Menactra® Vaccine

2 - 10 Year-old

Indication

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sanofi pasteur

Overview of Menactra Vaccine Clinical Trials (2–10 Years of Age)

Trial Number	Type of Study	Vaccine Study Groups	Ages (y)	Menactra Vaccine	Menomune Vaccine*
603-02[1]	Safety & Immunogenicity	Menactra vs. Menomune (A/C/Y/W-135)	2–10	696	702
MTA-17[2]	Evaluation of memory 2-3 y after priming		4–6	NA	171
MTA-15[3]	Evaluation of booster response in C conjugate experienced children		2–4	52	-
MTA-08	Safety Comparison	Menactra vs. Menomune (A/C/Y/W-135)	2–10	1712	1519

*A/C/Y/W135 PS vaccine

1. Pichichero M et al. *Pediatr Infect Dis J.* 2005;24:57-62. 2. Pichichero M et al. *Pediatr Infect Dis J.* 2006;25:995-1000.
3. Bashir HE et al. *Vaccine.* 2006;24:2544-2549

Safety of Menactra Vaccine in Children 2-10 years of age

Symptom (Reaction)	Menactra vaccine	Menomune–A/C/Y/W-135 vaccine
Immediate	0.4%	0.9%
Local*	58.8%	58.3%
Systemic*	53.5%	52.0%

No vaccine-associated serious adverse event (SAE) was reported in either group

***Local and systemic reactions reported within 7 days**

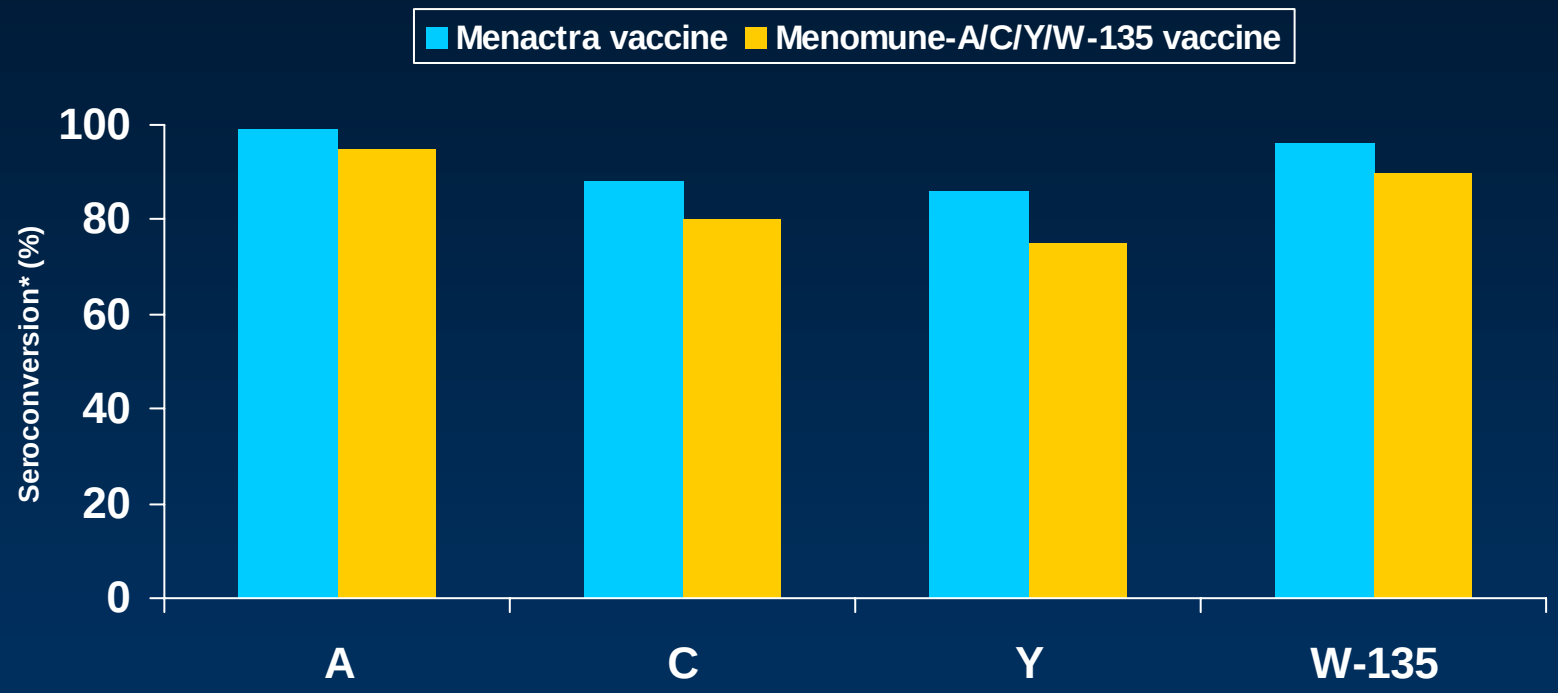
Pichichero M et al. *Pediatr Infect Dis J*. 2005;24:57-62

Safety of Menactra Vaccine in Children

- Most local events were mild or moderate
  - Total, 58.8% for Menactra vaccine vs. 58.3% for Menomune vaccine
  - Pain, 48.1% vs. 46.9%
- Most systemic events were mild
  - Total, 53.5% for Menactra vaccine vs. 52.0% for Menomune vaccine
  - Fussiness, 35.2% vs. 30.1%
  - Drowsiness, 26% vs. 24%
  - Fever, 11.4% vs. 12.0%
- All events were transient (most resolved within 2 days)

