

RECENT ADVANCES IN MENINGOCOCCAL B DISEASE PREVENTION: REAL WORLD EVIDENCE FROM 4CMENB VACCINATION

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BACKGROUND

The 4-component meningococcal serogroup B vaccine (4CMenB) is indicated for active immunization against invasive meningococcal disease caused by serogroup B. It is licensed worldwide based on immunogenicity and safety data. We comprehensively reviewed all available real-world evidence from effectiveness and impact gathered from use of 4CMenB since licensure.

OBJECTIVE

Available evidence on vaccine effectiveness (VE), impact, and safety of 4CMenB in routine use were reviewed.

VACCINE EFFECTIVENESS

Meningitis B disease risk estimation in vaccinated versus unvaccinated in individuals

VACCINE IMPACT

Meningitis B disease **reduction** at the population level in vaccine-eligible individuals regardless of vaccination status

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RESULTS

Significant VE of 4CMenB in preventing MenB invasive disease was demonstrated in fully vaccinated infants, young children, and adolescents

Country	Age group	Coverage	Vaccine effectiveness (95% CI)	Study design	
	INFANTS	88%		59 (-31, 87) SCREENING METHOD	VE of ≥3 doses of 4CMenB administered
	INFANTS	-		80 (71,87)* POISSON REGRESSIO	\mathbf{N}^2 from 59.1% to 93.6%.
	INFANTS	82% 84%	Veneto Tuscany	91 (60, 98) SCREENING METHOD 94 (55, 99)	³ Estimates were usually higher than
0	INFANTS TO ADOLESCENTS	47%		79 (45, 92) CASE-CONTROL METH	predicted strain
•	INFANTS TO YOUNG ADULTS	82%		79 (-231, 99)POPULATION-BASEDSURVEILLANCE5	the Meningococcal
(ADOLESCENTS	62%		100 CLUSTER RANDOMIZE	D ⁶ Antigen Typing
				00/	

*95% Bayesian credible interval.

4CMenB. 4-component meningococcal serogroup B vaccine; Cl. confidence interval; MenB. meningococcal serogroup B; VE, vaccine effectivenes



*rate ratios of post- versus pre-vaccination periods

4CMenB, 4-component meningococcal serogroup B vaccine; CI, confidence interval; MenB, meningococcal serogroup B.

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Case re	eduction (95% CI)	Follow-up	
	50% (29-75)*	1 YEAR ⁷	4
253	75% (64-89)	3 YEARS ¹	r
	90% (57-97)	3 YEARS ³	C
	94% (56-99)	4 YEARS ³	g
	100% (p<0.0001)*	2 YEARS ⁸	(
	96% (p=0.0013)*	4 YEARS⁵	6
	94% (p=0.0001)*	5 YEARS	C
	71% (15-90)	2 YEARS [®]	

50%-100% percentages in green are the minimum and maximum values

4CMenB reduced rates of invasive disease in all of the countries and age groups (infants/children/ adolescents/young adults) studied.

CONCLUSIONS

Substantial and consistent realworld data demonstrate 4CMenB effectiveness and impact in reducing MenB invasive disease.

The available data support the use of 4CMenB in preventing invasive meningococcal disease caused by MenB.

Estimates of VE are available from 5 countries: funded routine use in the United Kingdom (UK) and Italy; prospective observational studies in Portugal and South Australia; and outbreak control in Saguenay-Lac-Saint-Jean, Canada.

Effectiveness was sustained for 4 years in Quebec and for 2 years after the booster dose in young children vaccinated in infancy in the UK (Sup Table).

The safety profile of 4CMenB administered in real-world settings reflects that established in pre-licensure clinical trials. No safety concerns have been raised in postmarketing surveillance.

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