

## GENETICS

# US panel backs 'three-person' embryos

*But regulators cannot approve clinical trials.*

BY SARA REARDON

The US Food and Drug Administration (FDA) should approve clinical trials of a gene-therapy technique to create embryos with genetic material from three people — if certain conditions are met, the US National Academies of Sciences, Engineering and Medicine said on 3 February.

The controversial technique involves replacing the faulty energy-producing mitochondria in a woman's egg with mitochondria from the egg of a healthy donor. The aim is to prevent the transmission of disabling or fatal diseases caused by mutations in a mother's mitochondrial DNA. But concerns about the technique's safety, and the psychological and social implications of children with three genetic parents, have given US regulators pause. Moreover, a federal law approved late last year prevents the FDA from allowing any such trials in humans.

The academy panel suggests limiting the tests of mitochondrial replacement to male embryos as a safety precaution. Male offspring would not be able to pass their modified mitochondria to future generations, because a child inherits its mitochondria from its mother.

The report also outlines several extra steps to monitor the safety of mitochondrial replacement, such as attempting to track the children born as a result of the technique and sharing the resulting data with scientists and the public. If mitochondrial replacement is proved safe in male offspring, it could be expanded to female embryos, the advisory panel said.

By contrast, the United Kingdom last year approved mitochondrial replacement with no restrictions on the sex of a modified embryo.

Shoukhrat Mitalipov, a reproductive-biology specialist at the Oregon Health and Science University in Portland, sees the US advisory panel report as a hollow victory. In 2014, he applied to the FDA to perform a clinical trial of mitochondrial replacement therapy with human embryos — a trial that cannot take place under current US law.

Others disagree with the panel's conclusions. The new report "leapt to the conclusion that things should go forward despite all the concerns", says Marcy Darnovsky, executive director of the non-profit Center for Genetics and Society in Berkeley, California. ■



Pregnant women infected with the Zika virus are being monitored for effects on their unborn babies.

## PUBLIC HEALTH

# Scientists probe Zika link to birth defects

*Mosquito-borne virus is now present in 33 countries.*

BY ERIKA CHECK HAYDEN

Public-health authorities are investigating whether the Zika virus has caused an apparent surge in the number of infants born with microcephaly, or abnormally small heads, in Brazil. But conclusively determining whether the mosquito-borne virus is to blame could take months to years, researchers say.

Concerns rose after Brazil declared a national public-health emergency in November. As of 2 February, officials there had investigated 1,113 of 4,783 suspected cases of microcephaly reported since late last year, and confirmed 404 of them — 17 of which have so far been linked to Zika. On 1 February, a committee convened by the World Health Organization said that a causal link between Zika and microcephaly is "strongly suspected, though not yet scientifically proven".

That is not for a lack of effort. Work now under way includes case-control studies to compare rates of Zika infection in babies who are born with microcephaly and in those without it, as well as genetic sequencing of

the virus and efforts to develop a molecular diagnostic test for Zika infection.

Making progress has been difficult because scientists know relatively little about Zika; there is no easy-to-use test to diagnose infections; and physicians disagree about how to define microcephaly, says Bruno Andrade, an immunologist at the Fiocruz research institute in Bahia, Brazil. "All of this started less than two months ago — that's when everything stepped up," he says. "We are in the middle of this nightmare here."

So far, two lines of evidence support a link between the virus and microcephaly. Microcephaly cases in Brazil started to rise around 6 months after authorities confirmed Zika transmission there, hinting that the defect might have been caused by *in utero* exposure to the virus. And researchers in Brazil have found traces of the virus, or antibodies to it, in the amniotic fluid, brains or spinal fluid of 15 fetuses and babies diagnosed with microcephaly.

This is suggestive, but not conclusive. "Most of us believe it's highly plausible that Zika is the cause of this epidemic of microcephaly,

SCHNEIDER MENDOZA/AFP/GETTY

**CORRECTION**

The News story 'Scientists probe Zika link to birth defects' (*Nature* **530**, 142–143; 2016) wrongly stated that at least seven countries have shown abnormal rates of microcephaly; this has happened only in Brazil. In addition, the article implied that 404 confirmed cases of microcephaly in Brazil could be linked to Zika virus — only 17 of those 404 have been linked so far.