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.

Manufactured by:

Sanofi Pasteur Inc.

Swiftwater, PA 18370 USA

MKT16458-2

Product information as of April 2008

Printed in USA

5665-5666

MOC Data to Be Used In Quality Reporting

BY ALICIA AULT

A little-noticed provision of the health reform law will let physicians use data collected and reported as part of the maintenance of certification process as an alternative to the Medicare Physician Quality Reporting Initiative.

The details have yet to be worked out, but it would mean that physicians likely would have at least one fewer process to report quality data, said Dr. Christine Cassel, president and CEO of the American Board of Internal Medicine.

'Our concept is that it would be kind of an alternative pathway' and 'would include all the same conditions and measures as PQRI, but be even more comprehensive.'

The advantage of the maintenance of certification (MOC) process is that physicians are familiar with it, as more than 80% of all physicians participate in this process, Dr. Cassel said in an interview.

Physicians have been eligible to receive bonuses for participation in the Medicare PQRI, but they have complained about it as a redundant, burdensome, and confusing process, and have bemoaned botched or missing payments.

Even the Centers for Medicare and Medicaid Services has acknowledged problems with the reporting program.

In a statement, Dr. Kevin B. Weiss, president and CEO of the American Board of Medical Specialties, said that "MOC reporting will give patients, health plans, and others the information they need to choose physicians based on performance and other key qualifications, including diagnostic acumen, clinical reasoning, and medical knowledge.

"This [law] is a significant step forward in recognizing the value of MOC in advancing health care quality for the benefit of patients."

Under the Patient Protection and Affordable Care Act of 2010—one of the two major health reform laws—the Health and Human Services secretary will decide how MOC will fit into the PQRI process. The hope is that this will be clarified within the year, ABIM's Dr. Cassel said.

ABIM and other medical specialty boards seek to meet with CMS officials to help write the regulations for implementing the process, she said in the interview.

"Our concept is that it would be kind of an alternative pathway' and "would include all the same conditions and measures as PQRI, but be even more comprehensive," said Dr. Cassel.

Family physicians already have some experience with using MOC as an alternative to PQRI.

The American Board of Family Medicine received approval from Medicare to use its MOC registry for the PQRI process, according to Dr. Michael Hagen, ABFM's senior vice president.

Instead of using Medicare "G" codes, physicians report actual patient data.

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Most doctors are familiar with the MOC process, said Dr. Christine Cassel, shown here at a 2009 Senate hearing.

In 2008 (the first year of the registry), 260 family physicians participated. Participants could report on 15 patients over a 6-month period to receive half of the bonus, or 30 patients over a year to receive the full bonus, Dr. Hagen said in an interview.

Last year, all participants were required to report on the full year; about 720 family physicians participated, he said.

Dr. Hagen said that he doesn't expect the ABFM process to change anytime soon. "Our PQRI process will continue as it is until we see the final rules and regulations" regarding implementation of the new law.

Dr. Hagen said that he envisions a future in which physicians can submit data for PQRI, for MOC, and for meaningful electronic health records in one fell swoop.

That will be a big relief, he said. As the three programs are currently structured, "nobody wants the same information in the same way, and it's just driving people nuts." ■