Pichichero M et al. *Pediatr Infect Dis J*. 2005;24:57-62

Seroconversion Rates in Seronegative Children 2-10 Years of Age

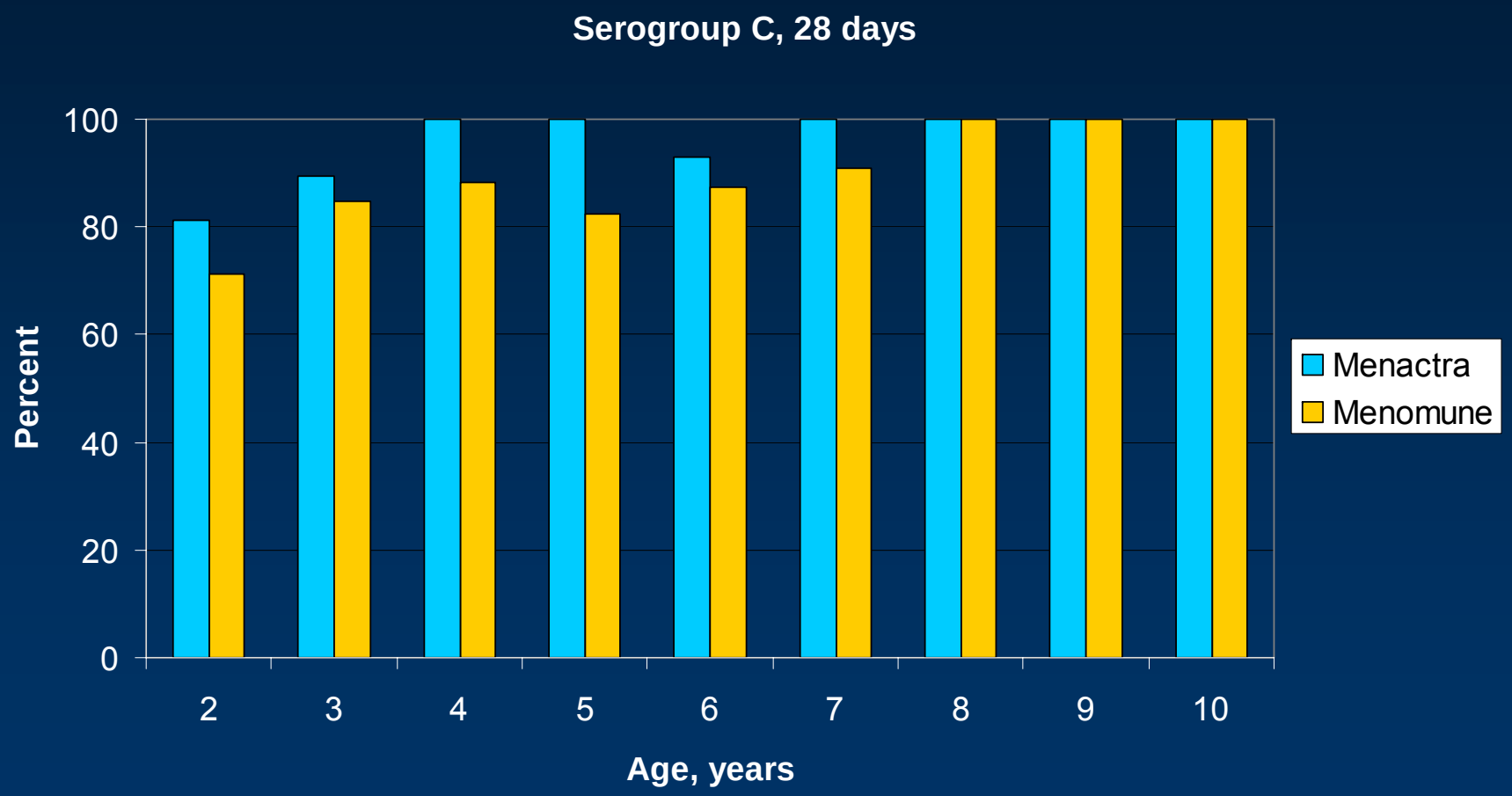


Menactra vaccine	99%	88%	86%	96%
Menomune–A/C/Y/W-135 vaccine	95%	80%	75%	90%

*Seroconversion: participants with titers < 1:8 on Day 0 who reached ≥ 1:32 on Day 28 post-immunization

Pichichero M et al. *Pediatr Infect Dis J*. 2005;24:57-62

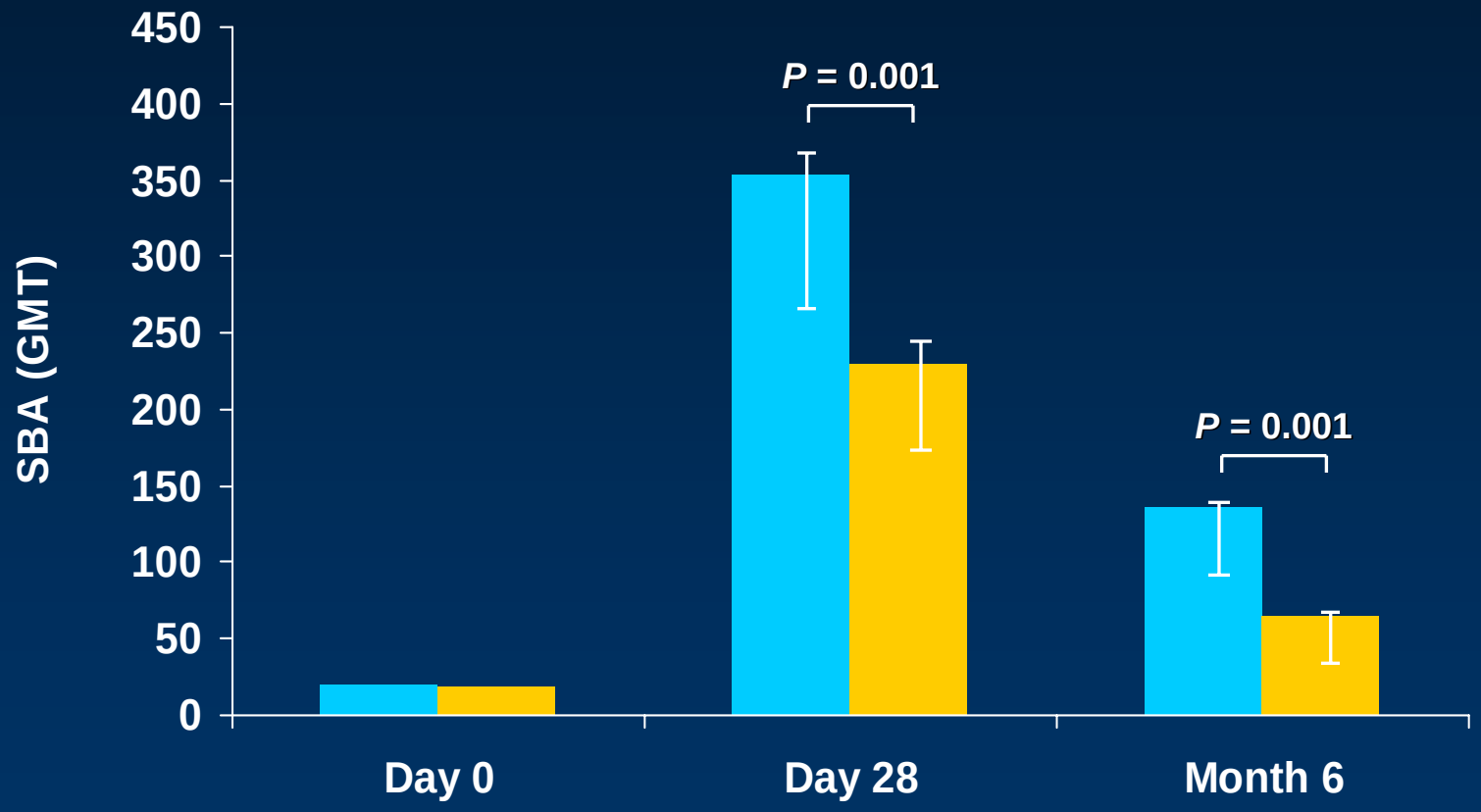
Menactra vs. Menomune, 2–10 Years of Age Serogroup C Seroconversion Rates, Day 28



Pichichero M et al. *Pediatr Infect Dis J.* 2005;24:57-62.

Seroconversion: Day 0 <1:8 and Day 28 ≥ 1:32

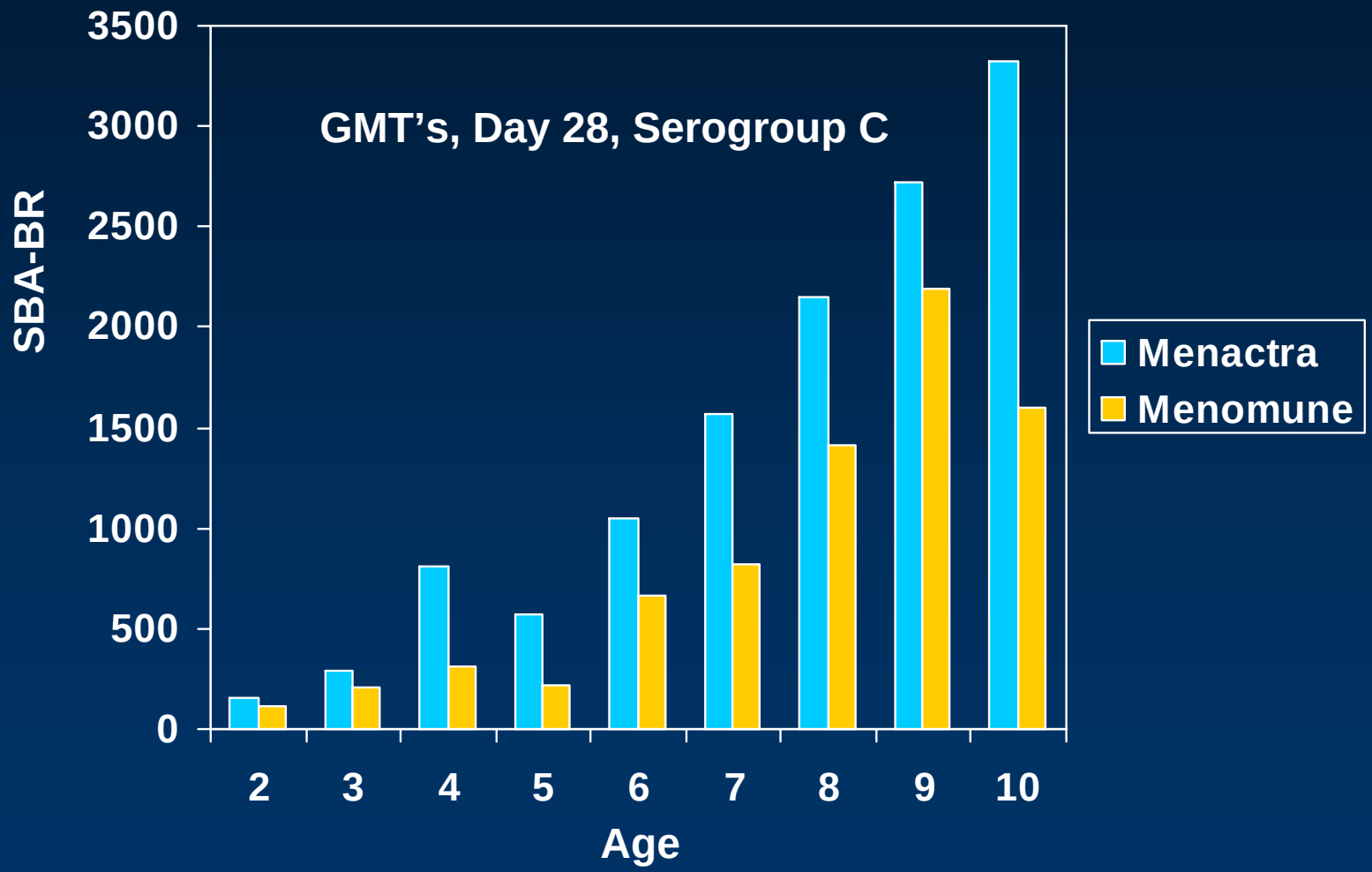
Geometric Mean SBA Titers in Children 2–10 Years of Age: Serogroup C



