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

	Menactra vaccine N*=1371			Menomune–A/C/Y/W-135 vaccine N*=1159		
Reaction	**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 ≥40.0ºC 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.

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LETTERS FROM MAINE

A Thousand Words

BY WILLIAM G. WILKOFF, M.D.

I've been a bit grumpy the last couple of weeks. We had to put down our 10-year-old electronic medical record system, and I am still working through the grieving process.

She was getting long in the tooth. Homemade by one of our doctors, she had served us well. Everybody loved her from Day 1. But keeping her healthy had become expensive and frustrating. She didn't interface with our off-the-shelf billing and prescribing platforms. She had to go.

What we pediatricians had liked about her was that she allowed us to handwrite our notes and scan them in quickly. Our new system is point and click or type in free text boxes. Dictation just doesn't fit our practice styles. For me, typing isn't much of an issue. In one of her wiser moments, my mom decided that I wasn't going to waste the entire summer of my 11th year at the town swimming pool. She taped over the keys of one of my Dad's old typewriters; gave me a water-stained copy of a learn-to-type book and set me to transcribing Reader's Digest articles. The result is that I am a fast but inaccurate typist whose brain is littered with deep pockets of useless knowledge and anecdotes.

I am trying to learn to keep my eyes off the keyboard and the screen. It's a struggle but I know I can make the adjustment. The reason for my persistent grumpiness is that while the keyboard can replace my handwriting (and probably should have years ago) it can't replace the scores of drawings that decorate my charts.

I have always been a drawer. Ask me for directions and I'll draw you a map. Ask me any question and the odds are 2:1 that I will pull out my pen and illustrate my answer on an old envelope or a paper napkin. It must be genetic. My mom was trained to be an art teacher. My dad always designed and made our Christmas cards. My sister is a whiz with fine-tipped colored markers. My college major was art history. I'm just a visual guy.

It's always been easier for me to draw the distribution of a rash than to describe it. "It hurts here" is more efficiently sketched than written about. The size, shape, and location of laceration are unmistakable when I can draw the wound. A quick outline of the tympanic membrane allows me to remember how much and where the fluid was collecting.

While I am a prolific medical illustrator, the quality of my work is spotty. I have certain favorites and strengths. I am particularly proud of my renderings of legs, fingers, trunks, and genitalia. My sketches of faces and noses are good, my tongues and tonsils are fair. Profiles, ankles, and teeth are pretty shaky but always unmistakable. Even my worst work offers our medical record staff multiple opportunities for a good laugh at the end of a long day.

I have never warmed up to the concept of adding my own lines and dots to the preprinted anatomically correct drawings available on off-the-shelf forms. Somehow it makes me feel that I am prostituting my artistic talents.

There is technology out there that might allow me to draw on the computer, but I've been told it won't be finding its way to our little corner of Maine for quite awhile. So I will be struggling to describe what I have been drawing for years. My vocabulary of anatomical names, which has atrophied from disuse, will have to be rebuilt. For decades I have relied on my sketches and shoddy penmanship to disguise my spelling deficiencies.

But in my darkest hours of grumpiness I am reassured that I will still need my pen and paper to illustrate my mini lectures for patients and parents. They need to "see" what a middle ear looks like and how an inguinal hernia forms. Or why a swollen prepatellar bursa is not as serious as an intra-articular effusion.

Every picture is worth a thousand words … at least. ■

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