# USE OF EXPANDED *NEISSERIA MENINGITIDIS* SEROGROUP B (MENB) PANELS WITH THE SERUM BACTERICIDAL ANTIBODY (SBA) ASSAY IN THE EVALUATION OF MENB VACCINE EFFECTIVENESS

**Authors and presenter:** Ray Borrow[1], Federico Martinón-Torres[2,3,4], Véronique Abitbol[5], Anar Andani[6], Scott Preiss[7], Alessandro Muzzi[8], Laura Serino[8], Woo-Yun Sohn[7]

[1]Meningococcal Reference Unit, UK Health Security Agency, Manchester Royal Infirmary, Manchester, UK

[2]Pediatrics Research Group (GENVIP), Instituto de Investigación Sanitaria de Santiago and Universidad de Santiago de Compostela, Galicia, Spain

[3]Translational Paediatrics and Infectious Diseases, Paediatrics Department, Hospital Clínico Universitario de Santiago, Santiago de Compostela, Spain

[4]Consorcio Centro de Investigación Biomédica en Red de Enfermedades Respiratorias (CIBER-ES), Madrid, Spain

[5]GSK, Rueil-Malmaison, France

[6]GSK, Wavre, Belgium

[7]GSK, Rockville, MD, USA

[8]GSK, Siena, Italy

**Presenting author**: Woo-Yun Sohn, woo-yun.w.sohn@gsk.com

**BACKGROUND** Measurement of MenB vaccine effectiveness (VE) is complicated by diversity in antigen expression among MenB strains. Since using the classical human complement SBA assay (hSBA) against all circulating strains is not feasible, a new assay is required to assess immunological VE against a large panel of disease-causing strains.

**AIM/METHODS** The characteristics of two methods for predicting MenB VE are discussed: hSBA using endogenous complement in each vaccinees' serum (enc-hSBA) against a panel of MenB isolates (110-strain), and classical hSBA using exogenous complement (exc-hSBA) against 14 (4+10) MenB strains.

**RESULTS** Enc-hSBA provides a binary assessment of killing activity elicited by vaccine-specific antibodies in individual vaccinees' sera, bypassing the need to identify suitable human complement. It accounts for inter-subject variability in bactericidal killing and synergistic effects of multiple MenB vaccine antigens. It

was qualified using 110 representative disease-causing MenB strains, randomly selected from a 442-strain US panel, representing ~89% of strains circulating globally and 95% of US strains, including the most prevalent clonal complexes and genetic variants of MenB vaccine antigens. Exc-hSBA 4+10 is a titre-based measure of killing activity of the bivalent MenB-FHbp vaccine via hSBA against four primary and 10 additional MenB strains selected following evaluation of factor H-binding protein (fHbp) sequence diversity and expression in 1263/1814 strains. These 14 strains represent ~80% of circulating strains in the US and Europe.

**CONCLUSIONS** Use of the hSBA against expanded MenB strain panels in immunological VE assessments helps account for diverse circulating MenB strains. With a large panel of randomly selected strains and the vaccinee's own complement, the enc-hSBA assay aims to measure immunological VE under conditions that are as close as possible to real-world settings.

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## Affiliations table:

| First name | Last name | Email address | Position (max character 100) | Credentials (can be n/a) | Presenting author? | Have you presented at either the 2022 or 2018 IPNC meetings? (Y/N) | Biographical Sketch (no more than a few paragraphs in length.) | ORCID | Institution/ Organization | City | State/Province/Region | Country |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ray | Borrow | Ray.borrow@ukhsa.gov.uk | Prof. | - | N | - | - | 0000-0002-0691-6568 | UK Health Security Agency, Manchester Royal Infirmary | Manchester | - | UK |
| Federico | Martinón-Torres | federico.martinon.torres@usc.es | Prof. | - | N | - | - | 0000-0002-9023-581X | Instituto de Investigación Sanitaria de Santiago and Universidad de Santiago de Compostela | Galicia | - | Spain |
| Véronique | Abitbol | veronique.x.abitbol@gsk.com | Dr. | - | N | - | - | 0000-0003-0369-7715 | GSK | Rueil-Malmaison | - | France |
| Anar | Andani | anar.s.andani@gsk.com | Ms | - | N | - | - | 0000-0003-0530-5340 | GSK | Wavre | - | Belgium |
| Scott | Preiss | scott.s.preiss@gsk.com | Dr | - | N | - | - | - | GSK | Rockville | - | USA |
| Alessandro | Muzzi | alessandro.x.muzzi@gsk.com | Dr | - | N | - | - | 0000-0002-8635-6424 | GSK | Siena | - | Italy |
| Laura | Serino | laura.x.serino@gsk.com | Dr. | - | N | - | - | 0000-0002-8618-9726 | GSK | Siena | - | Italy |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Woo-Yun | Sohn | woo-yun.w.sohn@gsk.com | Dr. | - | Y | - | - | 0000-0002-4034-4735 | GSK | Rockville | - | USA |