fact sheet

PARA SU INFORMACIÓN

Spongiform Encephalopathy and Immunizations

What is Bovine Spongiform Encephalopathy (BSE)?

BSE (bovine spongiform encephalopathy) is a progressive neurological disorder of cattle, and has been called "mad cow disease." Its symptoms are similar to "scrapie," a brain disease that occurs in sheep. Cattle affected by BSE experience progressive degeneration of the nervous system. Affected animals may display changes in temperament, such as nervousness or aggression, abnormal posture, incoordination and difficulty in rising, decreased milk production, or loss of body weight despite continued appetite. Affected cattle die. There is neither any treatment nor a vaccine to prevent the disease.

The incubation period (the time from when an animal becomes infected until it first shows disease signs) is from 2 to 8 years. Following the onset of clinical sign, the animal's condition deteriorates until it either dies or is destroyed. This process usually takes from 2 weeks to 6 months. Most cases in Great Britain gave occurred in dairy cows between 3 and 6 years of age.

Does BSE or a similar disease occur in humans?

Yes. The human diseases are very rare and occur sporadically worldwide at a rate of about one case per one million people. BSE belongs to a group of progressive degenerative neurological diseases known as transmissible spongiform encepalopathies (TSEs). TSE diseases are always fatal. The TSE diseases include scrapie, which affects sheep and goats; transmissible mink encephalopathy; feline (cat) spongiform encephalopathy; and chronic wasting disease of deer and elk. There are six TSE diseases that affect people: kuru, classical Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob (vCJD), Gerstmann-Straussler-Scheinker syndrome, fatal familial insomnia, and sporadic fatal insomnia.

What is Creutzfeldt-Jakob disease (CJD)?

CJD belongs to a group of neurological diseases known as transmissible spongiform encephalopathies (TSEs). TSE disease in humans are very rare but fatal. CJD is a slow degenerative human disease of the central nervous system. It is classified as a transmissible spongiform encephalopathy because of the characteristic spongy degeneration of the brain that occurs as the disease progresses. CJD occurs sporadically worldwide at a rate of 1 case per 1 million people per year.

What is variant Creutzfeldt-Jakob disease (vCJD)?

Variant Creutzfeldt-Jakob disease (vCJD) is another rare and fatal human neurological disease that falls into the category of transmissible spongiform encephalopathies (TSEs). Like Creutzfeldt-Jakob disease (CJD), vCJD causes a spongy degeneration of the brain. vCJD is a new disease which was first described in March 1996.

What is the association between BSE in cattle and vCJD in humans?

Some cases of variant Creutzfeldt-Jakob disease have been attributed to, among other possibilities, eating beef products from cattle infected with the agent of BSE. However, no evidence exists that cases of vCJD are related to the use of vaccines, and no cases of vCJD have ever been reported in the United States.

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Why are animal products used in the manufacture of vaccines?

Vaccines contain either killed or weakened forms of disease-causing bacteria or viruses, or components of these that stimulate a response by the body's immune system, which then protects against the development of disease. Although synthetic media have been developed for growth of many medically important microorganisms, some still require additional nutrients, which are provided by animal-derived products such as serum and blood. No bovine material has ever been used as an active ingredient of any vaccine.

In the late 19th century, microbiologists began to grow bacteria in the laboratory. The early bacteriologist tried to mimic as closely as possible the infected person's tissues by using sugars, salts, and various meat extracts to make "growth media." These kinds of conditions were quite successful in growing bacteria and then viruses in the lab, because these media supplied the many necessary nutrients.

Which bovine derived materials are used in vaccine manufacture?

Animal-derived products used in vaccine manufacture can include amino acids, glycerol, detergents, gelatin, enzymes and blood. Cow milk is a source of amino acids, and sugar such as galactose. Cow tallow derivatives used in vaccine manufacture include glycerol. Gelatin and amino acids come from cow bones. Cow skeletal muscle is used to prepare certain complex media. Many difficult to grow microorganisms require the addition of serum from blood to the growth media.

Do all bovine materials have the same risk of transmitting the BSE agent?

Scientists have found that different bovine tissues contain different amounts of the BSE agent. It is generally believed that the highest amounts of infectivity are found in the brain and spinal cords from animals in the final stages of clinical disease. Some tissues such as skeletal muscle and milk have never been shown to have any infectivity. However, the slaughtering and butchering methods used to obtain tissues and prepare materials can affect the amount of infectivity that may be present. Also the production processes used to prepare bovine-derived materials (such as heat sterilization and chemical treatment) may reduce or remove infectivity.

Which countries are on the U.S. Department of Agriculture list of countries where BSE is known to exist or where a substantial risk for BSE exist?

Initially, the USDA list included only countries and other regions in which BSE was known to exist, such as the United Kingdom, France, Switzerland, and the Republic of Ireland. In 1998, the USDA expanded the list to include countries and other regions in which BSE had not been documented but in which import requirements were less restrictive than requirements that would be acceptable for import into the United States or in which there was inadequate BSE surveillance. Thus, all European countries, even those that have had no reported cases of BSE are currently on the USDA list, which is published in the Code of Federal Regulations, title9, part 94 (9C.F.R., part 94).

What is the chance/risk that a vaccine on the market in the US contains the BSE agent?

Both the FDA and its joint advisory committee concluded that the risk for vCJD posed by vaccines is theoretical and remote. Studies of the BSE agent have shown that infectivity depends on nature of material used, how much is used and the route of administration. Other factors, such as the country of origin of the cattle used to supply the manufacturing material, also to be factored into any risk estimate.

