

Randomized Trial of 2 Schedules of Meningococcal B Vaccine in Adolescents and Young Adults, Canada

Appendix

Appendix Table 1. Adverse event severity grading for randomized trial of 2 schedules of meningococcal B vaccine in adolescents and young adults, Canada

| Adverse event and intensity score* | Parameter |
|--|--|
| Pain at injection site | |
| 0 | None |
| 1 Mild | Any pain neither interfering with nor preventing normal every day activities. |
| 2 Moderate | Painful when limb is moved and interferes with every day activities. |
| 3 Severe | Significant pain at rest. Prevents normal every day activities. |
| Redness or swelling at injection site | Record greatest surface diameter in mm |
| 0 | ≤20 mm |
| 1 Mild | >20 mm to ≤50 mm |
| 2 Moderate | >50 mm to ≤100 mm |
| 3 Severe | >100 mm |
| Fever† | Record temperature in °C or °F |
| 1 | >38.0°C–≤38.5°C (100.4°F–101.3°F) |
| 2 | >38.5°C–≤39.0°C (101.3°F–102.2°F) |
| 3 | >39.0°C–≤40.0°C (102.2°F–104°F) |
| 4 | >40.0°C (104°F) |
| Drowsiness; generalized muscle aches; or gastrointestinal symptoms (e.g., nausea, vomiting, or diarrhea) | |
| 0 | No reported symptoms |
| 1 Mild | An adverse event that is easily tolerated by the participant, causes minimal discomfort, and does not interfere with everyday activities |
| 2 Moderate | An adverse event that is sufficiently discomforting to interfere with normal everyday activities |
| 3 Severe | An adverse event that prevents normal everyday activities |

*Unsolicited adverse events were assigned to the categories of mild, moderate, or severe at the discretion of the investigator.

†Fever was defined as temperature >38.0°C or >100.4°F for oral, axillary, or tympanic route; the preferred route was oral.

Appendix Table 2. Percentage of participants with human serum bactericidal antibody titers $\geq 1:4$ to 3 strains of meningococcal B at each study visit in a trial of 4-component protein-based meningococcal B (MenB-4C) vaccine, Canada*

| Day of study, vaccine group | Sample size | No. (%) | 95% CI | p value |
|--|-------------|-----------|-----------|---------|
| 5/99 (Neisserial adhesin) | | | | |
| Day 0 | | | | |
| Accelerated | 60 | 41 (68.3) | 57.1–78.2 | 0.832 |
| Longer interval | 61 | 55 (90.2) | 81.5–95.6 | |
| Day 21 | | | | |
| Accelerated | 59 | 59 (100) | 95.0–100 | 0.000 |
| Longer interval | 60 | 59 (98.3) | 92.3–99.9 | |
| Day 42 | | | | |
| Accelerated | 59 | 59 (100) | 95.0–100 | 0.000 |
| Longer interval | 61 | 60 (98.4) | 92.5–99.9 | |
| Day 81 | | | | |
| Accelerated | 59 | 59 (100) | 95.0–100 | |
| Longer interval | 61 | 61 (100) | 95.2–100 | |
| Day 180 | | | | |
| Accelerated | 59 | 58 (98.3) | 92.2–99.9 | 0.002 |
| Longer interval | 60 | 60 (100) | 95.1–100 | |
| H44/76 (factor H binding protein) | | | | |
| Day 0 | | | | |
| Accelerated | 60 | 14 (23.3) | 14.7–34.0 | 0.758 |
| Longer interval | 61 | 27 (44.3) | 33.4–55.6 | |
| Day 21 | | | | |
| Accelerated | 59 | 58 (98.3) | 92.2–99.9 | 0.001 |
| Longer interval | 60 | 59 (98.3) | 92.3–99.9 | |
| Day 42 | | | | |
| Accelerated | 59 | 58 (98.3) | 92.2–99.9 | 0.000 |
| Longer interval | 61 | 57 (93.4) | 85.6–97.7 | |
| Day 81 | | | | |
| Accelerated | 59 | 58 (98.3) | 92.2–99.9 | 0.002 |
| Longer interval | 61 | 61 (100) | 95.2–100 | |
| Day 180 | | | | |
| Accelerated | 59 | 57 (96.6) | 89.7–99.4 | 0.006 |
| Longer interval | 60 | 60 (100) | 95.1–100 | |
| 982/54 (New Zealand outer membrane vesicle) | | | | |
| Day 0 | | | | |
| Accelerated | 60 | 31 (51.7) | 40.3–62.9 | 0.525 |
| Longer interval | 61 | 41 (67.2) | 56.0–77.1 | |
| Day 21 | | | | |
| Accelerated | 59 | 58 (98.3) | 92.2–99.9 | 0.002 |
| Longer interval | 60 | 60 (100) | 95.1–100 | |
| Day 42 | | | | |
| Accelerated | 59 | 59 (100) | 95.0–100 | 0.000 |
| Longer interval | 61 | 60 (98.4) | 92.5–99.9 | |
| Day 81 | | | | |
| Accelerated | 59 | 59 (100) | 95.0–100 | |
| Longer interval | 61 | 61 (100) | 95.2–100 | |
| Day 180 | | | | |
| Accelerated | 59 | 57 (96.6) | 89.7–99.4 | 0.003 |
| Longer interval | 60 | 59 (98.3) | 92.3–99.9 | |

*The accelerated schedule was MenB-4C vaccine at 0 and 21 days. The longer interval schedule was MenB-4C vaccine at 0 and 60 days