# WHO preferred product characteristics for gonococcal vaccines



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### Abbreviations

AMR antimicrobial resistance		
CHIM controlled human infection model	NAAT nucleic acid amplification test	
	<b>OMP</b> outer membrane protein	
GASP Gonococcal Antimicrobial Surveillance Programme	<b>OMV</b> outer membrane vesicle	
HICs high-income countries	PID pelvic inflammatory disease	
HIV human immunodeficiency virus	PPCs preferred product characteristics	
HPV human papillomavirus	PrEP pre-exposure prophylaxis (for HIV)	
lg immunoglobulin	SAGE WHO Strategic Advisory Group of Experts	
LMICs low- and middle-income countries		
	SRH sexual and reproductive health	
LOS lipooligosaccharide	<b>STI</b> sexually transmitted infection	
MenB Neisseria meningitidis serogroup B		
	WHO World Health Organization	
MSM men who have sex with men		

### **Executive summary**

The development of a vaccine for *Neisseria gonorrhoeae* is an important goal for improving sexual and reproductive health (SRH) worldwide. Gonorrhoea is a common sexually transmitted infection (STI); an estimated 82 million new gonococcal infections occurred worldwide in 2020 *(1)*. Gonococcal infection has substantial morbidity through a wide range of adverse SRH consequences, including pelvic inflammatory disease (PID), infertility, adverse pregnancy outcomes, elevated risk for HIV acquisition and transmission, and neonatal conjunctivitis. Increasing *N. gonorrhoeae* antimicrobial resistance (AMR) has raised the possibility of untreatable gonococcal infections, which would heighten the threat to SRH globally *(2)*.

The World Health Organization (WHO) Global Health Sector Strategy on STIs has set 2030 targets for reducing incidence of *N. gonorrhoeae* infection by 90% *(3)*. Recognizing that this reduction may not be achievable with current interventions, and given increasing AMR, the Strategy has emphasized the need to develop effective gonococcal vaccines. No currently licensed gonococcal vaccines exist. However, interest in gonococcal vaccine development has been reinvigorated not only by the marked increases in gonococcal AMR, but also by mounting scientific data suggesting gonococcal vaccines are biologically feasible, particularly observational studies suggesting that outer membrane vesicle (OMV)-based *Neisseria meningitidis* serogroup B (MenB) vaccines may provide cross-protection against *N. gonorrhoeae (4, 5)*.

WHO preferred product characteristics (PPCs) documents provide guidance on WHO's preferences for new vaccines in priority disease areas, including from the perspective of low- and middle-income countries (LMICs). Articulation of product attributes that meet the needs of LMICs, while PPCs, a WHO-convened group of experts identified two overarching public health goals, of equal priority, for gonococcal vaccines:

- to prevent adverse SRH outcomes related to gonococcal infection, and
- to reduce the impact of gonococcal AMR.

This document describes PPCs for gonococcal vaccines. To meet global public health goals, the preferred vaccine indication is prevention of gonococcal infection, given large numbers of asymptomatic infections that can lead to SRH complications and AMR. Preferred target populations may vary by setting, but include young people (defined as ages 10-24 years) and/or specific populations at higher risk for gonococcal infection, such as men who have sex with men (MSM), sex workers and other vulnerable populations based on country specificities. The choice of broad-based vaccination of young people and/or targeted vaccination of populations at higher risk will depend on such factors as gonococcal epidemiology, vaccine efficacy and cost effectiveness, duration of vaccine protection, and programmatic considerations. These factors can also help refine specific target ages for vaccination among all young people and higher-risk populations with the greatest need for vaccination, in different settings.

Although vaccines specifically formulated to optimize efficacy against gonococcal infection and related outcomes are preferred, this document also examines considerations for the potential use of MenB vaccines to prevent gonococcal infection, if these vaccines are found to provide some cross-protection against gonococcal infection in clinical trials. As these vaccines are already in

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