

Use of a meningococcal group B vaccine (4CMenB) in populations at high risk of gonorrhoea in the UK



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	Sponsor	Location	Objective	Study period	Population	Results
Observational impact study ⁶	MSSS ⁷	SLSJ, Quebec, Canada	Reduction in gonorrhoea cases after 4CMenB introduction	2006–17	59 373 target population aged 2 months to 20 years (83% vaccinated); ^{7,8} 231 cases	Estimated <i>N gonorrhoeae</i> risk reduction 59% (95% CI –22 to 84)*
Retrospective case-control study ⁹	CDC	New York City and Philadelphia, USA	4CMenB effectiveness against gonorrhoea	2016–18	167 706 infections among 109 737 individuals aged 16–23 years	4CMenB effectiveness against gonorrhoea 40% (95% CI 23 to 53) compared with no vaccination after adjusting for sex, race, and jurisdiction
Observational prospective cohort study ¹⁰	SA Health	South Australia	4CMenB effectiveness against gonorrhoea	2018–21	School immunisation programme for individuals aged 15–20 years	Two-dose 4CMenB effectiveness against gonorrhoea in adolescents and young adults 33.2% (95% CI 15.9 to 47.0)
Retrospective matched cohort study ¹¹	Kaiser Permanente Southern California	Southern California, USA	Assess association of 4CMenB with reduction in gonorrhoea rates	2016–20	6641 4CMenB recipients matched to 26 471 MenACWY recipients aged 15–30 years	Gonorrhoea rates 46% lower after 4CMenB vs MenACWY (HR 0.54; 95% CI 0.34 to 0.86) in multivariate analysis after adjusting for potential confounders
Unmatched case-control study ¹²	San Raffaele Scientific Institute	Milan, Italy	Effectiveness of 4CMenB against gonorrhoea	2016–21	1051 MSM living with HIV	Two-dose adjusted 4CMenB effectiveness against gonorrhoea 44% (95% CI 9 to 65) with a median follow-up of 3.8 years (IQR 2.1 to 4.3)
Retrospective case-control study ¹³	Oregon Public Health Division	Oregon, USA	Assess association of 4CMenB (vs MenB-FHbp) with gonorrhoea prevalence	2016–18	15 760 4CMenB recipients, 15 212 MenB-FHbp recipients aged 18–29 years after mass vaccination campaigns	Two-dose 4CMenB effectiveness in preventing gonorrhoea 47% (95% CI 13 to 68)

Three studies are completed with final results pending (as of October, 2023): (1) phase 3 DOXYVAC randomised controlled trial in France (NCT04597424); (2) phase 4 *N gonorrhoeae* immune response study in North Carolina, USA (NCT04094883); and (3) BexKPK gonococcal vaccine study in Kenya (NCT04297436). Three more studies have been completed with final results pending as of October, 2023: NCT04597424, NCT04094883, and NCT04297436. 4CMenB=meningococcal group B vaccine. CDC=Centers for Disease Control and Prevention. HR=hazard ratio. MenACWY=meningococcal groups ACWY vaccine. MenB-FHbp=meningococcal serogroup B-factor H binding protein vaccine. MSM=men who have sex with men. MSSS=Ministry of Health and Social Services. *N gonorrhoeae*=*Neisseria gonorrhoeae*. SLSJ=Saguenay-Lac-St-Jean. *Not statistically significant.

Table 1: Completed studies on the effect of 4CMenB against gonorrhoea