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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Hospitalist Believes in Giving 'VIP Treatment'

BY MARY ELLEN SCHNEIDER

Dr. Steve Narang, a pediatric hospitalist in Baton Rouge, La., has a deceptively simple philosophy about delivering care to his patients: He wants them to get the best care available, even if that isn't the latest and supposedly greatest therapy.

Over the last decade, he has worked with his colleagues to apply that philosophy in hospitals in the Baton Rouge area, and he has watched quality of care improve while costs decline. Now he is working with other pediatric hospitalists to spread his quality-improvement approach to hospitals around the country.

There is very little data to help physicians judge 'what makes something better to use than something else.'

DR. NARANG

"There's a lot of emphasis in our health care system on what is the newest drug, the newest technology," but very little comparative effectiveness data can be tapped to help physicians judge "what makes something better to use than something else," said Dr. Narang, who serves as the medical director for quality and safety at Our Lady of the Lake Regional Medical Center in Baton Rouge.

About 2 years ago, Dr. Narang joined forces with four other pediatric hospitalists to launch the Value in Inpatient Pediatrics (VIP) Network. The small, informal steering committee included Dr. Narang, Dr. Matthew D. Garber of the University of South Carolina in Columbia, Dr. Brian M. Pate of the University of Missouri–Kansas City, Dr. Shawn Ralston of the University of Texas Health Science Center in San Antonio, and Dr. Mark Shen of Dell Children's Medical Center of Central Texas in Austin.

The grassroots project had no funding source, but it did have a straightforward goal: "Let's ask people to share their secrets" was how Dr. Narang and the other VIP Network members expressed their intent.

They began by asking hospitals around the country that care for children to report benchmark data on one of the most common diagnoses in hospitalized children—bronchiolitis. They invited the hospitals to provide a mix of process and outcome data about such patients. They sought information on length of stay, utilization of therapies, readmission rates within 72 hours, and variable direct costs for the treatment of children with bronchiolitis.

The VIP Network members also asked hospitals to report on the percentage of such patients receiving bronchodilators, steroids, chest x-rays, respiratory syncytial virus antigen testing, and chest physiotherapy.

The project, which is now in its second year, so far has collected data on about 7,000 patients who were treated for bronchiolitis at about 30 hospitals.

The hospitals participating in the VIP Network can compare their performance with that of other institutions on a quarterly and annual basis.

But the more exciting part, Dr. Narang said, is that hospitals are beginning to form collaboratives within the network, and the best-performing hospitals are sharing how they achieved success. Dr. Narang said that he hopes that the VIP Network will be able to obtain funding and thereby continue to grow.

The network founders are applying for a grant from the Agency for Healthcare Research and Quality, which they would use to hire a paid staff member who could automate and validate the data coming from the hospitals in the network.

Although other organizations are also performing this type of benchmarking work, Dr. Narang said that the VIP Network offers something unique because it does not focus only on free-standing children's hospitals.

Approximately 75% of children are cared for outside of freestanding children's hospitals, he noted, so quality data from general hospitals are needed to find the quality gaps.

The other characteristic that makes the VIP Network stand out is that it links process and outcome data, while most databases contain information only on outcomes.

"I think the key thing that we're learning in health care is not only do you need outcome measures, you need performance drivers," Dr. Narang said. "How and why did these things occur?" ■

Tracking Young Wanderers

EmFinders EmSeeQ is a watch-like, wearable device that has been developed to locate children who have wandered away from caregivers. The device is designed to benefit children with autism and other conditions who are at risk of wandering.

The EmFinders product is fully integrated with 911 emergency systems and can locate the wearer who is indoors or otherwise blocked by a wall or building. For more information about EmFinders EmSeeQ, visit the company's Web site: www.emfinders.com. ■