

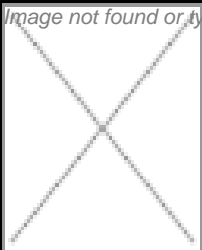
The stem cell potion

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heads the Regenerative Medicine group at Reliance Life Sciences. She has over 45 full text papers and is an invited speaker at several national and international meetings and symposia, in the area of stem cell banking, and plasma fractionation. She has an overall experience of about 28 years in this



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The scope of regenerative medicine extends much beyond the simple paradigm of providing new building-blocks to a failing organ, to processes that dynamically alter the molecular landscape within the tissue via a number of paracrine factors and other multiple potential reparative processes. Even though the feasibility and safety of stem cell use has been superior efficacy of stem cell therapy is yet to be proven.

It was after 1998, with the discovery of human embryonic stem cells [hES] the concept of using stem cells as potential therapeutics for solid organ disease gained widespread appeal. Due to the ethical issues involved regarding harvest of hES, the propensity for uncontrolled growth in vivo and the likely rejection upon differentiation, clinical focus shifted to the adult-derived phenotypes. The advent of bio-engineered pluripotent stem cells from adult somatic tissues has revolutionized the potential availability and applicability of personalized stem cells. The bioengineered platform has the potential to bypass the ethical and allogenic limitation of hES and allows patient derived tissue to be reprogrammed back to the embryonic phenotype and the opportunity to utilize the 'autologous' approach. As newer sources of pluripotent cells provide the capacity to achieve specified tissue differentiation from all three germinal layers, newer enabling technologies will probably be a stepping stone to maximize repair potency and has now ignited renewed clinical interest.

Further, ipre-clinical studies in disease models have demonstrated universal benefit following delivery of a diverse repertoire of stem cell phenotypes, despite a huge variation in dosage, the timing and site of delivery. Such proof-of-principle opens avenues for future optimization of this novel stem cell platform for translation into clinical practice in addition to being a model for drug discovery and development. This transition from a stable stem cell phenotype into reproducible and efficacious products involves extensive process validation; robust quality systems and a strong package of in vitro and preclinical data. None of these are cheap and the challenge lies with us to deliver a new generation of cost effective and efficacious therapeutic solutions. Genomic and proteomic evaluation of adult stem cells will throw more light on the small molecule development for the future, help in companion diagnostics, and make theranostics very significant.

Such approaches would move naïve “first generation” stem cells from achieving a specific limited therapeutic objective to another level of understanding delivery, evaluation of the risks and benefits of repeat therapy and use of well characterized, lineage specified stem cells, transplanted either alone or in combination, which will mark the beginning of “second generation” therapeutics. With a cohesive government initiative and appropriate funding, within 20 years, regenerative medicine will be the standard-of-care for replacing all tissue/organ systems in the body, in addition to its extensive industrial use for pharmaceutical testing. In the next two decades, we also hope to achieve major milestones starting with insurance reimbursable regenerative therapies, and establishment of standards for the regulatory approvals.

We also expect that the world will engineer smart degradable biocompatible scaffolding and develop micro-fabrication and nanofabrication technologies to produce tissues with their own complete vascular circulation, producing an in vitro sophisticated 3-D tissue and organ models that cannot be ordinarily regenerated through routine in vivo techniques. Just as discovery and usage of penicillin was the inflection point in the fight against infectious diseases, application of stem cell-based therapies will be the turning point in the treatment of hitherto inadequately treated or incurable diseases of the twentieth century.