ISMP cautions pharmacists about flu and COVID-19 vaccine mix-ups after cases reported

ISMP has reported multiple mix-ups between the influenza vaccine and COVID-19 vaccines since the former became available in September 2021. All of the mishaps arose in community and ambulatory care pharmacies, according to ISMP.

“Most of the mix-ups occurred in patients who consented to a flu vaccine but received one of the COVID-19 vaccines instead; however, in 2 cases, patients received the flu vaccine instead of the intended COVID-19 vaccine,” said ISMP in a news release.

CDC now states that both the flu and COVID-19 vaccines can be administered during the same patient visit without regard to timing.

An ISMP article discussed possible causative factors for the events as well as safe practice recommendations for practitioners.

ISMP noted, however, that because most of the errors were reported by consumers, details about the contributing factors were not provided in many cases.

Possible causative factors
- Increased demand and coadministration of the vaccines
- Syringes near each other
- Unlabeled syringes
- Distractions
- Staffing shortages

Safe practice recommendations
- Provide staffing support.
- Separate vaccination areas.
- Label the syringes.
- Separate the vaccines.
- Identify the patient and requested vaccine.
- Involve the patient/parent in the checking process.
- Document lot number/expiration date.
- Scan the barcode.
- Provide the intended vaccine.

Any vaccine errors should be reported internally as well as to the FDA Vaccine Adverse Event Reporting System (VAERS), which is mandatory for errors with the COVID-19 vaccines available under an EUA. ISMP also asks providers to report vaccine errors to the ISMP National Vaccine Errors Reporting Program (ISMP VERP).

USPSTF discourages use of aspirin to prevent heart attack or stroke

Health experts now believe that daily use of low-dose aspirin—once viewed as an inexpensive and effective prophylaxis against heart disease—has more potential harms than benefits.

The proposed new draft guidelines from the U.S. Preventive Services Task Force (USPSTF), released on October 12, 2021, apply to patients younger than 60 years with elevated risk for heart disease who may have been prescribed 81 mg to 100 mg of aspirin per day to avert a first heart attack or stroke. For those patients, the draft guidelines suggest that there is a small net benefit to such a regimen, but evaluations should be done on an individual basis.

For patients aged 60 years and older, USPSTF is now discouraging the regimen due to concerns about serious bleeding risks in this age demographic.

USPSTF is also stepping back from its 2016 guidance, where they recommended low-dose aspirin to prevent colorectal cancer, saying additional research is warranted.

The guidelines could affect tens of millions of adults with a high risk for cardiovascular disease.
In case you missed it: New study warns against acetaminophen use during pregnancy

A recent 2021 study published in *Nature Reviews Endocrinology* by Bauer and colleagues sheds light on the debate about acetaminophen use for pregnant women. After reviewing the medical literature on the topic going back 25 years, the research team is urging caution on the use of this common OTC during pregnancy because of the strong link associated with adverse neurological, urogenital, and reproductive outcomes in the resulting children.

Researchers say the findings point to the need for guidelines on the use of acetaminophen to be changed while more research is conducted.

“We believe the potential for harm from continued inaction exceeds the harm that might arise from precautionary action,” the authors write. “We recognize the limitations of the existing epidemiological literature and the need for rigorous meta-analyses … and therefore we call for a focused research effort.”

Roughly 65% of pregnant women in the United States take acetaminophen during pregnancy. Worldwide, the percentage is over 50%. Regulatory bodies such as FDA and the European Medicines Agency have for a long time considered acetaminophen an option for use in pregnancy, while NSAIDs are contraindicated for use in pregnant women in later pregnancy.

The authors say pregnant women should only take acetaminophen when medically indicated.

Uptake of newer diabetes products dominate trends in U.S. adults with diabetes

New research by Sarkar and colleagues published October 12, 2021, in *JAMA Network Open* finds that insulin glargine and other insulin analogs are the most-used forms of insulin in the United States, alongside pen devices as a delivery method.

The findings were derived from the Health National Disease and Therapeutic Index, which includes diagnostic and prescribing information for patients being treated by office-based physicians.

According to the study data, there were a total of 27,860,691 insulin treatment visits for type 2 diabetes from 2016 to 2020. Long-acting analog insulins were indicated in 67.3% of such visits in 2016, and 74.8% of them in 2020. Meanwhile, rapid-acting insulin analogs accounted for 21.2% of insulin-related treatment visits in 2016 and 16.5% in 2020. Intermediate- and short-acting human insulins made up only 3.7% of such visits in 2016 and 2.6% in 2020.

Analog insulins accounted for 92.7% and 86.3% of insulin treatment visits in 2016 and 2020, respectively, while the human insulins accounted for just 3.7% of such visits in 2016, and 2.6% in 2020. Biosimilar analog insulins first appeared in the Health National Disease and Therapeutic Index in 2017 and represented 2.6% of visits that year and 8.2% by 2020.