GMT, Geometric Mean Titers
SBA, Serum Bactericidal Activity

Pichichero M et al. *Pediatr Infect Dis J*. 2005;24:57-62

Menactra vs. Menomune in Children 2–10 Years of Age (GMTs): Serogroup C



Pichichero M et al. *Pediatr Infect Dis J.* 2005;24:57-62.

Key Findings

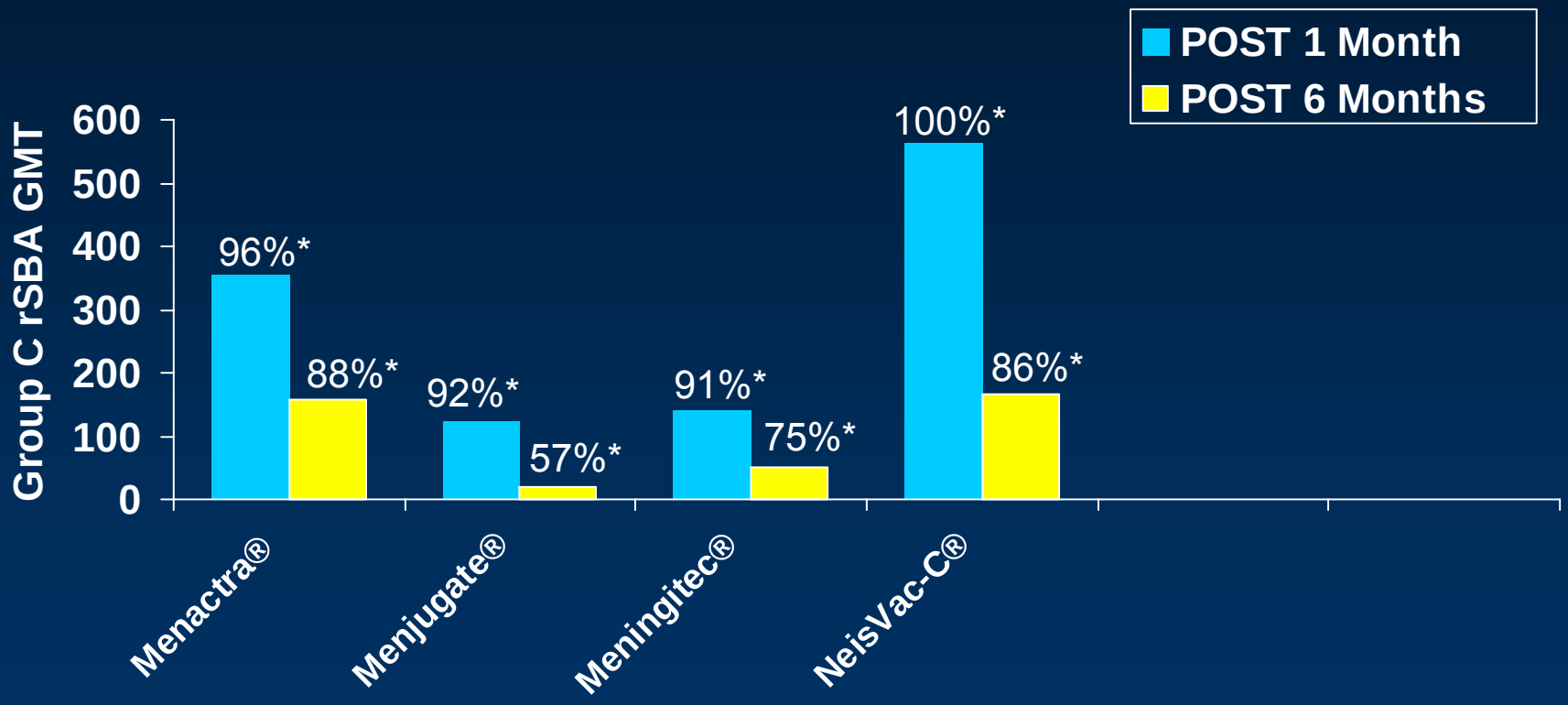
- Similar safety profile in 2- to 10-year-olds compared to Menomune vaccine
- By 28 days postvaccination, Menactra vaccine seroconverted (4-fold increase in titer) 86-99% of children who were initially seronegative for serogroups A, C, Y, and W-135
- For all 4 serogroups, Menactra vaccine produced:
  - Significantly higher SBA GMTs than Menomune vaccine at 28 days postvaccination
  - Significantly higher antibody activity 6 months following vaccination, as compared to Menomune

Menactra Present and Future

- Broadened adolescent recommendation led to increased uptake this summer
- Supply of Menactra vaccine has been consistent and has outpaced demand
- A growing surplus of unused vaccine will allow consideration of further program expansion in 2008 and beyond
- Menactra toddler vaccine on the horizon and will present the opportunity to broadly immunize the population and achieve results seen in other countries

Back-up

Serogroup C rSBA titres after 1 dose of MenC in children 12 to 18 months of age‡ compared with 1 dose of Menactra® in 2 to 10 yr-olds†

