Update on FDA's vCJD Risk Communication on US Plasma-Derived Factor VIII and UK Plasma-Derived Factor XI

ACBSA

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TOPICS

- Background
- Development of key points, questions and answers
- Review of
  - Key Points
  - Questions and Answers
- Communication Strategy
- Progress in FXI Risk Communication

Background: Draft Risk Assessment for U.S. Plasma-Derived Factor VIII and vCJD

- Emergence of vCJD transmission via red cell transfusion in December 2003 in the UK
- Concerns vCJD may potentially be transmitted through plasma-derived products including clotting factors
- Clotting factors such as plasma-derived FVIII (pdFVIII) made from human plasma are used in large quantities by many US patients
- Transmission of vCJD via FVIII is a potential hazard but magnitude of potential risk was unknown
- Fall 2004 FDA began developing a risk assessment of potential vCJD risk via pdFVIII manufactured from plasma collected in US

Background: Draft Risk Assessment for U.S. Factor VIII and vCJD

- FDA presented conceptual vCJD-FVIII risk assessment model at February 8, 2005 TSEAC
- FDA sought Committee discussion and advice on several risk assessment inputs at October 31, 2005 TSEAC
- Peer review of FDA Risk Assessment model and document by 3 external experts in Summer 2006
- Presentation of “Draft Quantitative Risk Assessment of vCJD Risk Potentially Associated with the Use of Human Plasma-Derived Factor VIII Manufactured Under United States (US) License From Plasma Collected in the US” at December 15, 2006 TSEAC
- FDA risk communication activities

Risk Communication Key Points and Q's and A's Development

Input from

- HHS (including FDA, CDC, NIH)
- Special Government Employees including patient advocates and TSEAC members
- Experts in risk communication

Asked SGEs:

Do you think the Issue Summary and the Summary Information documents adequately convey the findings, including the uncertainties, of the Risk Assessment?

Are the documents easily understood?

Comment on any aspects of the documents that may lack clarity.

Do you have suggestions about the delivery of the information from the point of view of a patient/family member?

Input from SGEs, TSEAC members, and risk communication experts helped to clarify and improve the public health messages

Key Points - pdFVIII

- In recent years, questions have been raised concerning the risk of variant Creutzfeldt-Jakob disease (vCJD) (a rare but fatal brain infection) to hemophilia A and von Willebrand disease patients who receive US licensed plasma-derived Factor Eight (pdFVIII, Antihemophilic Factor) products.

Key Points - pdFVIII

- Based on a risk assessment, the US Public Health Service (PHS), including FDA, CDC, and NIH, believes that the risk of vCJD to hemophilia A and von Willebrand disease patients who receive US licensed pdFVIII products is most likely to be extremely small, although we do not know the risk with certainty. vCJD risk from other plasma derived products, including Factor IX, is likely to be as small or smaller.

Key Points - pdFVIII

- Contacting a specialist in hemophilia or von Willebrand disease at a Hemophilia Treatment Center is a good way to learn about new information as it becomes available.

Additional Information Topics

- Why FDA has conducted a risk assessment about the potential transmission of vCJD through plasma derivatives
- FDA actions to reduce the potential of vCJD risk from blood components and plasma derivatives
- Uncertainties in the risk assessment
- Suggestions to patients and health care providers about further actions to take and where they can obtain more information
- Current status of vCJD risk

Questions and Answers

- What is vCJD and how is it spread?
- How does vCJD differ from Creutzfeldt-Jakob disease (CJD)?
- How many people in the US use pdFVIII products?
- Is it known that pdFVIII can transmit vCJD?
- What is the likelihood that a patient who receives pdFVIII could become infected with vCJD because of the potential risk for vCJD from the product?
- Why does FDA recommend deferral of some blood donors?
- Why does FDA recommend different deferral criteria for Source Plasma donors, whose plasma is used exclusively for further manufacturing, compared with blood donors whose blood is intended for transfusion?
- Why did FDA do a vCJD risk assessment for pdFVIII?

