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ISBN 978-92-4-003982-7 (electronic version)
ISBN 978-92-4-003983-4 (print version)

Suggested citation. WHO preferred product characteristics for gonococcal vaccines. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

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Acknowledgements

The Departments of Sexual and Reproductive Health and Research; Immunization, Vaccines and Biologicals; and Global HIV, Hepatitis and STIs Programmes at the World Health Organization (WHO) would like to thank the many individuals who contributed to the development of this document. The consultation process for developing gonococcal vaccine preferred product characteristics (PPCs) and preparation of this publication were coordinated by Sami Gottlieb and Nita Bellare, WHO Department of Sexual and Reproductive Health and Research (SRH), and Birgitte Giersing, Department of Immunization, Vaccines and Biologicals (IVB), with assistance from Anthony Marfin (PATH) and Maeve B. Mello, Global HIV, Hepatitis and STIs Programmes (HHS).

An initial gonococcal vaccine PPC consultation was convened in Switzerland in January 2019, and a follow-up consultation was convened virtually in May 2020. Both meetings played an important role in the development of this gonococcal vaccine PPC document. WHO would like to sincerely thank the following individuals who attended one or both consultations and commented on drafts of this document.

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All external attendees completed WHO Declaration of Interests statements, and their participation in the meeting and commenting on PPC document drafts were in accordance with the Organization's guidelines for Declaration of Interests for WHO experts.

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Industry observers at the two meetings: Kathrin Jansen, Pfizer, USA; Jacqueline McCluskey, Sanofi Pasteur, USA; Mariagrazia Pizza, GSK Vaccines, Italy; Obadiah Plante, Moderna Therapeutics, USA; Lingjiang Yang, Chengdu Institute of Biological Products, China.

WHO gratefully acknowledges the following meeting participants for providing additional input on the document drafts: Laith Abu-Raddad, Weill Cornell Medicine-Qatar, Qatar; Xiang-Sheng Chen, Chinese Academy of Medical Sciences Institute of Dermatology, China; Carolyn Deal, NIAID, USA; Sinead Delany-Moretlwe, University of Witwatersrand, South Africa; Edward (Ned) Hook III, University of Alabama at Birmingham, USA; Anthony Marfin, PATH, USA; Philippe Mayaud, Medical Research Centre, Uganda, and London School of Hygiene and Tropical Medicine, the United Kingdom; Robert McDonald, CDC, USA; Angélica Espinosa Barbosa Miranda, MoH, Brazil; Francis Ndowa, Skin and Genito-Urinary Medicine Clinic, Zimbabwe.

Finally, WHO thanks the members of the public and gonococcal infection prevention community who commented on the document through the online public consultation process, and the WHO Product Development for Vaccines Advisory Committee (PDVAC; https://www.who.int/groups/product-development-for-vaccines-advisory-committee) who gave a final round of input.

Funding

This work was supported by the UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (Grant U01AI139547). The January 2019 gonococcal vaccine PPC consultation was also supported by the Global Challenges Research Fund (GCRF) Networks in Vaccines Research and Development, which was cofunded by the Medical Research Council (MRC) and Biotechnology and Biological Sciences Research Council (BBSRC), through a BactiVac Catalyst Funding Grant (BVNCP-03).

Abbreviations

AMR..... antimicrobial resistance

CHIM ..... controlled human infection model

GASP ..... Gonococcal Antimicrobial Surveillance Programme

HICs..... high-income countries

HIV..... human immunodeficiency virus

HPV ..... human papillomavirus

Ig..... immunoglobulin

LMICs ..... low- and middle-income countries

LOS ..... lipooligosaccharide

MenB..... *Neisseria meningitidis* serogroup B

MSM ..... men who have sex with men

NAAT ..... nucleic acid amplification test

OMP ..... outer membrane protein

OMV ..... outer membrane vesicle

PID..... pelvic inflammatory disease

PPCs..... preferred product characteristics

PrEP ..... pre-exposure prophylaxis (for HIV)

SAGE..... WHO Strategic Advisory Group of Experts on Immunization

SRH..... sexual and reproductive health

STI..... sexually transmitted infection

WHO ..... World Health Organization

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