

Concept Note and Agenda

Background

Gonorrhoea, a sexually transmitted infection caused by *Neisseria gonorrhoeae*, is associated with a range of adverse health consequences including pelvic inflammatory disease, infertility, and adverse pregnancy outcomes. Increased emergence of *N. gonorrhoeae* antimicrobial resistance (AMR) has increased the possibility of future untreatable infections.^{1,2} Development of gonococcal vaccines has thus become increasingly important, for both sexual and reproductive health and the fight against AMR.^{1,3} Growing evidence suggests gonococcal vaccines are biologically feasible, in particular observational studies suggesting that vaccines against serogroup B *Neisseria meningitidis* (MenB), a closely related pathogen, might provide some cross-protection against gonorrhoea.^{4,5} Randomized controlled trials of MenB vaccines to prevent gonorrhoea are underway, and several other gonococcal vaccine candidates are in pre-clinical development.

In January 2019, WHO convened a global expert consultation on gonococcal vaccine development, to provide a foundation for understanding the potential value and use of gonococcal vaccines and for developing gonococcal vaccine preferred product characteristics (PPCs). Participants emphasized the need for vaccines to control *N. gonorrhoeae* infections with the ultimate goals of preventing adverse sexual and reproductive health outcomes and reducing the impact of gonococcal AMR.⁵ A follow-up virtual consultation in May 2020 resulted in a draft PPC document, which has now been through several rounds of input from experts and public comment.

The goal of this virtual session is to facilitate PDVAC review of the draft gonococcal vaccine PPC document, which has incorporated feedback from experts and the public. The intended outcome is to finalize the PPCs for publication, and to highlight critical aspects that require further consideration to facilitate future policy and implementation discussions.

Objectives of the meeting

1. Review the rationale and context for developing gonococcal vaccine PPCs
2. Evaluate the draft PPC document tables and discuss the following gonococcal vaccine PPCs for an ideal gonococcal vaccine:
 - vaccine indication(s)
 - target population(s)
 - vaccine delivery strategy(ies)
 - route of administration
 - duration of protection
3. Review additional considerations related to potential use of MenB vaccines for gonococcal infection if they are found to provide some cross-protection

PDVAC session on gonococcal vaccines
Concept Note and Agenda

Outcomes of the meeting

1. Finalization of the gonococcal vaccine PPC document for publication by WHO
2. Identification of critical product attributes/characteristics that require further consideration to facilitate future policy and implementation discussions

References

1. Wi T, Lahra M, Ndowa F, et al. (2017) Antimicrobial resistance in *Neisseria gonorrhoeae*: Global surveillance and a call for international collaborative action. PLOS Med 14(7): e1002344.
2. WHO Global Priority List Of Antibiotic-Resistant Bacteria to Guide Research, Discovery, and Development of New Antibiotics: <https://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/>
3. WHO Global Health Sector Strategy on Sexually Transmitted Infections, 2016-2021: <http://www.who.int/reproductivehealth/publications/rtis/ghss-stis/en/>
4. Petousis-Harris H, Paynter J, Morgan J, et al. (2017) Effectiveness of a group B outer membrane vesicle meningococcal vaccine against gonorrhoea in New Zealand: a retrospective case-control study. Lancet 390(10102):1603-1610.
5. Gottlieb SL, Ndowa F, Hook EW III, et al. (2020) Gonococcal vaccines: public health value and preferred product characteristics; report of a WHO global consultation, January 2019. Vaccine pii: S0264-410X(20)30317-0.

05:00 Seattle; 07:00 Lima; 8:00 Washington DC; 13:00 London; 14:00 Geneva; 15:00 Johannesburg; 17:30 New Delhi, 20:00 Beijing; 21:00 Seoul

Time (Geneva CEST)	Topic	Duration	Detail	Moderators, speakers
14.00 – 14.10	Introduction	10'	<ul style="list-style-type: none"> Welcome remarks, roll call, agenda and objectives 	Martin Friede (WHO)/ Meg Doherty (WHO) Ruth Karron (JHSPH) / Birgitte Giersing (WHO)
14.10 – 14.35	The rationale and context for development of PPCs for gonococcal vaccines	15 + 10'	<ul style="list-style-type: none"> Public health need for gonococcal vaccines Update on gonococcal vaccine development Modeling of gonococcal vaccine impact Gonococcal vaccine PPC process 	Sami Gottlieb (WHO) / Carolyn Deal (NIAID)
14.35 – 15.10	Facilitated discussion on selected PPCs for an ideal gonococcal vaccine	35'	<ul style="list-style-type: none"> Vaccine indication Target populations Vaccine delivery strategies, related to target populations Route of administration Duration of protection 	Sinead Delany-Moretlwe (Wits RHI) / Sami Gottlieb (WHO)
15.10 – 15.30	Facilitated discussion on additional considerations for MenB vaccines	20'	<ul style="list-style-type: none"> MenB vaccines and target populations MenB vaccines and vaccine delivery strategies Other considerations related to MenB vaccines 	Sinead Delany-Moretlwe (Wits RHI) / Sami Gottlieb (WHO)
15.30 – 16.30	Discussion (closed session) – PDVAC only What are PDVAC's recommendations with respect to the draft text for the product attributes listed above (please see 'Focus Questions' document).			