

TABLE 3: PERCENTAGE OF PARTICIPANTS 18–55 YEARS OF AGE REPORTING SOLICITED ADVERSE REACTIONS WITHIN 7 DAYS FOLLOWING VACCINE ADMINISTRATION

Reaction	Menactra vaccine N [*] =1371			Menomune–A/C/Y/W-135 vaccine N [*] =1159		
	Any	Moderate	Severe	Any	Moderate	Severe
Redness [‡]	14.4	2.9	1.1 [†]	16.0	1.9	0.1
Swelling [‡]	12.6 [†]	2.3 [†]	0.9 [†]	7.6	0.7	0.0
Induration [‡]	17.1 [†]	3.4 [†]	0.7 [†]	11.0	1.0	0.0
Pain [§]	53.9 [†]	11.3 [†]	0.2	48.1	3.3	0.1
Headache	41.4	10.1	1.2	41.8	8.9	0.9
Fatigue	34.7	8.3	0.9	32.3	6.6	0.4
Malaise	23.6	6.6 [†]	1.1	22.3	4.7	0.9
Arthralgia	19.8 [†]	4.7 [†]	0.3	16.0	2.6	0.1
Diarrhea	16.0	2.6	0.4	14.0	2.9	0.3
Anorexia [#]	11.8	2.3	0.4	9.9	1.6	0.4
Chills	9.7 [†]	2.1 [†]	0.6 [†]	5.6	1.0	0.0
Fever ^{**}	1.5 [†]	0.3	0.0	0.5	0.1	0.0
Vomiting ^{††}	2.3	0.4	0.2	1.5	0.2	0.4
Rash ^{††}	1.4			0.8		
Seizure ^{††}	0.0			0.0		

* N = The number of subjects with available data; † Denotes $p < 0.05$ level of significance. The p values were calculated for each category and severity using Chi Square test; ‡ Moderate: 1.0–2.0 inches, Severe: >2.0 inches; § Moderate: Interferes with or limits usual arm movement, Severe: Disabling, unable to move arm; || Moderate: Interferes with normal activities, Severe: Requiring bed rest; # Moderate: 3–4 episodes, Severe: ≥5 episodes; * Moderate: Skipped 2 meals, Severe: Skipped ≥3 meals; ** Oral equivalent temperature; Moderate: 39.0–39.9°C, Severe: ≥40.0°C; †† Moderate: 2 episodes, Severe: ≥3 episodes; ††† These solicited adverse events were reported as present or absent only.

Local and Systemic Reactions when Given with Typhim Vi Vaccine

The two vaccine groups reported similar frequencies of local pain, induration, redness and swelling at the Menactra injection site, as well as at the Typhim Vi injection site. Pain was the most frequent local reaction reported at both the Menactra and Typhim Vi injection sites. More participants experienced pain after Typhim Vi vaccination than after Menactra vaccination (76% versus 47%). The majority (70%–77%) of local solicited reactions for both groups at either injection site were reported as mild and resolved within 3 days post-vaccination. In both groups, the most common systemic reaction was headache (Menactra + Typhim Vi vaccine, 41%; Typhim Vi vaccine + Placebo, 42%; Menactra vaccine alone, 33%) and fatigue (Menactra + Typhim Vi vaccine, 38%; Typhim Vi vaccine + Placebo, 35%; Menactra vaccine alone, 27%). Between the groups, differences in rates of malaise, diarrhea, anorexia, or vomiting were not statistically significant. Fever ≥40.0°C and seizures were not reported in either group.

Post-Marketing Reports The following adverse events have been reported during post-approval use of Menactra vaccine. Because these events were reported voluntarily from a population of uncertain size, it is not always possible to reliably calculate their frequency or to establish a causal relationship to Menactra vaccine exposure. Immune system disorders - Hypersensitivity reactions such as anaphylactic/anaphylactoid reaction, wheezing, difficulty breathing, upper airway swelling, urticaria, erythema, pruritus, hypotension. Nervous system disorders - Guillain-Barré syndrome, vasovagal syncope, facial palsy, transverse myelitis, acute disseminated encephalomyelitis. Musculoskeletal and connective tissue disorders - Myalgia.

DOSAGE AND ADMINISTRATION

Menactra vaccine should be administered as a single 0.5 mL injection by the **intramuscular** route, preferably in the deltoid region. Do not administer this product intravenously, subcutaneously, or intradermally. The need for, or timing of, a booster dose of Menactra vaccine has not yet been determined. Parenteral drug products should be inspected visually for container integrity, particulate matter and discoloration prior to administration, whenever solution and container permit.

Concomitant Administration with Other Vaccines

Safety and immunogenicity data are available on concomitant administration of Menactra vaccine with Typhim Vi, and Td vaccines (see **ADVERSE REACTIONS** section). Concomitant administration of Menactra vaccine with Td did not result in reduced tetanus, diphtheria or meningococcal antibody responses compared with Menactra vaccine administered 28 days after Td.⁴ However, for meningococcal serogroups C, Y and W-135, bactericidal antibody titers (GMTs) and the proportion of participants with a 4-fold or greater rise in SBA-BR titer were higher when Menactra vaccine was given concomitantly with Td than when Menactra vaccine was given one month following Td. The clinical relevance of these findings has not been fully evaluated.⁴ Concomitant administration of Menactra vaccine with Typhim Vi vaccine did not result in reduced antibody responses to any of the vaccine antigens.⁴ The safety and immunogenicity of concomitant administration of Menactra vaccine with vaccines other than Typhim Vi or Td vaccines have not been determined. Menactra vaccine must not be mixed with any vaccine in the same syringe. Therefore, separate injection sites and different syringes should be used in case of concomitant administration.

