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Current Situations, Limitations, and Risks of Cell Therapy in Taiwan

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Abstract

As medical technology advances rapidly, cell therapy and regenerative medicine involving cells or genetically-modified cells can address many unmet medical needs. They have infinite commercial opportunities and have become the one of the most rapidly developing directions for therapy in the last decade. Cell therapy is under various limitations and faces numerous challenges. The research and development, preparation sites, supplies, clinical trials, treatments, and follow-up procedures of cell therapy differ greatly from medicine management; thus, the regulations or norms for medicine management cannot be applied to cell therapy. The keys to successful cell therapy include comprehensive legislation, cultivation and recruitment of professionals, cost reduction, and integration with artificial intelligence technologies. To enable patients in need to smoothly receive cell therapy at ease, making cell therapy affordable to all people is our primary and most critical expectation and goal.

Keywords: cell therapy; regenerative medicine; unmet medical needs; three acts related to regenerative medicine; Regulations Governing the Application or Use of Specific Medical Techniques or Examinations, or Medical Devices; induced pluripotent stem cells (iPSC)

國內細胞治療的現況、限制與風險

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摘要

隨著醫療科技的快速突破，細胞或基因改造過的細胞治療、再生醫療可解決許多未被滿足的醫療需求，再加上商機無限，已成為近10年進展最快的一種治療方向。細胞治療具有許多限制及挑戰，從研發、製備場所、供應、臨床試驗、治療到追蹤，皆與藥物管理有很大差異，無法依相同法規或規範執行。而法規齊備、專業人才培育與延攬、降低費用及結合AI科技等，都是細胞治療成功的關鍵。如何讓有需求的病人能順利、安心的接受治療，而不只是「富人醫療」，是我們最大且重要的期望及目標。

關鍵詞：細胞治療、再生醫療、未被滿足的醫療需求、再生醫療三法、特定醫療技術檢查檢驗醫療儀器施行或使用管理辦法、誘導性多功能幹細胞