the form of deviation from the pre-COVID-19 projections of GDP (see Figure 1). Table 4 summarises these results by country income group and shows that the difference between project and estimated GDP growth in 2020 were largest in upper MICs, followed by HICs, lower MICs, and LICs.

Table 4. Projected and estimated GDP growth in 2020 (IMF 2021b).

Indicator	HICs	Upper MICs	Lower MICs	LICs
Pre-COVID-19 projection	2.062457627	4.552076923	4.072865385	4.71096
Revised estimate	−6.736576271	−7.321538462	−2.835826923	−0.80292
Difference	8.799033898	11.87361538	6.908692308	5.51388

One channel through which COVID-19 has affected macroeconomic performance is reduction in working hours and employment. Across the world, people's ability to work during the pandemic has been hindered by government restrictions on workplaces, supply disruption, and macroeconomic contraction in general. Table 5 shows the percentage change in working hours from 2020 to 2019 by country income group. The decline was largest in lower MICs, followed by HICs, upper MICs, and LICs.

Table 5. Percentage change in working hours in 2020 compared to 2020.

Indicator	HICs	Upper MICs	Lower MICs	LICs
Percentage change	−8.3%	−7.3%	−11.3%	−6.7%

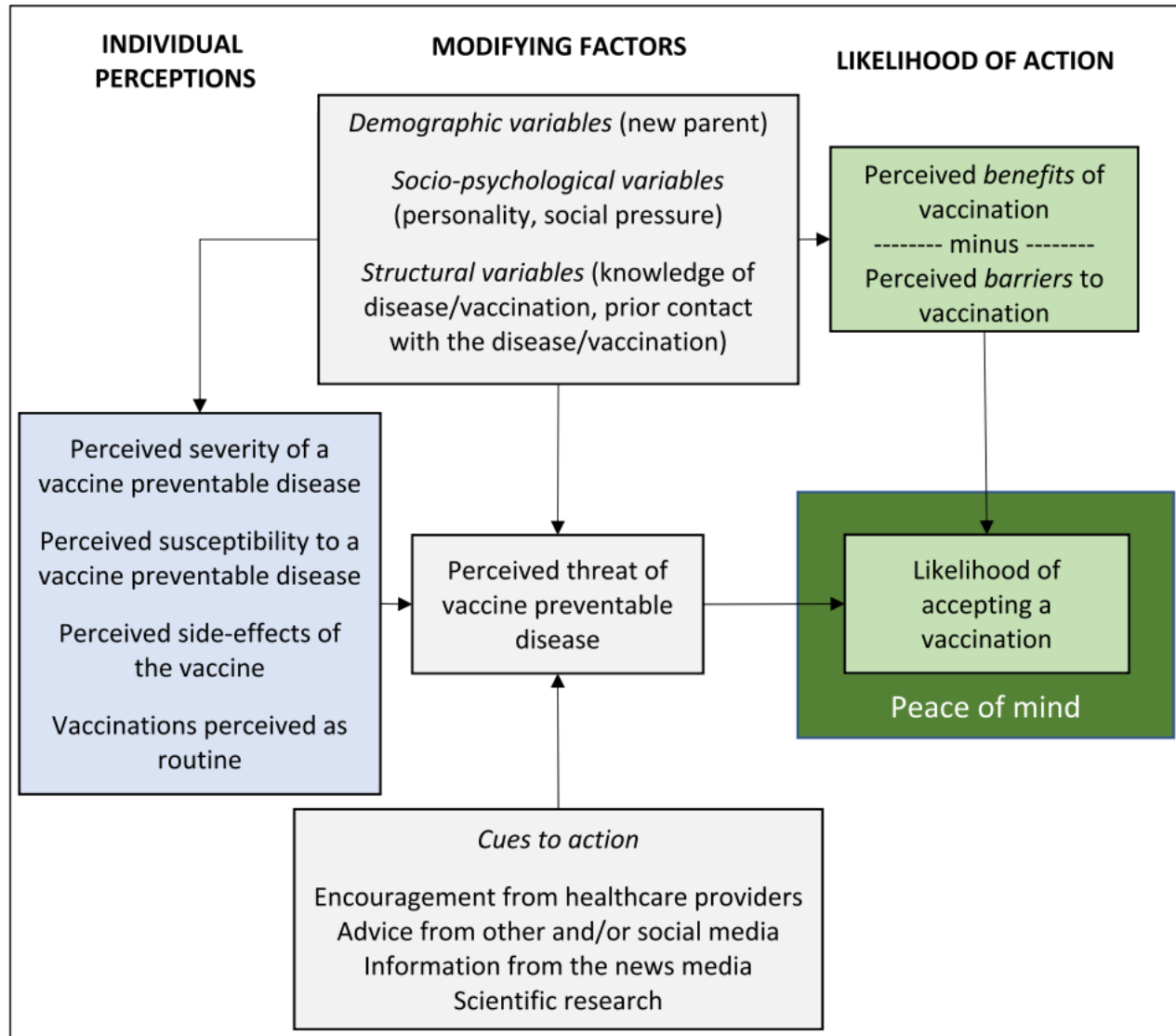


Fig. 1. Factors related to vaccine associated PoM and the likelihood of accepting a vaccination.