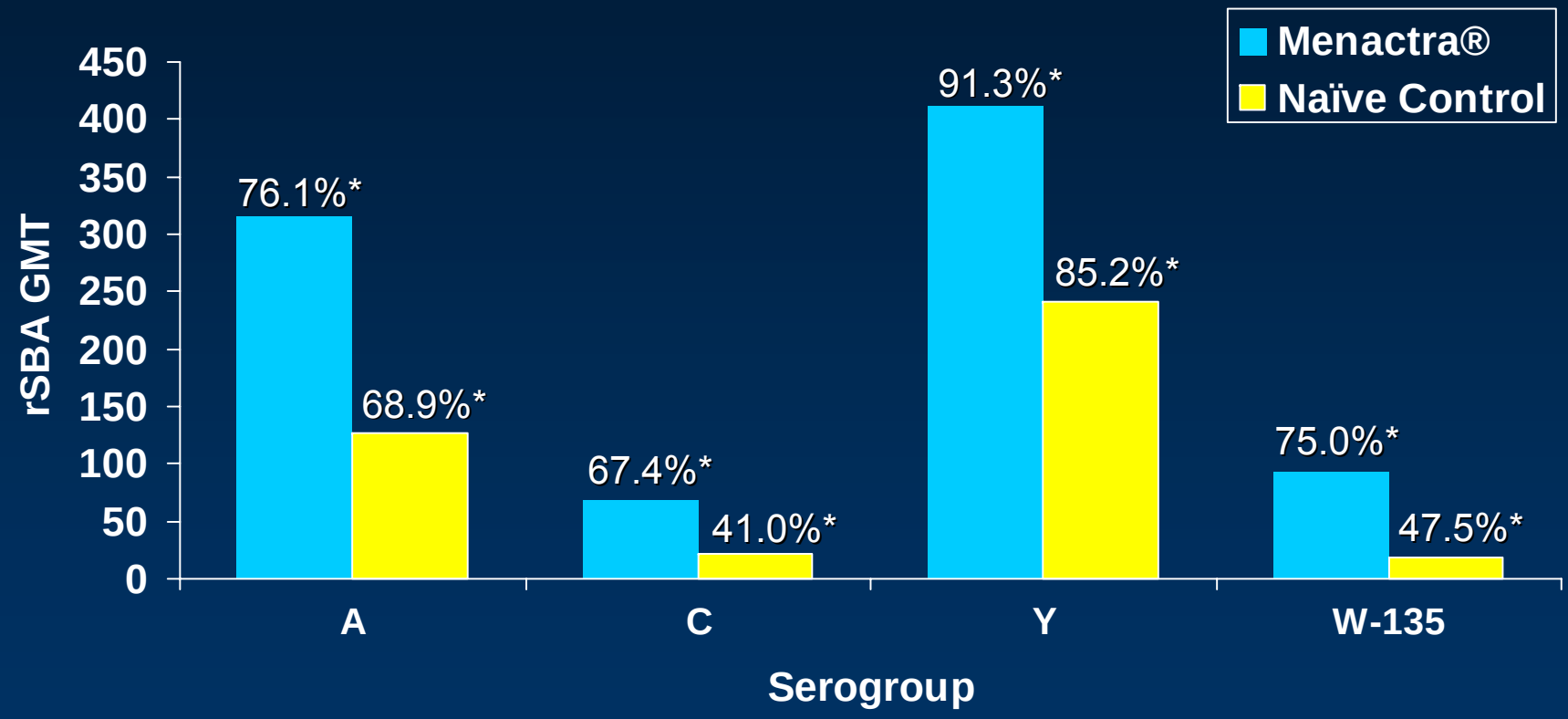


** Percentages refer to proportion with an rSBA titer ≥1:8*

‡ Richmond P., et. al. *JID* 2001; 183:160-3

† Pichichero M., et. al. *PIDJ* 2005; 24:57-62

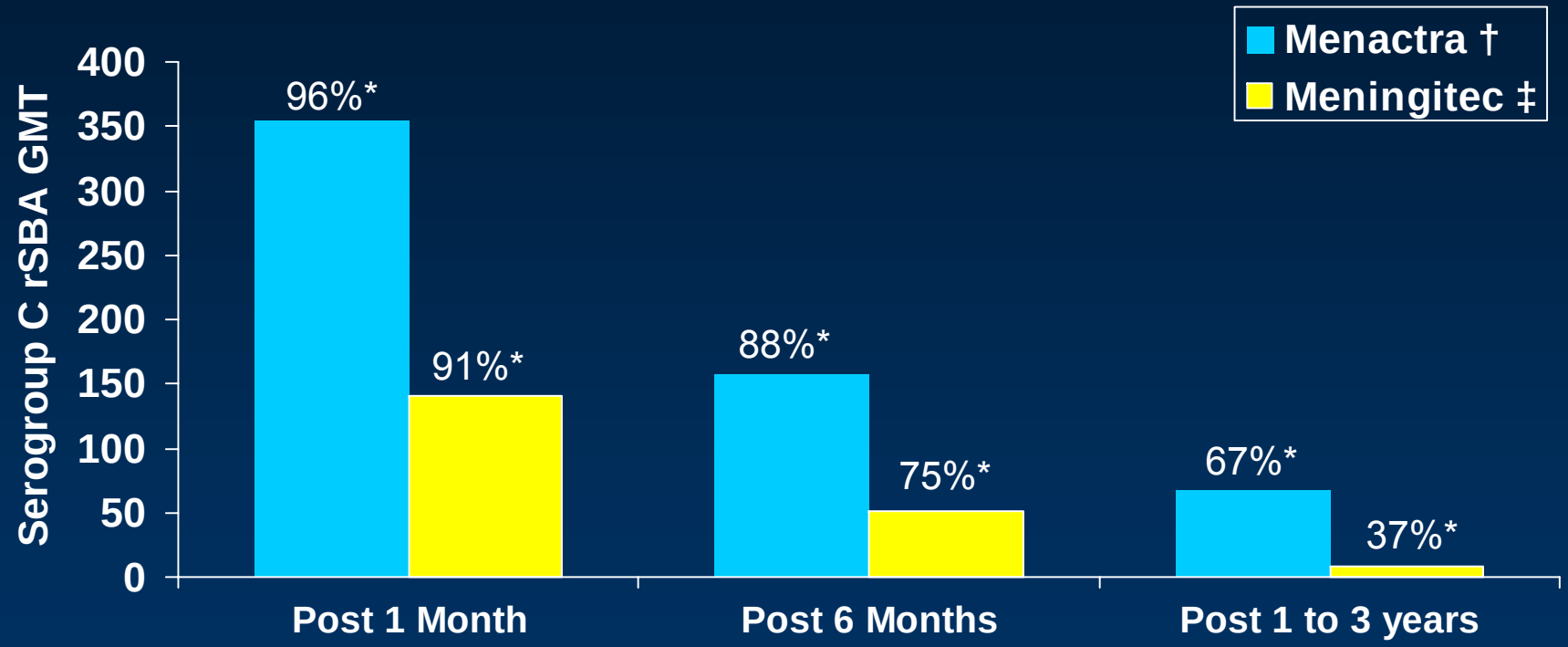
rSBA titres 2 to 3 years after 1 dose of Menactra® in children 2 to 3 years of age (n = 92) compared with age-matched naïve controls (n = 61)†