The proportion of treatment visits for insulin vials/syringes declined from 63.9% in 2016 to 41.1% in 2020, while visits for insulin pens increased from 36.1% to 58.7%.

HPV vaccination program yields positive results on cervical cancer reduction in England

A new study by Falcaro and colleagues published November 3, 2021, in *The Lancet* finds that HPV vaccination greatly reduced the incidence of cervical cancer for young women in England.

An observational study assessed the effect of the HPV bivalent vaccine on clinical outcomes in young women in England, who were offered the vaccine starting in September 2008. Specifically, researchers calculated the rate of cervical cancer and cervical cancer in situ—particularly grade 3 cervical intraepithelial neoplasia (CIN3)—among 3 cohorts of vaccinated females and earlier cohorts who did not receive the HPV vaccine.

Using a combined 13.7 million years of follow-up data for women aged 20 to 29 years, investigators determined relative reduction rates in cervical cancer, stratified according to age at vaccination. For the young women vaccinated at 12 to 13 years, the rate came down by 87% versus 52% for those vaccinated at 14 to 16 years and 34% for those vaccinated at 16 to 18 years. For CIN3, the risk reductions were 97%, 75%, and 39% in those respective age brackets.

The data underscore the success of England’s HPV immunization program, which was particularly effective among females vaccinated at 12 to 13 years. The campaign has nearly eradicated cervical cancer among women born since September 1995 and markedly reduced the incidence of CIN3.
New impurities lurking in some heart medications

Over the past few years, blood pressure medications have been recalled due to concerns about N-nitrosodimethylamine (NDMA), a probable carcinogen. But this may not be the only impurity to be worried about in these medications. As drug companies have addressed the NDMA issue, they have also found potentially dangerous chemicals known as azido impurities.

Regulatory authorities say azido impurities are mutagenic, indicating they can alter people’s DNA and potentially raise their cancer risk. Earlier this year, Canada and European countries asked drugmakers to recall certain heart medications after finding azido impurities; the United States has yet to do so.

According to documents, an FDA inspector found that at least one large India-based manufacturer, Hetero Labs Ltd., used a faulty system for controlling the impurities when the inspector visited the production plant in August 2021. The plant makes the active ingredient for the blood pressure medication valsartan. Health Canada announced recalls of valsartan, an ARB, in May 2021 for elevated levels of azido impurities.

Other drugs in the same class, losartan and irbesartan, were recalled as well over the past few months. Teva Pharmaceuticals recalled ARBs in the United Kingdom in June 2021, followed by Sanofi in August 2021, according to UK’s Medicines and Healthcare products Regulatory Agency.

CDC: Drug overdose deaths hit new high

Preliminary CDC data show that drug overdose deaths in the United States hit a record high in the 12-month period ending in March 2021.

According to CDC, there were 96,779 fatal overdoses during that period—a nearly 30% increase from the 74,679 overdose deaths reported in the 12-month period ending in March 2020. In the 12-month period ending this past March, all but 3 states—New Hampshire, South Dakota, and New Jersey—reported increases in overdose deaths. CDC noted the figures are provisional and said the final total could be closer to 99,100 overdose deaths.

Drug overdose categories include heroin; natural opioid analgesics, including morphine and codeine; natural and semisynthetic opioids, including drugs such as oxycodone, hydrocodone, hydromorphone, and oxymorphone; methadone; synthetic opioid analgesics other than methadone, including drugs such as fentanyl and tramadol; cocaine; and psychostimulants with abuse potential, including methamphetamine.

Study examines association of self-reported COVID-19 and ongoing physical symptoms

A study published in JAMA Internal Medicine suggests that persistent physical symptoms after COVID-19 infection should not be automatically attributed to COVID-19 infection. The French study investigated whether constant physical symptoms during the COVID-19 pandemic are due to an individual’s self-diagnosis or to actual, clinically confirmed infection.

Researchers considered nearly 27,000 adults from the country’s CONSTANCES population-based cohort. Volunteers were screened for anti-SARS-CoV-2 antibodies between May and November 2020. Between December 2020 and January 2021, they reported whether they suspected having COVID-19 and if they suffered fatigue, breathlessness, or other symptoms during the previous 4 weeks that lasted at least 8 weeks.

The cross-sectional analysis found that self-belief of infection positively correlates to stubborn physical symptoms, also known as “long COVID.” A blood test confirming infection, however, was positively associated only with persistent anosmia, or loss of smell.

The findings suggest that lingering physical symptoms after COVID-19 may have more to do with a person’s belief in having been infected with COVID-19 than with actually having been infected as verified by serology screening. This belief may directly influence perception, the study authors report, or encourage maladaptive health behaviors.

“Patients in this situation should be offered a medical evaluation to prevent their symptoms from being erroneously attributed to COVID-19 infection and to identify cognitive and behavioral mechanisms that may be targeted to relieve the symptoms,” the study authors write.