Impact of Respiratory Syncytial Virus on Child, Caregiver, and Family Quality of Life in the United States: Systematic Literature Review and Analysis

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Table 4. Data Synthesis and Estimation of QALY Loss Due to an RSV Episode in Children, Caregivers, and Family Unit^a

Measure ^b	Child		Caregiver		Family	
	RSV Illness	Healthy Controls	RSV Illness	Healthy Controls	RSV Illness	Healthy Controls
Average utility ^c	83.6	94.2	88.7	90.6	90.6	94.7
Lost value (range, 0–100)	16.5	5.8	11.3	9.4	9.4	5.3
QALYs lost per day ^d	0.1645	0.0583	0.1132	0.0944	0.0939	0.0530
Study period as fraction of a year	0.1643	0.1643	0.1643	0.1643	0.1643	0.1643
QALYs lost in RSV episode or control group in premature infants	0.0270	0.0101	0.0186	0.0155	0.0154	0.0087
QALYs lost in a year, less the effect of prematurity	0.0169		0.0031		0.0067	

Abbreviations: QALY, quality-adjusted life-year; RSV, respiratory syncytial virus.

^aBased on Leidy et al [21] alone because this was the only study to utilize the same scale (global rating of health) for the child and others.

^bAll groups were infants and children with a history of prematurity, gestational age at birth of ≤ 35 weeks.

^cOn the global rating of health scale with a maximum health value of 100.

^dTreating value as a utility.

Reducing Hospital Capacity Needs for Seasonal Respiratory Infections: The Case of Switching to High-Dose Influenza Vaccine for Dutch Older Adults

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VALUE IN HEALTH

APRIL 2023

Table 1. Estimated remaining hospitalizations after vaccination of senior Dutch citizens with QIV-SD or QIV-HD, showing hospitalizations additionally averted by QIV-HD (including the uncertainty interval), during the 2019/2020 influenza season, taking the estimated average level of influenza-related respiratory hospitalizations with the use of QIV-SD during the 2010/2011 through 2017/2018 seasons² and 2019/2020 vaccine coverage rates as the baseline.^{19,20}






Age category in years	Complication	QIV-HD	QIV-SD	Difference
60-64	Respiratory	30	34	5
	Cardiovascular	56	66	10
	All	86	101	15
65+	Respiratory	405	471	66
	Cardiovascular	765	905	140
	All	1170	1375	205
Total (60+)	All	1256	1476	220 (197-244)

HD indicates high dose; QIV, quadrivalent influenza vaccine; SD, standard dose.

Conclusions: We demonstrate that a relevant improvement in influenza vaccination among older adults in The Netherlands can be achieved by switching from the current QIV-SD to QIV-HD. Not only comes a switch from QIV-SD to QIV-HD with a significant reduction in pressure on hospital capacity but also with notable cost savings.

Funding/Support: This study was supported by EU IMI project on Vaccines and Infectious Diseases in the Ageing Population project (VITAL, awarded to Drs Zeevat, Boersma, and Postma).

Global and regional burden of attributable and associated bacterial antimicrobial resistance avertable by vaccination: modelling study

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Conclusion Increased coverage of existing vaccines and development of new vaccines are effective means to reduce AMR, and this evidence should inform the full value of vaccine assessments.

lives.¹ However, antimicrobial resistance (AMR) is a growing global public health threat in the 21st century.² Resistance occurs