** Percentages refer to proportion with an rSBA titer ≥1:8*

Source: Pichichero M., et. al. *PIDJ* 2006; 25:995-1000

Antibody Persistence for Menactra Compared to Meningitec



** Percentages refer to proportion with an rSBA titer ≥1:8*

‡ Richmond P., et. al. *JID* 2001; 183:160-3

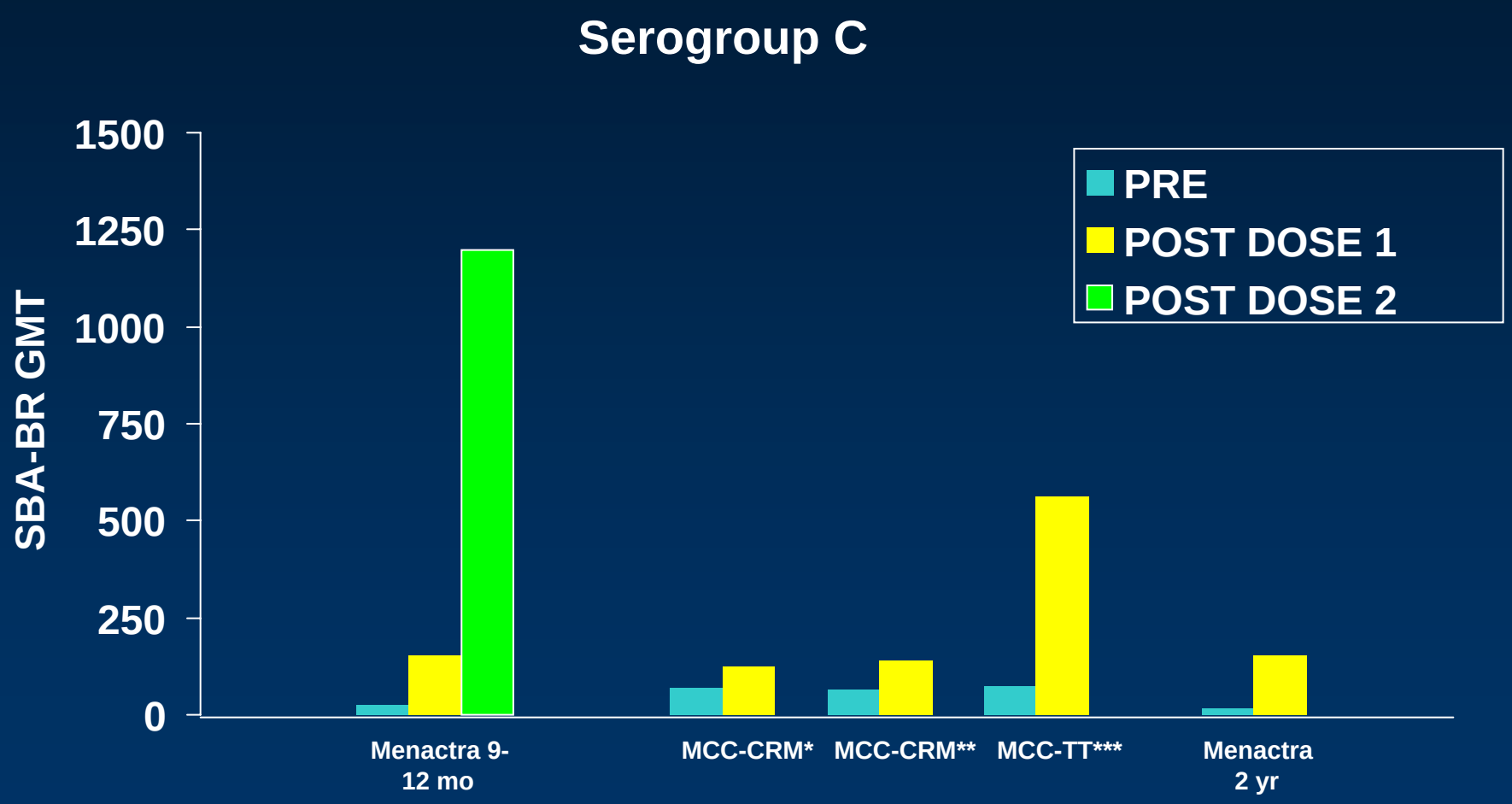
Snape MD, et al. PIDJ 2005; 24:128-131

† Pichichero M., et. al. *PIDJ* 2005; 24:57-62

Pichichero M., et. al. PIDJ 2006; 25:995-1000

Persistence of serogroup C rSBA titres 2 to 3 years after 1 dose of Menactra® in children 2 to 3 years of age compared with 1.2 to 2.7 years after 1 dose of Meningitec® in children 1.4 to 3 years of age†

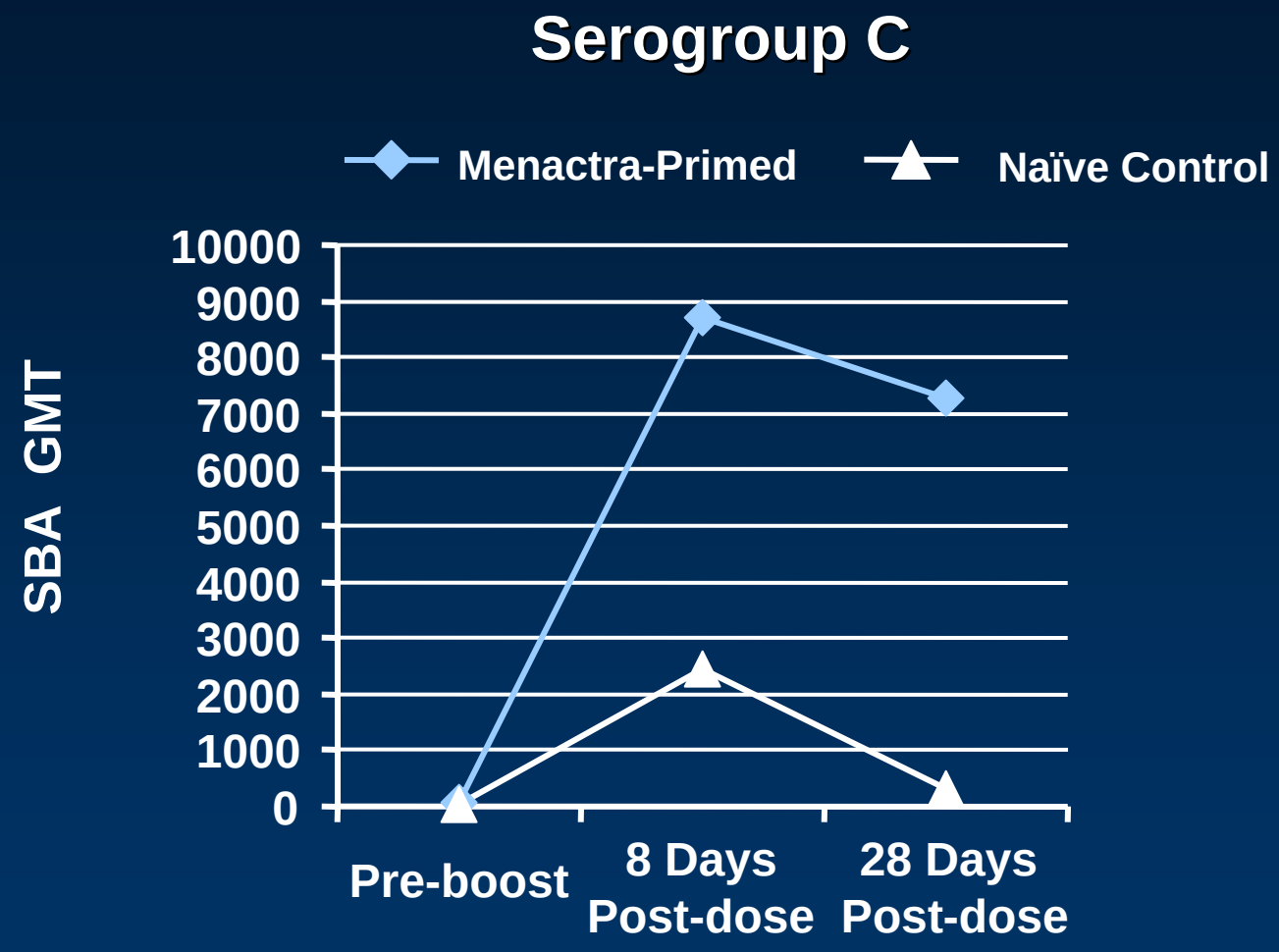
Comparison of Menactra vs. Licensed MCC Vaccines in Toddlers



Pichichero M., et. al. *PIDJ* 2005; 24:57-62 Richmond P., et. al. *JID* 2001; 183:160-3

