Japanese regulations on regenerative medicine are failing patients

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The Act on the Safety of Regenerative Medicine (ASRM) targets to regulate medical practices that aim to achieve the "reconstruction, repair, or formation of human body structures or functions" or the "therapy or prevention of human disease or illness" and that use "processed cells" (excluding blood transfusion, hematopoietic stem-cell transplantation, and assisted reproductive technology). Credit: KyotoU ASHBi

Many nations around the world, including Japan, are making significant investments in regenerative medicine. This is largely due to its potential to cure people of spinal injuries and help with recovery from strokes, among other various anticipated benefits. However, it is growing increasingly difficult for patients to unambiguously distinguish regenerative medical therapies that are medically proven from those still undergoing scientific investigations.

To overcome these issues, Japan passed the Act on the Safety of Regenerative Medicine (ASRM) in 2014. However, a new study in *Cell Stem Cell* by Professor Misao Fujita and colleagues investigated the types of regenerative medicine being performed under the ASRM in Japan and found that revisions are necessary if it is to effectively prevent patients from mistakenly selecting unproven treatments.

Among regenerative medicines, applications of cell therapies have generated the most interest. Japan's strength in stem cell research has pushed the country to aggressively fund many types of cell therapies in the hope of curing intractable diseases and putting Japan at the forefront of this potentially revolutionary patient care.

Indeed, many countries have seen extraordinary promise in cell therapies, but so too have many unethical clinics, which has led to serious complications and even death in more than a dozen countries,

including Japan.

"The ASRM requires any provision plan for a therapy be accompanied by explanatory and informed consent documents. In 2017, revisions to the act required these documents be published on the MHLW (Ministry of Health, Labor and Welfare) website," said Fujita.

In the study, Fujita and colleagues referred to the MHLW website for information about clinics offering cell interventions in Japan, collecting explanatory and informed consent documents on 3,467 provisional plans in total.

Alarmingly, the study found there were treatments on the website that would be subjected to international criticism. The study cautioned about three structural issues in the ASRM: the absence of a scientific verification requirement, the failure to distinguish research from treatments, and the absence of any clear definition for medical innovations and unproven interventions.

"The ASRM does not prohibit interventions so long as they follow the procedures stipulated by law," said Fujita.

In other words, even if a treatment is scientifically unproven, it can be administered. Moreover, she worried, its presence on the MHLW website may provide what she calls a "seal of approval" that the treatment is safe and effective even when it actually is not.

Moreover, 2% of the examined plans failed to include the required explanatory documents, putting further doubt on the quality of the review process.

For Fujita, the study shows that the ASRM should address at least these three points before patients can be confident about the cell therapies

provided under this law.

"The ASRM has already undergone revisions. We hope our study will guide more changes to strengthen its quality," she said.

More information: Misao Fujita et al, Current status of cell-based interventions in Japan, *Cell Stem Cell* (2022). DOI: 10.1016/j.stem.2022.08.003

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