

Japan's transplant law 'is too stringent'...

[TOKYO] Japanese patients awaiting organ transplants are calling for a revision of the legislation covering transplantation following Japan's first legal heart, liver and kidney transplants last week. The organs were all taken from one donor.

Without such revision, patients fear that the stringency of the current regulations, which include the need for a family's permission before organs can be taken from a brain-dead donor, will prevent such operations being widely available.

Last week's operations were carried out successfully at several hospitals across Japan, including hospitals at Osaka University and Tohoku University. They came 16 months after legislation was passed allowing the transplantation of organs from brain-dead patients.

While the event has raised hopes for similar future operations, many still think it unlikely that organ transplants will become the medical norm in Japan.

In addition to the general reluctance of the Japanese population to accept the idea of organ transplants, the lack of donors and the strict regulations imposed by the current legislation are seen as serious impediments.

For example, the transplant law requires written consent from both the donor and the donor's family. This means the family can overrule a brain-dead patient's intention to donate the organs.

The law also prevents children from having transplants by requiring that donors are no younger than 15, while children under six cannot be organ recipients.

The high number of patients requiring organs and the low number of potential donors will continue to force people to turn to hospitals overseas, says Yoshi Aranami from Trio Japan, an organization that coordinates organ transplants for Japanese patients.

According to Aranami, 44 Japanese patients, ranging in age from 1 to 55 years, have gone overseas for heart transplants in the past 15 years, while 200 patients have similarly received liver transplants, most of which were successful.

"We just have to explain to patients that going abroad for transplant operations is a more reliable option than staying in Japan," he says.

But with more than 600 patients requiring organ transplants every year, many feel that the legislation must be relaxed to secure more donors. Patients' support groups, such as the Association to Protect Children with Heart Diseases, are calling for the earliest possible revision of the law, instead of the evaluation the government intends next October.



Organs in demand: more than 600 patients require organ transplants each year in Japan.

Hiromu Nonaka, the chief cabinet secretary, has stressed the importance of creating an environment that will make organ transplants more common in Japan. "We must implement policies that give full consideration towards establishing such transplants in Japan," he said at a press conference last week.

Last week's operations were the first to be carried out since Japan's first heart transplant was performed at Sapporo Medical

College in 1968. The operation, commonly known as the 'Wada transplant' after the chief surgeon, attracted wide public criticism when some individuals suggested that the donor may not have been brain-dead when his heart was removed from his body. There was also speculation that the recipient's condition was not severe enough to require a transplant.

The patient's death led to a murder charge against the chief surgeon Juro Wada, although he escaped prosecution through lack of evidence. But the repercussions were long lasting — the incident resulted in a 30-year ban on organ transplants from brain-dead donors until the new transplantation law was passed in 1997 (see *Nature* 387, 835; 1997), and left surgeons and researchers out of touch with advances in transplantation technology.

"We have come a long way to make this heart transplant happen," says Hikaru Matsuda, the chief surgeon at Osaka University Hospital who performed Japan's second heart-transplant operation last week. But he cites the lack of donors and the shortage of skilled surgeons as problems that must be urgently addressed.

Asako Saegusa

... but the pill may be legalized at last

[TOKYO] The Japanese government is expected soon to lift its ban on the contraceptive pill, almost nine years after the first application for its use. The approval of the drug will come almost 40 years after its release in the West.

According to the Central Pharmaceutical Affairs Council, which advises the health minister, approval will probably be recommended during a council meeting in June, with a view to having the drug on the market by the autumn.

The move comes after public criticism of the speed with which the Ministry of Health and Welfare approved Viagra, the male impotence treatment, just six months after the first application.

In contrast, the contraceptive pill has been entangled in a debate over its possible risks to human health. However, as far back as 1985 legalization seemed on the horizon, and the

Japan Obstetrics and Gynaecology Society and the Japan Motherhood Protection Medical Association were asking the Ministry of Health and Welfare to allow clinical tests (see *Nature* 317, 760-761; 1985). Although the government came close to approving it in 1992, they backed down at the last moment amid fears that the release could lead to an increase in AIDS and other sexually transmitted diseases.

The government has since cited concerns about the contraceptive pill being an endocrine disruptor — the man-made chemicals suspected of affecting human reproductive functions — but such claims have so far been brushed aside by scientists.

The government's reluctance to legalize the pill is said to result from a powerful medical lobby that

opposes threats to its lucrative abortion business. According to the ministry, one in five unwanted pregnancies ends in abortion, with more than 340,000 such operations performed each year.

There is also speculation that conservative politicians concerned about the low birth rate in Japan are strongly opposed to approval of the pill.

Approximately 200,000 women are taking the high-dose pill — available in Japan as a treatment for menstrual disorders — for contraceptive purposes.

A spokesman from Schering, the German pharmaceutical company that is one of the nine drug firms awaiting approval of their oral contraceptive, says they are "crossing their fingers" that the health ministry will keep its promise and not reverse its decision at the last moment again.

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