USDA Fact Sheet: How Avian Influenza Vaccine is Developed
May 2015

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Fact Sheet

The USDA Agricultural Research Service (ARS), Southeast Poultry Research Lab (SEPRL) is working to evaluate and develop avian influenza (AI) vaccines. As part of the SEPRL mission, the lab routinely evaluates existing AI vaccines against new and emerging AI viruses as well as develops vaccine seed strains that offer the best protection for poultry against AI. There are many steps that need to be taken when SEPRL scientists evaluate or develop AI vaccine. It occurs in many stages and because the next steps are dependent on the outcomes of these stages, USDA cannot predict when a vaccine has reached the stage for use in poultry.

Evaluation

First, SEPRL evaluates new avian influenza viruses by sequence analysis and serologic characteristics, which provides a good estimation of how close the new viruses are to other influenza viruses and existing vaccines.

Before a vaccine can be made, scientists must isolate and study the virus in question and learn how it causes disease. Based on the preliminary data, SEPRL sets up avian influenza vaccine studies to learn how to best protect birds against the disease:

- What is the best quantity of vaccine to give?
- What is the best method for administering the vaccine?
- Does one dose of the vaccine work?
- Do additional doses help even more?
- How long does protection last?

Researchers test existing AI virus seed strains, viruses shown to be effective vaccines, from the United States and other countries. In some cases, SEPRL must develop new vaccine seed strains or coordinate with commercial companies to develop new vaccines if existing vaccines are not adequate.

Developing Vaccines

AI vaccines are made using the same components found in the disease-causing virus, but in a form that is not harmful to birds. Scientists use different strategies to develop the vaccines:

- Inactivating the virus—the virus is completely inactivated or killed. By killing the virus, it cannot reproduce itself or cause disease.

- Using partial virus—Only one part of the virus is removed and used as a vaccine. This process can be used when an immune response to one part of the virus is responsible for protection against disease. One approach is to use other vaccine viruses to express the influenza proteins, viral-vectored vaccines, which provides the benefits of a live vaccine.

SEPRL also uses the challenge strain as the seed for a killed vaccine with the expectation that the homologous vaccine will provide the best results. A homologous vaccine is made from the same virus that is causing disease.

Measuring Efficacy

Vaccine effectiveness is measured by reduction in clinical disease and reduction in the amount of virus shedding after experimental challenge. Detection of the amount of virus found in body secretions, virus shedding, is important in virus transmission and infection. Most vaccines do not prevent infection, so if birds are challenged with a high dose, they will become infected. However, a good vaccine will reduce the amount of virus shedding to a greater degree.

Preliminary vaccine results and virus characterization allows SEPRL to provide recommendations on the best available vaccines and the best way these vaccines can be used in the field.

Because of the number of different avian species and the differences in production methods, a single vaccine or vaccine protocol cannot be used and the vaccination program needs to be targeted.

With the interest in being able to differentiate vaccinated from infected animals, the so-called DIVA strategy, companion diagnostic tests need to be developed or validated for field use.

SEPRL conducts vaccine seed strain development and testing as routine research activity, but does not manufacture AI vaccines nor decides when or if vaccines should be used in field. The licensing and use of a vaccine is determined by USDA's Animal and Plant Health Inspection Service.