Models of biomedical innovation and global governance. The case of stem cell treatments.

Introduction
Health consumers regularly access the global healthcare market for both established and innovative therapies like stem cell therapies. Politically, governance of the innovative stem cell therapy market is problematic as a majority of the therapies is supplied by providers utilizing practice-based models of biomedical innovation whilst very little is supplied by the orthodox science-based model of innovation. Interestingly, much of the analysis of the governance problem has adopted a supply-side perspective informed by the values of the orthodox model, arguing that (trans)national regulation has failed to impose appropriate standards on the ‘illicit’ supply of stem cell therapies.

Aims
We propose a political economic analysis with a strong demand side perspective, arguing that ‘stem cell tourism’ is embedded in the demand-supply relationship of the health consumer market and its mediation by different models of stem cell innovation governance. Given the nature of the market dynamic, policy recommendations on stem cell innovation governance that neglect this perspective are unlikely to be productive.

Method
This paper draws from interviews conducted in UK, India and China to investigate i) the nature and implications of the political and economic demands by health consumers on the global healthcare market, ii) the engagement between these demands and different models of stem cell innovation governance i.e. how innovation models mediate between consumer demand and the emerging healthcare supply—and its implications for the global competitiveness of a particular model, and iii) the synergies and dissonances in the interaction between market dynamic and existing structures of (trans)national stem cell innovation governance.

Models of Innovation

Science and Medical Innovation: Value Conflict

*Scientific innovation: scientifically generalisable knowledge

*Medical innovation: benefit of the individual patient

Stem Cell Innovation Model I

Stem Cell Innovation Model II

Stem Cell Innovation Model III

Stem Cell Innovation Model IV

The Demand Side: Global Health Consumers

- Globalised health care market
- Treatment for a wide range of conditions
- Worth $40-60 billion
- Growth rate 15-25%
- Established and emerging markets
- ‘Pull factors’ stimulated by asymmetric positive information from:
  - Stem cell science
  - Stem cell therapy suppliers
- ‘Push’ factors from consumers with low health status (disabilities, pain, death)
- Generating economic and political demand (e.g., Italian case 2013)

The Supply Side: Global Health Consumers

- Timing and quantity of the supply of therapies is determined by innovation model employed
- Four models:
  - Scientific innovation
  - Medical innovation (2 types)
  - Scientific and medical innovation
- Models based on different professional groups, ethics and regulatory arrangements.
  - Innovation models compete for position in the demand-supply relationship

Conclusions

National Regulation: Jurisdiction and Innovation Model

- Global market dominated by the supply generated by Innovation Models II, III and IV
- National regulatory debates dominated by values and components of Model I (Scientific Innovation)
- Medical innovation is regarded by Western commentators as marginal and suspect
- Health consumer (demand) side is ignored as a governance issue.

Reference:
Ms Saheli Datta
Professor Brian Salter, KCL
Dr Yinhua Zhou, KCL

"Medical innovation in cellular therapy may be viewed as the ethical and legitimate use of non-approved therapy by qualified healthcare professionals in their practice of medicine."

International Society for Cellular Therapy (2010)

"In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician’s judgement it offers hope of saving life, re-establishing health or alleviating suffering."