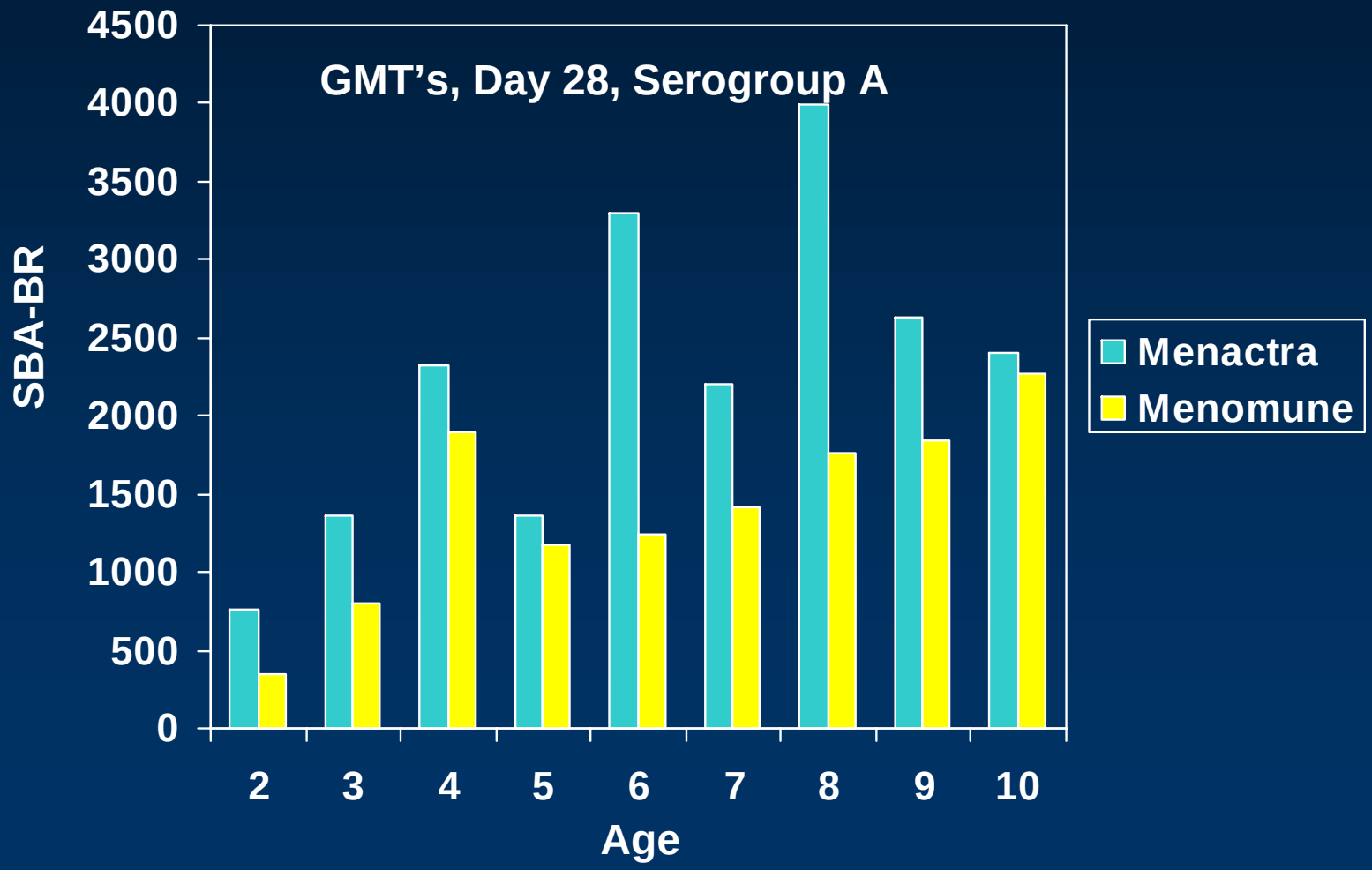
* Chiron ** Wyeth *** NAVA

Immune Memory: 5-µg PS Challenge: Children (2-10 years) Primed 2-3 Years Prior with Menactra vs. Naïve:

