

South Korean scandal rocks stem cell community

More than a month after South Korean cloning star Woo-Suk Hwang admitted to lying about the source of eggs used in his research, allegations continue to surface about the scientific accuracy and ethics of his landmark papers.

As Seoul National University and scientific journals try to sort out the truth, researchers are grappling with the potential ramifications. "It's going to have a chilling effect not just on the public debate [about stem cell research] but also on the scientific community," says Kevin Eggan, a stem cell researcher at Harvard University.

Hwang, a veterinarian, became famous in 2004 for establishing the first stem cell line from a cloned human embryo (*Science* 303, 1669–1674). A few months later, an article in *Nature* suggested that two junior members of Hwang's team—both of whom were authors of the paper—had donated eggs, a crucial resource in the experiment (429, 3; 2004).

Hwang dismissed the report as based on a language misunderstanding and, over the next year, continued to deny the allegations (*Nat. Med.* 11, 464; 2005). In November, he shocked the world when he admitted that the two women in his laboratory had donated the eggs.

Soon after, his 2005 paper, which reported 11 stem cell lines tailored to diseased patients, (*Science* 308, 1777–1783), came into question when corrections to the data fueled rumors that some of the results might have been fabricated.

The second author on the paper, MizMedi hospital's Sung-Il Roh, told reporters that Hwang had fabricated data. Hwang later asked *Science* to



Troubled times: Celebrated cloning researcher Woo-Suk Hwang faces allegations of fraud.

retract the paper, but insists that the problems are a result of small errors in management rather than of scientific misconduct. He says many of the cell lines have been destroyed, but promised to prove the authenticity of his work by thawing some remaining cell lines.

Hwang is now fighting an uphill battle to regain credibility. His once-bustling lab in the hilly Seoul National University campus is roped off. Access by team members has been restricted and closed circuit televisions monitor the lab.

There is some evidence, still unaddressed, that one of the donors might have felt under pressure to give their eggs. According to Roh, a fertility expert who collected the eggs for Hwang, one laboratory member donated her eggs to make up for the hundreds of eggs she had wasted early in the experiment. Roh, who says he tried to dissuade her from donating, quoted her as saying,

"If I don't sacrifice, the project can't succeed."

An investigation by the ministry of health concluded in November that the donations were voluntary. But determining whether there was any pressure from Hwang might require more information. "The egg donor and lab scientist have conflicts of interest," says Seoul National University's Ock-Joo Kim, head of the Korean Association of Institutional Review Boards.

Kyu-Won Jung, a bioethicist at Hanyang University who helped Hwang's group revise its informed consent protocols for the 2005 paper, says the possibility of pressure from senior researchers has to be carefully weighed. "If I were the IRB member who should decide the approval, I would not approve the donation by a lab member," he says.

A resolution might be in the offing. The National Bioethics Committee is looking into Hwang's donor recruitment procedures as well as the role of the Internal Review Board that oversaw his experiment. Seoul National University is also investigating the allegations. That inquiry might include DNA tests that would determine whether the cell lines are true clones.

As *Nature Medicine* went to press, scientists were also questioning the seminal 2004 paper that demonstrated the ability to create stem cell lines from cloned human embryos. "I think at this point, we can assume nothing," says Eggan. "One can never really know how far back an indiscretion goes."

David Cyranoski, Tokyo

Unchecked by guidelines, Indian stem cell scientists rush ahead

With all eyes on the stem cell controversy in South Korea, an Indian physician announced that she had used embryonic stem cells to treat 100 individuals, without ethical oversight from India's regulatory agencies.

Geeta Shroff, director of the Delhi-based infertility clinic Nutech Mediworld, said at a press conference on 16 November that her team had injected stem cells to treat heart, nerve and immune disorders and injuries.

The Indian Council of Medical Research, the country's premier biomedical research agency, had in 2003 rejected Shroff's proposal to use stem cells for treating diabetes, citing inadequate details on the source of the cells and study protocol.

In a bizarre turn, Prasanna Hota, secretary of the health ministry, which oversees the ICMR, attended Shroff's press conference and praised her work. "She's a daring soul who's dedicated herself to this work without any government support," Hota said.

But on 8 December, India's health minister Anbumani Ramadoss told *Nature Medicine* that his ministry does not support treatment with embryonic stem cells until legal guidelines are in place.

India does not yet have enforceable rules to regulate stem cell research, but both the ICMR and the federal Department of Biotechnology have issued guidelines. The two agencies in March 2005 launched a joint project to draft legislation, due to be finalized by December.

In the meantime, all stem cell work is considered experimental and should therefore comply with ICMR guidelines, notes Vasantha Muthuswamy, ICMR's senior deputy director general. Shroff's work violates the agency's guidelines, says Muthuswamy.

This is not the first time Indian scientists have made stem cell claims. In February 2005, for instance, P. Venugopal, director of the prestigious All India Institute of Medical Sciences, said he had treated 35 heart patients

using stem cells from bone marrow. These scientists also did not attain ICMR clearance or publish their results in peer-reviewed journals. In many cases, they cited approval from their institutional ethics committees.

But "who has checked who the members of these committees are?" Muthuswamy asks. "We need a statutory body with adequate powers to punish violators in experiments with humans."

Maverick claims by some scientists will hurt the credibility of all Indian scientists, warns Prakash Narain Tandon, member of an ethics committee at the Medical Council of India.

Tandon has asked the council to investigate whether Shroff is qualified to conduct stem cell studies and whether the facilities are adequate. "People are misutilizing the liberal environment in the country," he says. "Until India has enforceable rules, such violations will continue."

T V Padma, New Delhi