

Environment, health, & safety

Vaccines, antivirals are crucial aspects of influenza strategy

By Katie Brewer, MSN, RN

Vaccines and antivirals are important interventions to thwart a widespread outbreak of influenza, which is capable of causing massive economic and social disruption and strain on an already overtaxed healthcare system, not to mention many illnesses and deaths.

These interventions, known as “countermeasures” in the lingo of emergency preparedness, are not much different from the things used to prevent and treat seasonal influenza every year. What makes these countermeasures different in the pandemic scenario is that there will be unprecedented numbers—hundreds of millions, perhaps—of people receiving them. This changes the game for liability, regulation, and safety monitoring, since use in so many people will create different implications for the companies that make these products and the people in the community who administer them.

The vaccine for H1N1 has undoubtedly dominated the attention of the media and the public, and is the primary countermeasure for preventing people from getting sick with H1N1. Two common myths—that vaccine safety cannot be assured and the fear that this is a new, untested product—are often cited as reasons for declining or being suspicious of the immunization. But the fact is that the H1N1 vaccine is just a variation of the seasonal vaccine that millions of people get each year. It was approved by the Food & Drug Administration as a “strain change” to the current license that several companies have to produce and distribute seasonal vaccine in the United States, in a process used every year to approve seasonal vaccine. A “strain change” indicates that all the inactive ingredients and manufacturing processes are the same, but it is just the antigen, or strain of influenza, that is different. There is no reason to believe that the safety of the H1N1 vaccine will be any different than that of the seasonal vaccine—which has had a very good safety record for more than a decade.

Antiviral drugs are another important pharmaceutical intervention. While antivirals can be used as prophylaxis in some instances, the more common use is to treat someone who is already ill. However, when antivirals are in wide use to treat a strain of influenza, the strain can develop resistance. This risk of overuse of antivirals is often cited by critics as a reason not to use them as the main way to prevent influenza.

So what does this mean for liability? What protections

are available for the people who may have an injury or illness resulting from the use of these products? What does this mean for nurses who will be administering these products?

It is true that the federal government granted the vaccine and antiviral manufacturers protection from liability for injuries or illnesses directly caused by their products. This was done through the 2005 Public Readiness and Emergency Preparedness Act (PREP Act), and provides protection for those interventions that are designated as countermeasures during a public health emergency. The PREP Act states that the federal government assumes responsibility for these illnesses or injuries, barring willful misconduct, and will compensate claims accordingly. Individuals can be compensated for lost wages from missing work, out-of-pocket medical expenses and, if need be, survivor benefits.

While this may seem like letting manufacturers off the hook, one benefit it provides individuals is a faster and less expensive way of receiving compensation than going to court. It also protects nurses who administer vaccines or antivirals from being named in lawsuits (again, barring willful misconduct). Also, it should be noted that for more than 20 years, the Vaccine Injury Compensation Program has compensated individuals injured by vaccines in a similar fashion to the PREP Act. To learn more about the PREP Act and how it compensates people, go to www.hrsa.gov/countermeasurescomp/.

Even though the H1N1 vaccine is expected to be very safe, ongoing safety surveillance is a priority for government health officials. Nurses play an important role in this process. Healthcare providers and the public are encouraged to use the Vaccine Adverse Event Reporting System (VAERS) to report events that occur postvaccination, so that trends or problems can be picked up on and quickly investigated.

VAERS, while criticized by its skeptics as a passive system that cannot guarantee that all adverse events are captured, allows anyone to file a report, and any postvaccination event can be reported. (VAERS accepted a report of a man who believed he was turning into the Incredible Hulk after a vaccine!) Nurses should report any event—even if they are not sure if the vaccine caused the event—and should encourage those who get the vaccine to do the same. The VAERS website is www.vaers.hhs.gov; information on VAERS is also on the H1N1 vaccine information statement (which is required by law to be given to anyone receiving the vaccine). ★

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