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 ≥40.0°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.

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LETTERS FROM MAINE

Collateral Damage

BY WILLIAM G. WILKOFF, M.D.

"Oops" is probably my most frequently used subject when creating e-mails. The recipient is immediately alerted that in the text they are going to find an extensive mea culpa. Often I am apologizing for forgetting to attend a meeting. Although "forgetting" may not be the most accurate word when it comes to group exercises destined to go nowhere slowly.

Warriors have their own versions of "oops." Both conjure up horrible and tragic images of death and destruction. One is "friendly fire." The other is "collateral damage," a term that refers to devastation outside the expected target area.

A few months ago I opened the Sunday morning paper and encountered an explosive event on page 4. You have probably read or heard other versions of the story of a 56-year-old pediatrician from Lewes, Del., who is in jail awaiting prosecution for a 471-count indictment for sexually molesting some of his patients over at least 11 years in practice.

The details of the case that have come to light so far are complex and terribly disturbing. The ground zero for this horrible explosion is predictably the children who were molested, particularly those who have some memory of the events. Sharing the epicenter are their parents whose anger is directed outward to the alleged perpetrator. And inward at themselves for not acting on the occasional uneasy feeling that the physician whom they had trusted with their children seemed a little too weird.

We can only hope that with time both parents and children will find a physician with whom they can feel comfortable. For some I am sure it will take many years to repair the damage. But, because we live in an age of instant and global communication, this horrible bomb of mistrust is radiating and will continue to radiate damage far beyond the borders of that tiny town on the Delaware Coast.

Parents from Portland, Maine, to San Diego will be looking at their pediatricians with a new and suspicious eye. "Does he seem overly interested in my daughter's private parts?" "Does she spend too much time trying to find my 8-month-old son's testicle?" "Doesn't that beard make him seem just a little too weird?" Those of us who wear oversized polka dot bow ties or occasionally don red clown noses to put our patients at ease may be in for special scrutiny.

Although some of us may feel we need to traditionalize our attire, sartorial alterations are relatively easy to make. Behavioral adjustments will present more of a problem. Doctoring can and at times must be hands on. In some circumstances private places must be carefully inspected. Complicating matters is the fact that even on our most hectic days we don't just tolerate our patients. We like them.

There are times when this genuine affection emerges in a big hug for the 4-year-old who has weathered his preschool shots with only a glint of a tear in his eyes. Or a pat on the head for a 3-year-old who has finally mastered the skill of holding still for an ear exam. Two-month-old infants can be too cute not to cradle in one's arms.

But because of the alleged and horribly inappropriate behavior of one of our number, some things will have to change. We will always have to explain what and why we are doing the sensitive portions of our exams. We can no longer assume that because we are pediatricians, our behavior will be interpreted as appropriate.

But what won't and mustn't change is our affection for our patients. However, we may have to begin asking permission for some things that once came so naturally. Unfortunately, the spontaneous hug may have become a casualty of collateral damage. ■

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