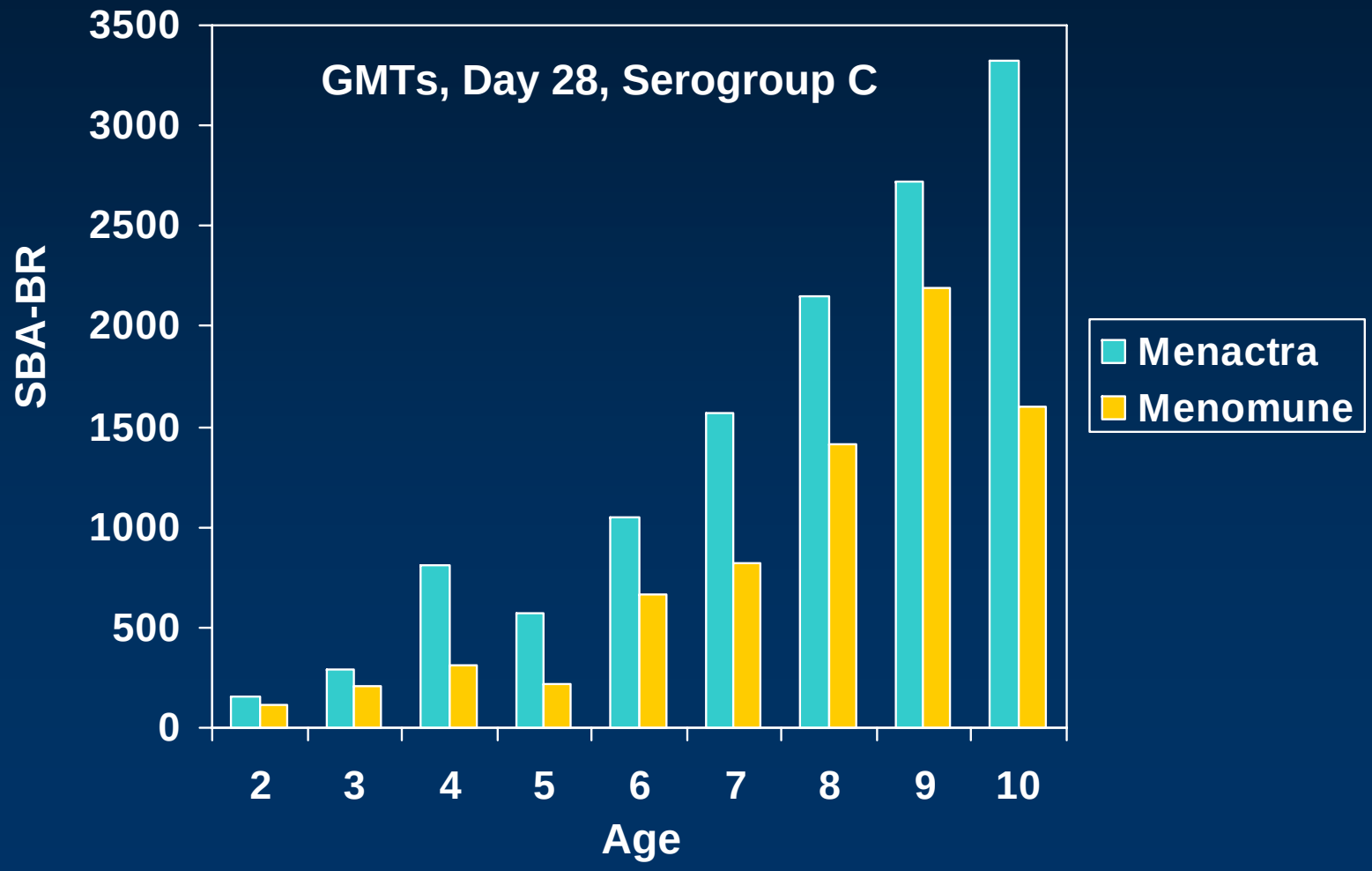


Source: Pichichero M., et. al. *PIDJ* 2006; 25:995-1000

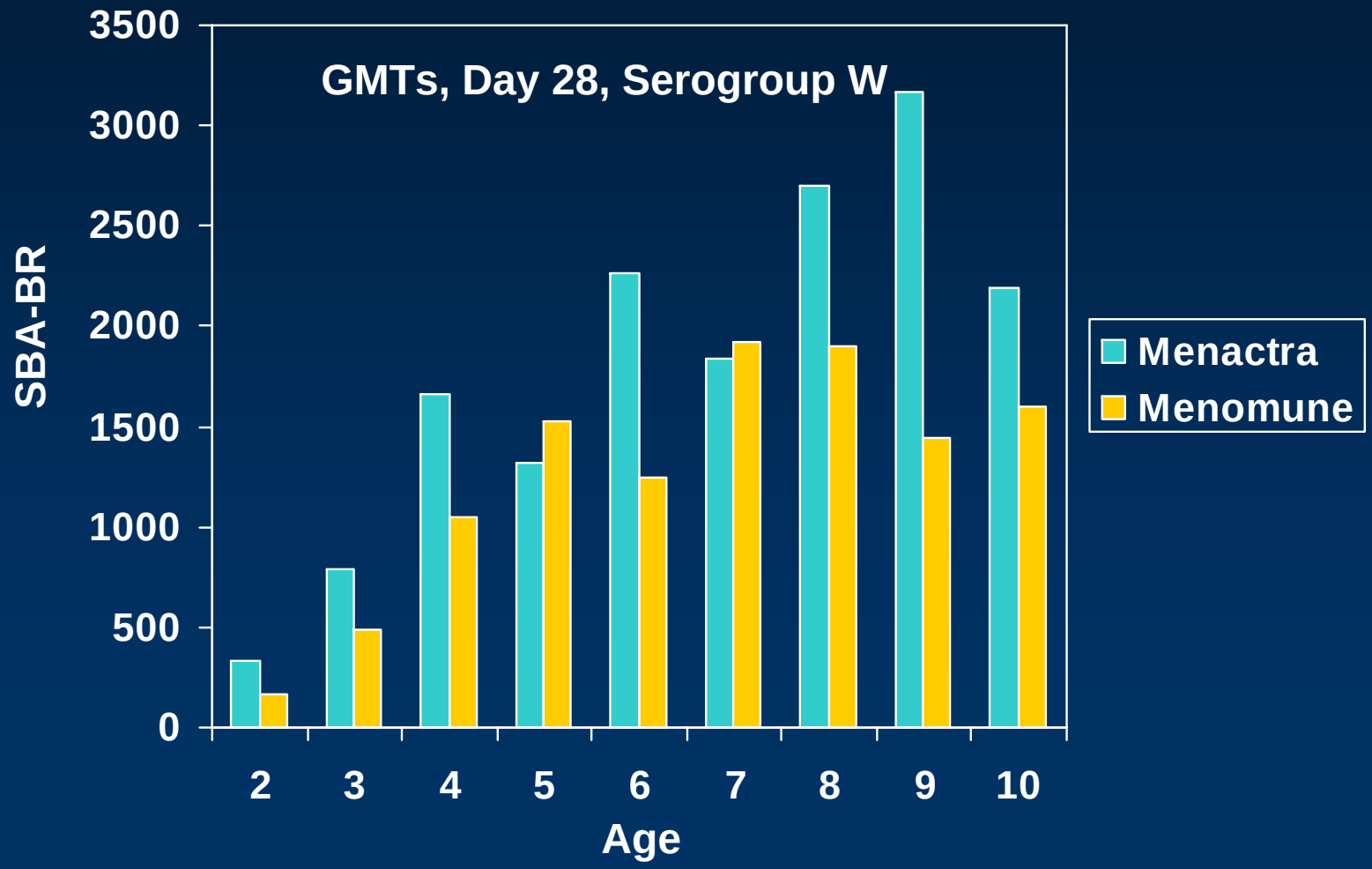
Menactra vs. Menomune, 2–10 Years of Age Serogroup A GMTs, Day 28



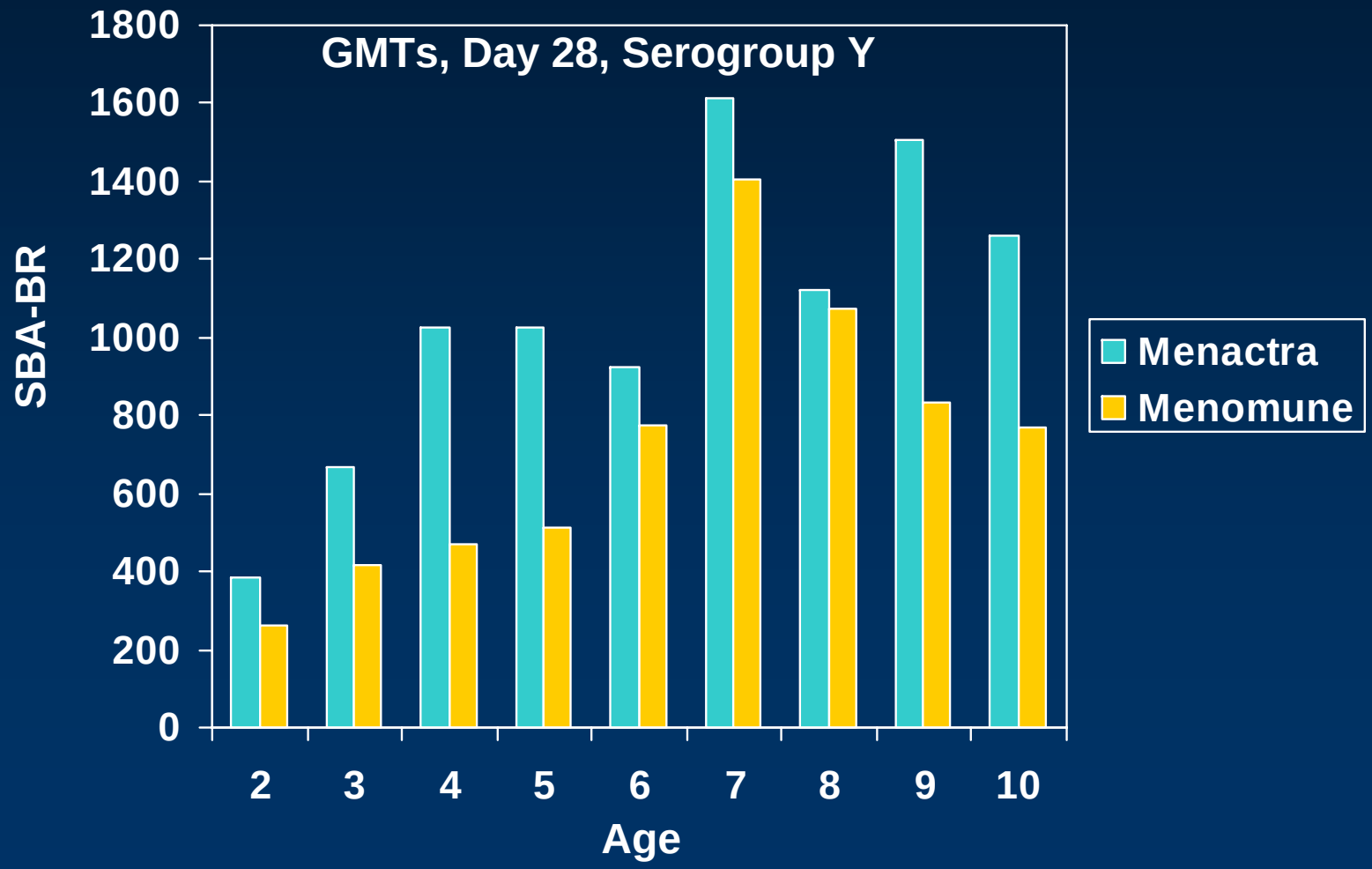
Menactra vs. Menomune, 2–10 Years of Age Serogroup C GMTs, Day 28