Both European Community and the US Pharmaceutical industry have presented risk assessment calculations which attempt to account for all these factors. In 1999, the Council on Scientific Affairs (CSA) of American Medical Association considered the risk of BSE to public health and determined that the current risk of transmission of BSE in the US is minimal, concluding that adequate guidelines exist to prevent high risk bovine materials from contaminating products intended for human use. The report from the CSA did not address the possibility that regulated industry might not follow all of the recommendations made by the FDA. However, both FDA and the joint advisory committee meeting have considered the risks posed

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by bovine material in vaccines and concluded that any risk is remote and theoretical.

What is the risk of getting vCJD if a vaccine contained the BSE agent?

There is no evidence to date that vaccines have contributed to the cases of vCJD seen in Europe. Nor is there evidence that any vaccines harbor the BSE agent. Vaccines are given a very limited number of times via the intramuscular, subcutaneous or oral route. Even in experimental studies, these routes of administration are less effective at spreading the agent than the intracerebral route usually used to assess infectivity in animal studies. The amount of infectivity present and the efficiency with which the BSE agent passes from cow material to humans will also affect the likelihood of infection.

How did FDA derive its risk estimates and decide the risk of vCJD from vaccines was remote and theoretical?

Scientists, regulatory authorities in Europe and the pharmaceutical industry of the U.S. have considered the risks of BSE in pharmaceutical products. In estimating these risks it is necessary to consider the country of origin of any bovine material, the type of bovine tissue used, the steps used to process the bovine tissue, the amount of bovine derived material used and the stage of vaccine manufacture at which the bovine material is used. Using previously published methods for calculating theoretical risk of cases of vCJD from pharmaceutical products, FDA has calculated a conservative estimation of the risk of a vaccine causing a case of vCJD. These estimates were presented in public session at the joint advisory committee meeting on July 27, 2000. FDA believes these estimations are a realistic worst case scenario and that the real risk any US licensed vaccine could cause vCJD is even lower than the estimates presented (link to risk assessments and transcripts).

What steps has the FDA taken to ensure that people are not exposed to the BSE agent in vaccines?

FDA has taken a number of measures to minimize any chance that the BSE could be introduced into biologic products during manufacture. Most recently, FDA has directed manufactures not to use products from animals born, living, or slaughtered in countries where BSE has occurred, or countries where there is a high or unknown risk of BSE. In this recent action, the FDA has requested that vaccine manufactures replace bovine-derived materials obtained from countries on the USDA list with materials obtained from countries not on the USDA list. This recommendation, which is consistent with existing FDA guidance first issued in 1993 on the sourcing of bovine-derived materials, is intended to reduce even the remote risk for vCJD from vaccines.

My child was just immunized. Should I be worried?

No. The Public Health Service (PHS) recommends that all persons continue to be vaccinated according to current schedules. No evidence exist that cases of vCJD are related to the use of vaccines, and no cases of vCJD have ever been reported in the U.S. In addition, there is no evidence to date that vaccines have contributed to the cases of vCJD seen in Europe. Nor is there evidence that any vaccines harbor the BSE agent. As a result, PHS has no preference for using one licensed vaccine product over another based on the source of bovine-derived materials used in vaccine production.

Why is the Food and Drug Administration now requiring that vaccine manufactures not use bovine-materials from cattle born, raised, or slaughtered in countries where BSE is known to exist or where there is a risk that BSE may exist?

The FDA is taking this action as a precautionary measure. This action is intended to reduce even the remote risk for vCJD from vaccines.

When will vaccine manufactures finish replacing cow-derived materials in vaccines with materials obtained from countries free of BSE?

All of the affected manufacturers have agreed to implement these changes or have already done so. FDA anticipates that most of these changes will be completed in 2001.

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Should I delay an immunization order to reduce the chances of being exposed to the BSE agent?

No. The Public Health Service (PHS) recommends that all persons continue to be vaccinated according to current schedules. No evidence exists that cases of vCJD are related to the use of vaccines, and no cases of vCJD have ever been reported in the U.S. In addition, there is no evidence to date that vaccines have contributed to the cases of vCJD seen in Europe. Nor is there evidence that any vaccines harbor the BSE agent. As a result, PHS has no preference for using one licensed vaccine product over another based on the source of bovine-derived materials used in vaccine production.

Why is FDA leaving vaccines on the market that did not follow its own recommendations regarding sourcing of bovine-derived materials?

The FDA has looked at the benefit of vaccines and the risk of vCJD from vaccine use. Vaccines have a proven benefit in reducing the incidence of serious, often life-threatening diseases. Conversely, the Public Health Service, FDA, and the members of FDA'S advisory committees on TSE and Vaccines and Related Products (VRBPAC) believe the risk that anyone will get vCJD from a vaccine is remote and theoretical. Failure to obtain recommended vaccinations with licensed vaccines puts a person at risk for serious disease. Without routine vaccination, the incidence of disease would increase. This was seen in Sweden, Japan and the UK when the number of children vaccinated against pertussis decreased due to concerns about vaccine adverse events associated with the whole-cell DTP vaccines from the market could cause insufficient supply and potentially increase the number of unvaccinated or under vaccinated individuals at risk from preventable diseases.

Where can I obtain additional information?

Information about BSE or vaccines manufactured with bovine-derived materials from countries on the U.S. Department of Agriculture's list can be obtained from the FDA web site at http://www.fda.gov/cber/BSE/BSE.htm or from CBER's Office of Communication, Training and Manufacturers Assistance at (800) 835-4709.

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