CANADIAN STUDY SHOWS RISK OF PRION DISEASE FROM URINE-DERIVED, INJECTABLE FERTILITY PRODUCTS

Vancouver, BC - Women who are injected with urine–derived fertility products may be at risk of developing prion disease, according to a just–released study by an international research team from Canada, France and the United States.

The study, published in the Public Library of Science (PLoS) ONE, for the first time documents the presence of prion protein in urinary–derived fertility products. Prion protein is naturally found in the human body in a harmless form, but is the major constituent of infectious prions in an aggregated misfolded form. Prions are the infectious agents responsible for such transmissible and fatal neurodegenerative diseases as Creutzfeldt–Jakob disease (CJD) in humans, and bovine spongiform encephalopathy (BSE), commonly known as "mad cow disease," in cattle.

More than 300,000 women in Canada and the United States each year are prescribed gonadotropins (fertility hormones), including those that are urine–derived. Although CJD has never been reported in a recipient of urine–derived fertility hormones, the study, which looked at dozens of urine–derived drug samples from various pharmaceutical companies and batches, demonstrated a previously unrecognized risk of contamination with infectious prions.

Transmission of human prion disease can occur through blood transfusion as well as through medical or surgical procedures, including injection of hormones - such as gonadotropins - historically extracted from cadaver pituitary glands. In some cases, prions can incubate in humans for decades when transmitted by medical or surgical procedures.

"While urine donors are screened for symptomatic neurological disease, a lengthy symptomfree incubation period for prion disease, during which the urine of affected donors may be infectious, is impossible to exclude without invasive testing," said Dr. Neil Cashman, Scientific Director of PrioNet Canada and Canada Research Chair in Neurodegeneration and Protein Misfolding Diseases at the University of British Columbia, who authored the paper with Dr. Daniel Krewski, Director of the R. Samuel McLaughlin Centre for Population Health Risk Assessment at the University of Ottawa.

According to Dr. Cashman, disorders such as CJD - suffered by roughly one in 10,000 people - typically develop in the 60 to 70 year–old age group. With urine donations tending to come from older women, the risk of transmission of infectious prions may

increase, he said. Unlike the blood–donor system, current urine–collection systems pool the urine of thousands of donors, so individual donors cannot be traced.

"PrioNet Canada's mission is to help manage the risks of prion diseases to Canadians, and society at large," said Dr. Cashman. "By participating in this international research study, we are fulfilling our objectives."

"Based on the information we now have - including the detection of prions in urine of experimental animals, the relative ease of human-to-human transmission, the risk of prion infection through fertility drug injections, and the young age of fertility drug recipients - it is important to consider whether the risks of these products may now outweigh their benefits," Dr. Cashman emphasized, adding that the extent of the risk is at this point difficult to determine and further scientific study is required.

According to Dr. Krewski: "Risk management paradigms are shifting towards more proactive, rather than reactive, approaches that are intended to help regulatory systems anticipate and prevent risks to population health."

"Careful examination of the risk of transmission of human prion disease in pharmaceuticals is now warranted," Dr. Krewski said, explaining that the study results indicate a need for better screening and tracking of prion diseases related to donor–derived pharmaceuticals. Further investigation into the use of synthetic substitutes that can achieve the same therapeutic results and the extent of prion contamination of urine–derived products, is also needed, he added.

media contact:

Gail Bergman
Gail Bergman PR
Tel: (905) 886–1340
Email: info@gailbergmanpr.com

Background

This paper was a result of research into the risk of prion disease transmission led by Dr. Neil Cashman, Scientific Director of PrioNet Canada and Canada Research Chair in Neurodegeneration and Protein Misfolding Diseases at the University of British Columbia. Dr. Daniel Krewski, Director of the R. Samuel McLaughlin Centre for Population Health Risk Assessment and Natural Sciences and Engineering Research Council of Canada Chair in Risk Science at the University of Ottawa, collaborated in the study, examining the

risk management implications of the study results. Dr. Alain Van Dorsselaer, CNRS Research Director at Strasbourg University and Director of the Analytical Sciences Department at the Hubert Curien Institute in France, applied proteomic techniques to document the presence of prion protein in urine–derived fertility drugs.

About PrioNet Canada (www.prionetcanada.ca)

PrioNet Canada is a national network that capitalizes on fundamental, applied, and social research to develop strategies to help solve the food, health safety, and socioeconomic problems associated with prion diseases. The network brings together academia, industry, and public sector partners through its multidisciplinary research projects, training programs, events, and knowledge translation activities. One of Canada's Networks of Centres of Excellence, PrioNet Canada is hosted by the University of British Columbia and the Vancouver Coastal Health Research Institute in Vancouver.