MenB vaccines and prevention of gonococcal infection: a global perspective

Dr Sami Gottlieb
World Health Organization
Dept of Sexual and Reproductive Health and Research
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Development of vaccines for gonococcal infection: increasingly important and promising

- **AMR**: renewed focus on gonococcal vaccines given risk of infertility, adverse pregnancy outcomes, etc
- Evidence that vaccines against Ng are feasible
- New Zealand: after mass vaccination with MenB OMV vaccine, gonorrhoea cases declined
- Large case-control study: *estimated vaccine effectiveness* 31% (21%-39%)

Source: Petousis-Harris et al, Lancet, 2017
### Randomized controlled trials of 4CMenB vaccination to prevent gonococcal infection

<table>
<thead>
<tr>
<th>Country</th>
<th>Phase</th>
<th>Population</th>
<th>n</th>
<th>Primary Outcome</th>
<th>Timing</th>
<th>Sponsor</th>
<th>Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>III</td>
<td>MSM</td>
<td>130</td>
<td>Time to infection (oropharyngeal, urogenital, anorectal)</td>
<td>Started Jan 2020</td>
<td>Gold Coast University Hospital</td>
<td>ACTRN12619001478101</td>
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<tr>
<td>Australia</td>
<td>III</td>
<td>MSM</td>
<td>730</td>
<td>Time to infection (oropharyngeal, urogenital, anorectal)</td>
<td>Started July 2021</td>
<td>Kirby Institute</td>
<td>NCT04415424</td>
</tr>
<tr>
<td>USA and Thailand</td>
<td>II</td>
<td>Men and women (18-50y)</td>
<td>2200</td>
<td>Incidence of infection (urogenital or anorectal)</td>
<td>Started Dec 2020</td>
<td>National Institute of Allergy and Infectious Diseases</td>
<td>NCT04350138</td>
</tr>
</tbody>
</table>

Delays due to COVID-19, but first results may be available as soon as Aug 2023
WHO undertaking efforts to assess value of gonococcal vaccines, define PPCs

- PPCs to be released this month, for ideal gonococcal vaccines + considerations for potential use of MenB vaccines
- Target populations = Young people (ages 10-24 yrs) AND/OR specific populations at higher risk
- Choice of target populations in different settings and potential use of MenB vaccines depend on:
  - Epidemiology
  - Vaccine efficacy
  - Duration of vaccine protection
  - Costs and cost-effectiveness
  - Existing programmes/platforms
Some countries have relatively high gonococcal infection prevalence in general populations

Epidemiology:
- Varies widely but highest in LMICs; many countries without data
- Peak incidence: age 20-24 yrs
- In ALL settings, higher in specific sub-populations

Rowley et al, manuscript in preparation.

Studies from general populations; samples collected in 2010 or later.
In many countries: low general population rates, but high rates in specific subpopulations

**Figure 26. Gonorrhea — Estimated Rates of Reported Gonorrhea Cases by MSM, MSW, and Women, STD Surveillance Network (SSuN)\(^{\dagger}\), 2010–2018, USA**

**Source:** https://www.cdc.gov/std/stats18/default.htm

MSM = men who have sex with men
MSW = men who have sex with women

\(^{\dagger}\) Sites include Baltimore, Philadelphia, New York City, Washington State, San Francisco, and California (excluding San Francisco).

* Estimates based on interviews among a random sample of reported cases of gonorrhea (n=21,417); cases weighted for analysis. Data not available for 2014; 2013–2015 trend interpolated; trends lines overlap for MSW and women in this figure.

* Per 100,000.
Global epidemiology of invasive MenB disease

- Variability by location and over time; some unpredictable outbreaks
- Peak incidence in infants
- 4CMenB licensed in 45 countries, mostly HICs
- Only a fraction have it in NIPs or strong recommendations for use

Epidemiology of gonorrhoea and MenB disease

- HICs with higher MenB incidence and vaccine use have low gonorrhoea prevalence
- LMICs with higher gonorrhoea are not using 4CMenB
- Some settings and target population overlap

Gonorrhoea prevalence in women age 15-49.

Annual incidence/100,000 people, 2000-2015

Need better data for both!

MenB vaccines and gonorrhoea: considerations

• Where MenB vaccine target populations might already include young people or key populations, overlapping with gonorrhoea target groups:
  • The potential to have an impact on both conditions strengthens argument for vaccinating for MenB
  • Duration of protection will be a consideration

• If preferred target populations in a setting comprise a small proportion of the population, expanding an existing vaccine may be more favorable than developing a de novo vaccine
  • HICs using MenB vaccines could easily expand to key populations
MenB vaccines and gonorrhoea: considerations

- For settings with very high gonococcal infection prevalence, even modest efficacy of 4CMenB against gonorrhoea could be beneficial
  - Expanding indications of a MenB vaccine to include gonococcal prevention could change cost-effectiveness and affect decisions to introduce it in more settings
- Delineating public health value in terms of both pathogens essential
  - Collecting better data on both conditions; modelling
  - Ongoing RCTs of MenB vaccines to prevent gonococcal infection will provide critical data
Thank you!

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