Questions and Answers

- What is the risk of vCJD to patients in the US who receive blood components like red blood cells and plasma?
- Why is FDA informing patients, healthcare providers, and the public about vCJD and pdFVIII now?
- Should hemophilia A or von Willebrand Disease patients inform their primary health care providers about a possible vCJD exposure from US licensed pdFVIII?
- Do patients who receive pdFVIII need to do anything special when seeking dental or surgical care?
- What can recipients of pdFVIII do with this information?
- What are Hemophilia Treatment Centers, and where can I find out about them?
- Where can I find more information about vCJD and pdFVIII?

Communication Strategy

- Key Points, Questions and Answers, Risk Assessment, and Issue Summary are posted on an FDA web page
- Hemophilia Treatment Centers have been notified about this issue, have provided input, and have disseminated information
- Patient advocacy organizations have also been briefed, and have helped to publicize these findings through newsletters and other media
- PHS has done outreach to trade and physician organizations
- The Key Points and Questions and Answers lists sources for further information and answers to questions

Webpage (Posted on 3/15/07)

http://www.fda.gov./cber/blood/vcjdrisk.htm

Content:

- Documents Regarding US Licensed pdFVIII, and Other US Licensed Plasma Derivatives Including pdFIX
  - Potential vCJD Risk From US Licensed Plasma-Derived Factor VIII (pdFVIII, Antihemophilic Factor) Products: Summary Information, Key Points
  - Risk Assessment (PDF, 582 KB)
  - Risk Assessment Appendix (PDF, 623 KB)
  - Questions and Answers on vCJD and pdFVIII
  - Questions and Answers on vCJD and Plasma Derivatives Other than pdFVIII
- Guidance on Donor Deferral Related to CJD and vCJD
- Other Sources of Information
- Patient Organizations

Factor XI Risk Communication

Issue

- There is a possible health risk to approximately 50 individuals who, between 1989 and 2000, received an investigational (non-U.S. licensed) product, plasma-derived Factor Eleven (pdFXI), made in the UK to prevent or treat bleeding due to a rare problem, a deficiency of FXI.

Issue

- The pdFXI was made using plasma from donors in the UK, where the human disease vCJD has occurred.
- The pdFXI product was **not** made from the plasma of anyone known to have developed the disease and no one who received this product is known to have become infected.
- Although the product used was **not** made from plasma of anyone known to have developed vCJD, it is still possible that a person using the pdFXI product could have been exposed to the agent that causes vCJD if someone who felt well was carrying the infection at the time of blood donation.

CBER Response

- FDA used a computer model to conduct a risk assessment.
- FDA reported the preliminary risk assessment results in a TSEAC open session in February 2005. Following input from the TSEAC in February and October 2005, FDA revised its risk assessment.
- TSEAC advised FDA to consult with SGEs, including patient advocates, to obtain input on risk assessment and communication materials (message points).

CBER vCJD Risk Communication Plan for UK Plasma Derived FXI

- CBER completed a draft risk assessment “Potential Exposure to the variant Creutzfeldt-Jakob Disease Agent in United States Recipients of Factor XI Coagulation Product Manufactured in the United Kingdom” http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4088b1.htm (posted in 2005)
- CBER has revised the risk assessment and has finalized communication materials with input from patient advocates and communication experts.

CBER vCJD Risk Communication Plan for UK Plasma Derived FXI

- CBER is communicating with IND holders to share information with them, answer questions, and suggest they contact patients (subjects)
- FDA's webpage will be updated to contain finalized materials after communicating with IND holders
- Hemophilia Treatment Centers, and patient advocacy organizations will be notified about the web page posting

Summary

- FDA has prepared risk communication materials regarding vCJD and US pd FVIII and investigational UK pdFXI, with input from TSEAC, PHS, communication experts, and SGEs
- These materials as well as links to other sources of information are available on an FDA webpage
- FDA will continue to update risk communication material as new information becomes available