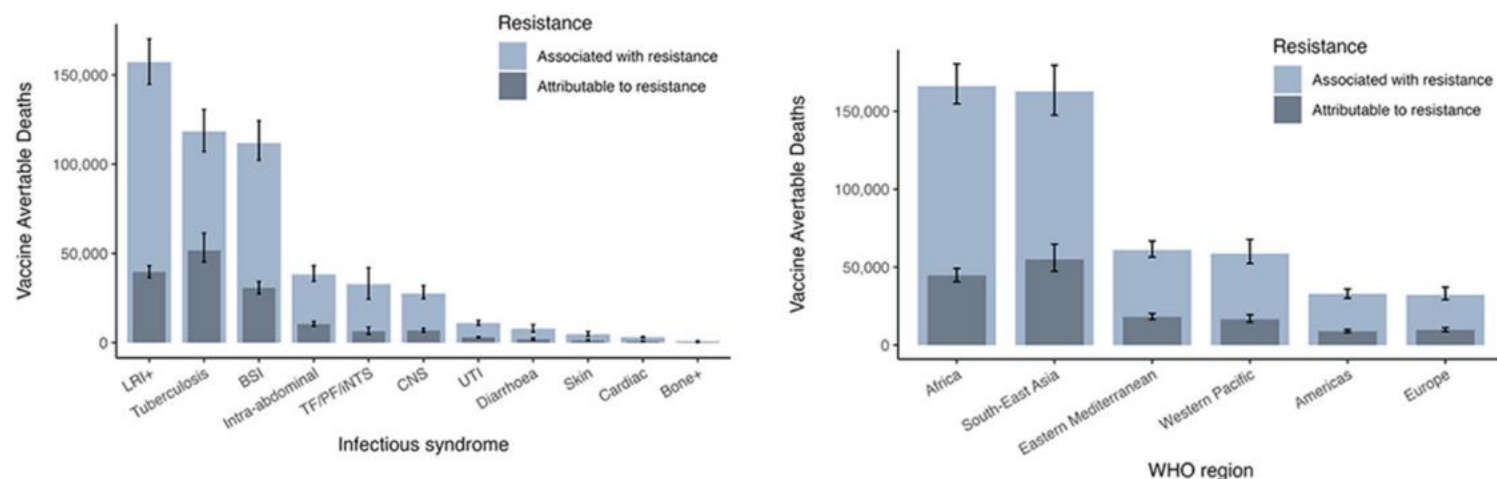


Figure 2 Vaccine impact on AMR burden by (pathogen-specific) vaccine profile, infectious syndrome, and region. The estimates (median and 95% uncertainty intervals) of the vaccine avertable deaths attributable to and associated with bacterial antimicrobial resistance in 2019 were aggregated by (pathogen-specific) vaccine profile, infectious syndrome, and WHO region in the baseline scenario. (Bone+ = infections of bones, joints, and related organs; BSI = bloodstream infections; cardiac = endocarditis and other cardiac infections; CNS = meningitis and other bacterial CNS infections; intra-abdominal = peritoneal and intra-abdominal infections; LRI+ = lower respiratory infections and all related infections in the thorax; skin = bacterial infections of the skin and subcutaneous systems; TF–PF–iNTS = typhoid fever, paratyphoid fever, and invasive non-typhoidal *Salmonella* spp; UTI = urinary tract infections and pyelonephritis).

Comparative-Effectiveness Research/HTA

Guiding Principles for Evaluating Vaccines in Joint Health Technology Assessment in the European Union: Preparing for the European Union's Regulation on Health Technology Assessment for Vaccines

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The urgency of improving the appraisal of vaccines was heightened by the adoption of the EU's Regulation⁸ on HTA in January 2022. The goal of the Regulation is to improve the availability of innovative health technologies, ensure the efficient use of resources, strengthen the quality of HTAs, and improve business predictability. The Regulation provides guidance on the use of common HTA tools, methodologies, and procedures to evaluate pharmaceuticals, medical devices, and diagnostics in clinical HTAs.⁹ The Regulation will become applicable for oncology products and advanced therapy medicinal products in 2025 and for all new centrally approved medicinal products, including vaccines, in 2030⁹ by requiring them to undergo a joint clinical assessment (JCA) at the EU level.^{9,10} Although their content is not

Conclusions

Vaccine-specific factors are rarely considered by HTABs across EU member states, contrary to NITAGs, raising concerns about the applicability of the Regulation on HTA for vaccines when it becomes effective in 2025. Failure to consider vaccine-specific factors could underestimate the broad value of vaccines and cannot provide a strong evidence base to support decision making. This, in turn, may limit the eligible population covered under governmental programs, prevent equitable population access to vaccines, and diminish the benefits for public health, the economy, and society. All experts involved in this study agreed on the need to include vaccine-specific factors in JCA.

CONCLUSIONS



Efficacious and safe RSV vaccines are undergoing full HTA-assessments and decisions for both infants and elderly



RSV vaccines further close the gaps in protection against LRTIs

- Cost-effective
- At potentially realist prices
- With a broad range of values
- ... and broad societal impact



Within an existing methodology, develop and apply *transparent* vaccine-specific approaches including broader impacts

- Consistently
- Comparatively
- Innovatively
- Within JCA-context