No Safety Concerns for H1N1 Vaccine So Far

BY MIRIAM E. TUCKER

BETHESDA, MD. — Monitoring of influenza A(H1N1) vaccine safety in studies conducted across multiple U.S. government agencies have shown no safety signals of concern so far, nationally or internationally.

The multiple data collection efforts—some pre-existing and others a result of the pandemic H1N1 outbreak—represent "strengthened collaboration and communication among government agencies and internationally, with enhanced capacity for timely signal detection, strengthening, and confirmation," Dr. Hector Izurieta told the Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee.

In addition to the FDA, other participating agencies include the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, the Centers for Medicare and Medicaid Services, and the Indian Health Service, said Dr. Izurieta, who is chief of the FDA's analytic epidemiology branch.

"Not every system has the same degree of sophistication, or of populations served. The studies are complementary, and also provide redundancy that is helpful in detecting signals," he said in an interview.

For example, the CDC is currently evaluating 205 reports of serious adverse events following H1N1 vaccine from in the Vaccine Adverse Events Reporting System (VAERS). Of those, 70 are among pregnant females. All but 13 were nonserious and none involve maternal death.

Eight deaths following receipt of H1N1 vaccine have been reported to VAERS, including two following live attenuated (intranasal) vaccine and six after inactivated (injected) vaccine.

The three that have been evaluated so far had severe underlying conditions. There have been 29 reported cases of anaphylaxis, which is consistent with published estimates following other vaccinations, he said.

Two cases of "possible or probable" Guillain-Barre syndrome have been reported within one day of H1N1 vaccine receipt. The short interval "decreases but does not eliminate" the possibility that H1N1 vaccine caused the event. However, to date the rate of reported GBS cases is less than the background rate in the population, Dr. Izurieta said.

Dr. Claudia Vellozzi, of the CDC's Immunization Safety Office, described the Vaccine Safety Datalink, an active surveillance program of both the CDC and managed care plans that cover more than 9.5 million people, or 3.1% of the U.S. population, is used to follow up on safety "signals" obtained from VAERS.

Thus far, VSD analyses of pregnant women and of 10 GBS cases identified so far show no significant associations with either H1N1 or seasonal vaccine, although it's still early. The VSD will continue to monitor both vaccines on a weekly basis, she said.

Dr. Richard Platt of Harvard Pilgrim Health Care and Harvard Medical School, Boston, described a new safety analysis that his institution will conduct in collaboration with health plans covering approximately 25 million people and nine state immunization registries comprising a total population of 14 million.

That system, called Post-Licensure Rapid Immunization Safety Monitoring (PRISM), is looking specifically for Guillan-Barre syndrome, as well as other neurologic problems and pregnancy complications following receipt of H1N1 vaccine, Dr. Platt said.

Another new effort, within the Indian Health Service, will use electronic health records to monitor selected health events following vaccine receipt among a population of 1.4 million, Dr. Izurieta said.

In all, these efforts have coalesced as a result of the H1N1 vaccine outbreak but are expected to continue beyond to monitor safety of all vaccines given to the U.S. population as well as populations worldwide, he said in the interview.

"We are investing ourselves with the idea that this goes beyond H1N1. This is for vaccine safety in general, going well beyond passive surveillance." ■

Boehringer Ingelheim

NEW FOR HYPERTENSION

APPROVED & AVAILABLE

TWYNSTA® (telmisartan/amlodipine) tablets are indicated for the treatment of hypertension, alone or with other antihypertensive agents.[1]

TWYNSTA may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.[1]

IMPORTANT SAFETY INFORMATION

WARNING: AVOID USE IN PREGNANCY
When used in pregnancy, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, TWYNSTA® (telmisartan/amlodipine) tablets should be discontinued as soon as possible (*See Warnings and Precautions*).

Correct any volume depletion or salt depletion before initiation of therapy. Observe for signs and symptoms of hypotension, in particular in patients with severe aortic stenosis.

In patients with heart failure, renal artery stenosis or severe renal impairment, care should be exercised with dosing of TWYNSTA. In patients with severe heart failure, decline in renal function and, rarely, acute renal failure and/or death has been associated with inhibiting the renin-angiotensin system.

TWYNSTA is not recommended as initial therapy in hepatically impaired patients.

Use of telmisartan with an ACE inhibitor is not recommended.

Uncommonly, increased frequency, duration, and/or severity of angina or acute myocardial infarction have developed in patients treated with calcium channel blockers, particularly patients with severe obstructive coronary artery disease.

Please see Brief Summary of Prescribing Information on adjacent page.

Reference: 1. Twynsta PI. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; 2009.

NEW TWYNSTA® (telmisartan/amlodipine) tablets
40/5 • 40/10 • 80/5 • 80/10 mg

Copyright © 2009, Boehringer Ingelheim Pharmaceuticals, Inc. All rights reserved. Printed in U.S.A. (10/09) TW68414