

China's effort to make centralised regulations effective

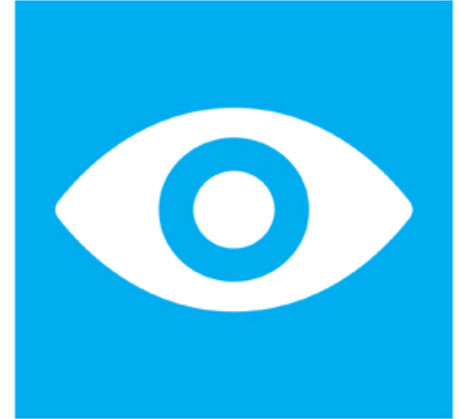
Original publication:

Making sense of stem cell policies in China

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Over the past two decades China has implemented a series of policies to regulate research and clinical use of stem cells and regenerative medicines. Successive policies have corresponded with different 'centralised' and 'mobilised' forms of government, which have attempted to address the challenges faced by local authorities to implement uniform policies. These phases of governing and adopting new regulations have likely hindered China's ability to advance its regenerative medicine program.



What questions & challenges are raised?

With new technologies and medicines comes a need for new governmental regulations; stem cells and regenerative medicine are no exception. Around the globe, different governments have sometimes struggled to define how stem cells and regenerative medicines should be regulated because these new areas of biological science don't fit with previously established policy. Dr Haidan Chen's commentary discusses China's struggle to effectively regulate stem cells and regenerative medicine. She suggests several aspects of China's approach to governance have led to practices that promote international criticism, such as permitting institutions to carry out unproven stem cell therapies. Dr Chen points out that tension arises when China's desire to govern stem cell and regenerative medicine industries with a central top-down authority clashes with effective management of problems as they arise. This tension results in periodic shifts between a centralized bureaucratic mode of governance and a 'mobilised' mode of governance that temporarily pauses governing systems to rectify deficient regulations. Dr Chen suggests that this flux between forms of governance may have contributed to China's slow progress in translating scientific advancements in stem cell research into clinical and industrial applications.

What insight & direction does this give for research policies?

Dr Haidan Chen points out that while other countries are now approving stem cell-based treatments for clinical use, China has yet to approve any. She claims that the transition of stem cell governance between centralised normal governance and mobilised governance methods "seriously impeded the progress of clinical stem cell research". Chen acknowledges that the present governance system may limit the number of institutes offering unproven stem cell treatments, but local governments may face the same difficulties enforcing the 2015 centralised policy that were encountered with the original centralised policies in 2004. In many ways the current mode of governance has reverted back to the 'old road', including calling stem cell-based technologies 'biological drugs' once again. Dr Chen suggests that the current governance restricts innovation and China should consider new methods of governance to permit progress. She proposes that China might follow the lead of the United States, European Union, Japan and other nations, which have adopted regulatory exemptions for stem cells or new, more flexible approaches to stem cell product approvals and regulations.

What background and point are discussed?

China categorised stem cell products as 'biological drugs' between 2004 and 2006 and centralised regulation of stem cell research under the State Food and Drug Administration (SFDA), China's agency for reviewing and approving clinical trials. By 2006 the SFDA suspended review of stem cell-based products because they didn't fit established standards for conventional drugs. Stem cell-based products were re-categorised in 2009 as category 3 medical technologies by the Chinese Ministry of Health (MoH). However, implementing these new regulations was never fully realised. From 2002 to 2011, a number of institutes adopted flexible practices regarding national stem cell regulations in order to overcome their own local challenges and accommodate pressures by local governments endeavouring to become leaders in China's stem cell research. As such, institutes developed their own safety and efficacy standards, some adopted stringent standards that were inhibitory to research, while others were lax and began offering unproven stem cell therapies to desperate patients. To gain control over this divergence of standards, the government transitioned to a 'mobilised' mode of governance. The MoH issued the Notification of Self-Evaluation and Self-Correction Work in 2011, which gave institutes one year to review and assess their stem cell work. The policy decentralised authority by having implementation and enforcement via regional authorities and provincial department personnel. The aim was to diminish the use of unproven stem cell treatments, but only a small number of stem cell treatment centres were shut down by provincial regulatory agencies. Dr Haidan Chen states, "The self-evaluation and self-correction work merely acted as a warning to research institutions with national financial support."

In 2013, an effort to once again centralise stem cell regulation began with the MoH and SFDA releasing three draft regulations for public comment. After two years of input, these policies became the Regulation for Clinical Stem Cell Research (Trial) in 2015. This new policy again classified stem cell-based technologies and treatments as biological drugs, but it also set important standards, including quality control guidelines and rules for conducting clinical studies. Additionally, committees were created to offer technical and ethical guidance on stem cell clinical studies. Policy implementation was again decentralised to each province, requiring the province to review local institutions with their own ethics and expert committees. Documentation from institutes is now also recorded by China's national agencies.