STORAGE Store between 2° to 8°C (35° to 46°F). DO NOT FREEZE. Product that has been exposed to freezing should not be used. Do not use after expiration date.

REFERENCES: 1. Ball R, et al. Safety Data on Meningococcal Polysaccharide Vaccine from the Vaccine Adverse Event Reporting System. CID 2001;32:1273-1280. 2. CDC. Guillain-Barré Syndrome Among Recipients of Menactra[®] Meningococcal Conjugate Vaccine - United States, June 2005-September 2006. MMWR 2006;55(41): 1120-1124. 3. CDC. General recommendations on immunization. Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). MMWR 2002;51(RR02): 1-36. 4. Data on file, Sanofi Pasteur Inc. - 092503.

Manufactured by:
Sanofi Pasteur Inc.
Swiftwater, PA 18370 USA
MKT16458-2

Product information
as of April 2008
Printed in USA
5665-5666

LETTERS FROM MAINE

Saving Lives?

I snaked my way between the crowded tables of Friday evening revelers, late again. Despite continuous tweaking and re-tweaking of our schedules, we still manage to run late at least 25% of the time. If your goal is to never be too busy, you'll never be busy enough to pay the bills.

"Hey, Willis, how many lives did you save today?" The familiar voice told me I was nearing our table of regulars. I mulled over the perfunctory greeting I had received.

How many lives had I saved today? None! In fact I couldn't remember the last time I had actually saved a life. Sure, every time I give an immunization I am protecting the herd. And two or three times every year I have to jump start a newborn who had had a particularly harrowing obstetrical adventure.

But I don't consider that saving lives, certainly not like in the gold old days when *Haemophilus influenzae* stalked the infants and toddlers and new diabetics stayed in town instead of being shipped to the big city before the urine dipstick had dried. So who or what am I saving?

I thought back over the high points of the day I had just completed. Late in the morning I had seen a 6-year-old who had fallen on the playground and gotten a big goose egg on his forehead. Luckily his mother arrived at the school just before the ambulance did, and she had the good sense to call our office. The 15-minute visit did not include a head CT. In addition to saving him the radiation dose, I saved someone a \$2,000 emergency room bill.

Just after lunch I saw a child whose left arm was hanging limply at his side. Within 2 minutes he was using it to reach eagerly for a sticker held over his head. I know that half of my partners would have ordered an x-ray before attempting a reduction, and I am sure that, had he been seen in an emergency room, he would have had the x-ray and maybe an orthopedic consult. Savings for this child were

somewhere between \$150 and \$1,000.

At 3:15 p.m., I saw a new mother with a 2-week-old who was finally doing well at the breast and gaining weight. It had been a struggle over several visits that nearly exhausted my bag of tricks.

Now the mom was confident and ready to nurse for at least 6 months. Savings to that family would be at least \$600 in formula costs alone.

The last patient of the afternoon was an 18-month-old I had never seen before. His record documented several ear infections. He had a new cold and had been a bit fussy. His parents were

convinced that he had another ear infection or that the last one was still bothering him. They had already been on the Internet and found an ear, nose, and throat specialist in Boston and were planning on having him insert pressure equalization tubes. The child's tympanic membranes were transparent and moved briskly on insufflation, a procedure the parents had never seen before.

Although it was late on a Friday afternoon, I decided to share with the family what I knew about the natural history of otitis media and the role of surgical management in its management. It's too early to tell, but I think I may have saved them a trip to Boston. Cost of travel, parking, and lost time at work could easily have run to \$250.

So as my pint of ale arrived I did a little quick math. I had saved these four families at least \$3,000. So, I guess when it comes to saving these days, at least for the primary care physician it's all about the money. For a pediatrician, though, the bulk of the rewards comes from intangibles like watching parents relax and seeing children grow into happy, productive adults. ■

DR. WILKOFF practices general pediatrics in a multispecialty group practice in Brunswick, Maine. E-mail Dr. Wilkoff at pdnews@elsevier.com.



BY WILLIAM G. WILKOFF

EDITORIAL ADVISORY BOARD

LILLIAN M. BEARD, M.D., George Washington University, Washington

LEE SAVIO BEERS, M.D., George Washington University, Washington

SUZANNE C. BOULTER, M.D., Dartmouth Medical School, Hanover, N.H.

KAREN E. BREACH, M.D., private practice, Charlotte, N.C.

STUART A. COHEN, M.D., M.P.H., University of California, San Diego

H. GARRY GARDNER, M.D., Northwestern University, Chicago

COLLEEN KRAFT, M.D., Virginia Tech Carilion School of Medicine, Roanoke, Va.

KEVIN T. POWELL, M.D., Ph.D., pediatric hospitalist, Cardinal Glennon Children's Medical Center

KEITH S. REISINGER, M.D., M.P.H., private practice and research, Primary Physicians Research Inc., Pittsburgh

SARAH E. SCHLEGEL, M.D., University of Connecticut, Hartford

JACK T. SWANSON, M.D., private practice, Ames, Iowa

DEBORAH TOLCHIN, M.D., Albert Einstein College of Medicine, New York