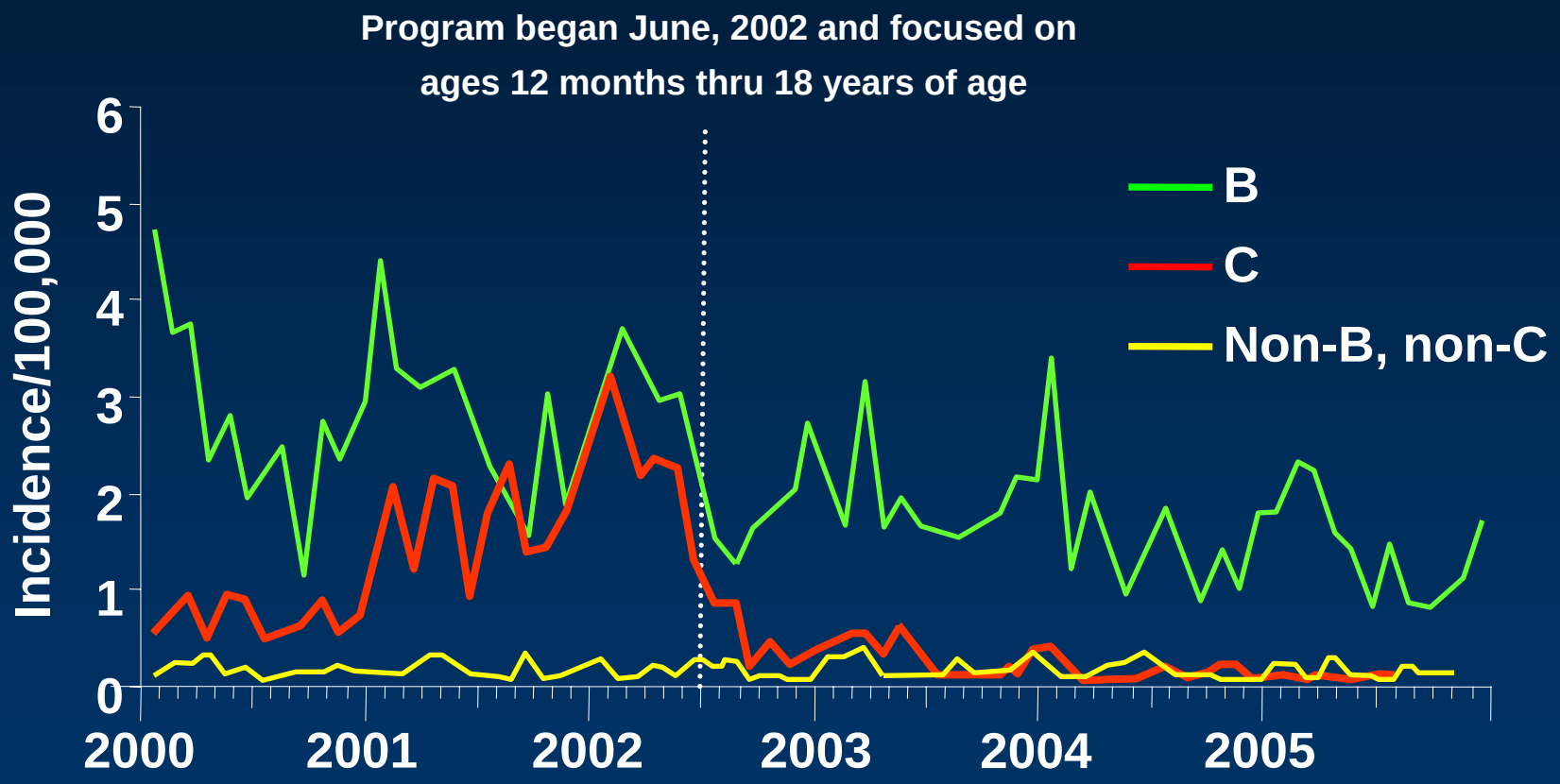
Menactra vs. Menomune, 2–10 Years of Age Serogroup W GMTs , Day 28



Menactra vs. Menomune, 2–10 Years of Age Serogroup Y GMTs , Day 28

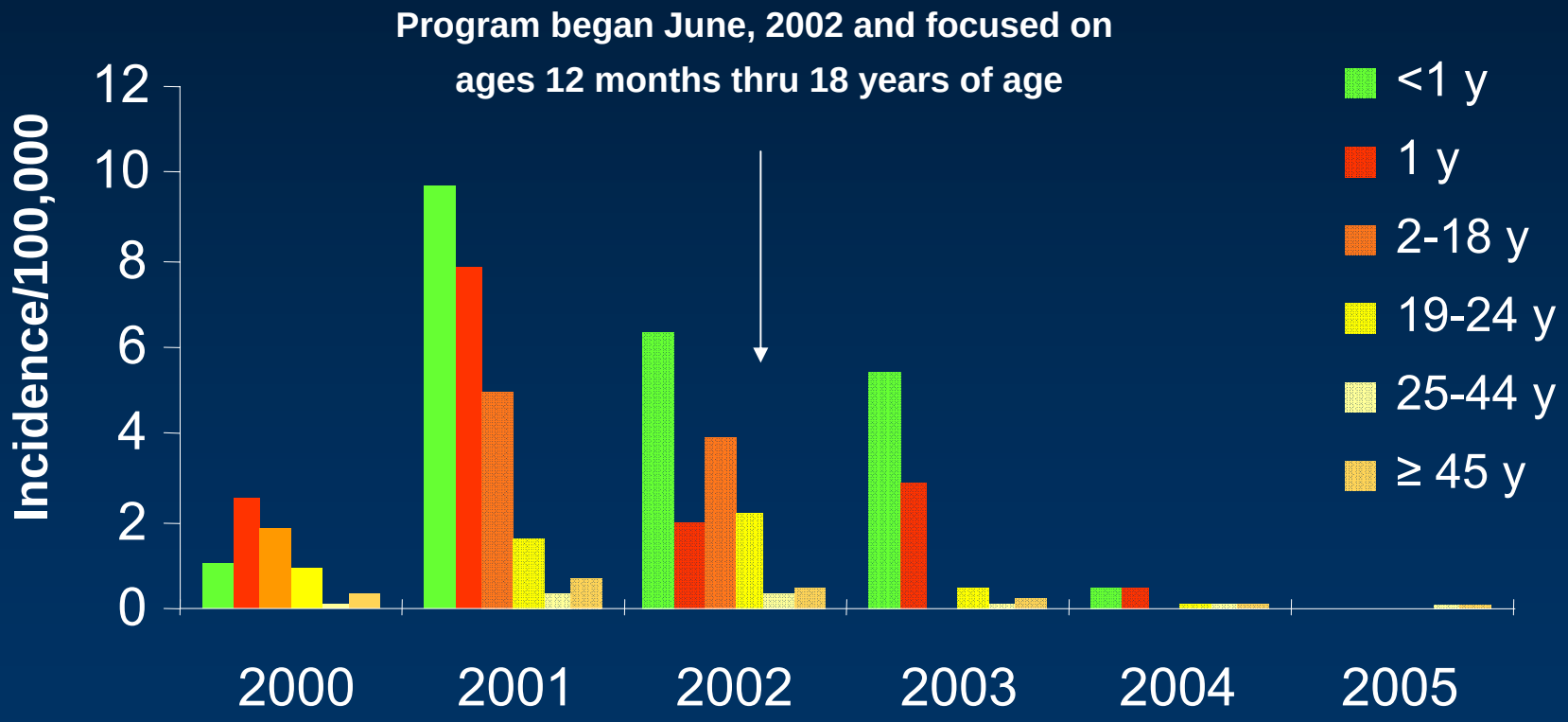


Incidence of Meningococcal C Disease in the Netherlands Decreased Overall (2000-2005)



de Greeff SC et al. *Pediatr Infect Dis J.* 2006;1:79-80
Updated results. Available at: http://www.rivm.nl/isis/rbm/meningokok_RBM.html

Incidence of Meningococcal C Disease Also Decreased Across All Age Groups



de Greeff SC et al. *Pediatr Infect Dis J.* 2006;1:79-80
Updated results. Available at: http://www.rivm.nl/isis/rbm/meningokok_RBM.html

Immunization Dramatically Reduced the Incidence of Meningococcal C Disease in the Netherlands: 2005 vs. 2001

Age Group	Reduction
<1 y	100%
1-2 y	100%
2-18 y	100%
19-24 y	100%
25-44 y	89%
≥45 y	95%

de Greeff SC et al. *Pediatr Infect Dis J.* 2006;1:79-80
Updated results. Available at: http://www.rivm.nl/isis/rbm/meningokok_RBM.html

Incidence of Meningococcal C Disease in the Netherlands Continued to Decrease in 2006

- The number of patients with meningococcal C disease has sharply decreased, from 276 in 2001 to only 4 in 2006.
- As of February 2007, no cases in previously vaccinated persons have been reported, suggesting that a single dose of conjugated meningococcal C vaccine in the second year of life or later might provide long-lasting protection.
- The incidence of meningococcal serogroup C disease in non-vaccinated individuals has also decreased, most likely due to the loss of the main reservoir of group C meningococci in children (ie, herd immunity).

de Greeff et al. Submitted to European Monitoring Group on Meningococci, Rome, June 2007