Progressive and retrospective: China's regulation of regenerative medicines

Original publiction:
Lost in Translation? Accountability and Governance of Clinical Stem Cell Research in China

Author:
Joy Zhang

Over the past fifteen years China has reformed its stem cell policies several times in a rather post-hoc pragmatic manner to address international criticisms. This in combination with a 'soft centralization' of governance on stem cells policy has hampered growth of China's regenerative medicine efforts. Examining previous policies illustrates that China's current 2015 regulations could be successful if accompanied by a pro-active approach to addressing ethical issues and engaging with diverse stakeholders.

What questions & challenges are raised?

Over the past two decades China has made large investments into the life sciences, particularly stem cell (SC) research and its medical translation. This investment has not yet led to any marketable regenerative medicines (RMs), nor has it dramatically enhanced China's reputation in the field of RM. In her recent article, Dr Joy Zhang from the University of Kent shows that this 'loss in translation' may be the result of China's approach to SC regulation. Dr Zhang shows that China's policies over the past 15 years have historically taken a post-hoc pragmatic approach, only implementing policies in response to incidents that prompt international criticism. Additionally, China has historically governed SC and RM research with what Dr Zhang calls 'soft centralisation' policies. Such policies include controlling research by restricting access to national funding and having multiple overlapping authorities that issue approvals. As sources of research funding diversify, such policies are growing less effective, weakening China's ability to regulate SC research and treatments throughout the country.

What insight & direction does this give for research policies?

Dr Zhang states that post-hoc pragmatic policies have been particularly disruptive to SC research and largely contributed to China's poor reputation as a country lacking oversight. This reputation undermines China's effort to become a leader in the RM field. Additionally, Dr Zhang points to 'soft governance' policies as contributing to ineffective regulation over SC research institutes. Controlling which centres receive government funding and labelling research outside these centres 'illegal' many not be enough to deter businesses that cater to patients' desperation for new treatments. Dr Zhang states that effective regulation of SCs and RMs will require China to address issues of accountability, jurisdiction, and enforcement of current policies. Governing bodies must engage with researchers, clinics, patients, businesses and others to develop policies that take into account their needs and interests. Although a much better approach was taken to develop and implement China's new 2015 regulations, the 2016 death of Wei Zexi shows that some of the old mentality of post-hoc governing and soft centralisation may still persist. Hopefully Chinese regulators realise that more transparent and inclusive frameworks will be essential for China to become a trusted player in global SC research.

What background and point are discussed?

Dr Zhang's historical perspective of China's SC regulation begins with Chen Xigu, who had a research team that created the world's first human-rabbit hybrid embryos in 2001. This spurred international outcry and led to the perception of China as the 'Wild East' of SC research. In response the Chinese government established the "Ethical Guidelines for Research on Human Embryonic Stem Cells" in 2003. Over the next few years a growing number of clinics and hospitals began offering unapproved stem cell therapies to desperate patients. This reinforced international perceptions that SC research is largely unregulated in China. In 2009 the "Regulations of Clinical Application of Medical Technology" were issued to reign in unapproved SC treatments. In both cases the policies lacked procedural specificity and penalties for non-compliance. Dr Zhang also points out that the use of 'soft centralisation' policies, such as controlling what labs received national funding, meant that these regulations had little effect on self-funded companies. An estimated 200 Chinese hospitals continued to charge patients for unapproved SC treatments. A subsequent ban on unapproved SC research and clinical treatments in 2012 went largely unheeded. In 2013 Chinese regulatory authorities presented three draft regulations that contrasted previous regulations by laying out a more clear and comprehensive framework. It aimed to reduce financial incentives for SC treatments in hospitals, defined various stem cell treatments and practices, required the central registration of clinical trials, and provided guidance on clinical trial standards. After two years these drafts were expanded into a new 2015 SC policy that provided further clarity on how researcher could officially proceed with registration, certification and review of SC research and clinical trials. As institutions began to register and get approvals for SC research, this new policy looked promising. However, these efforts were undercut in 2016 by the death of Wei Zexi, a 21 year-old patient receiving an experimental SC therapy from a Chinese police hospital. Due to the structure and jurisdictions of China's regulatory bodies, the promising new 2015 regulations did not apply to military/police facilities. In response to Wei's death the government halted all clinical applications of SCs for immunotherapy, a large area of clinical stem cell research. Over the past ten years commercial investment for SC research has grown. The 2015 regulations attempt to limit SC clinical studies to elite researchers who are the beneficiaries of state-sponsorship. These regulations doesn't mesh well with the 200 companies in China currently developing SC treatments and may drive some existing SC practices in this grey area underground.