
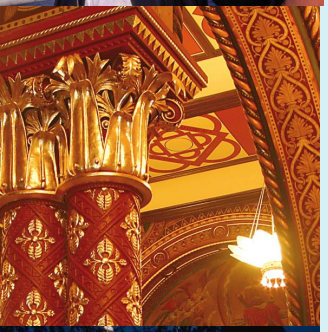

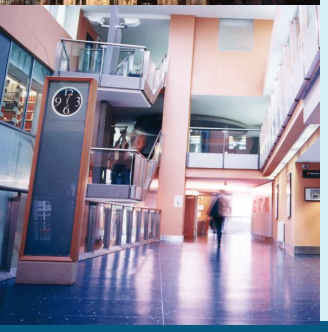

KING'S College LONDON

Health consumers and stem cell innovation: new markets new models

Professor Brian Salter

King's College London, 29th May 2014

State strategies of governance in global biomedical innovation: the impact of China and India

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Case Studies

- Regenerative medicine
  - Stem cells
  - Tissue engineered wound care
- Personalised medicine
  - Pharmacogenomics
  - Bioinformatics

Policy workshops

Fourth in series:

- London, March 2013 - Global governance of human embryonic stem cell research and therapy – an example from India
- Beijing, October 2013 - The political economy of the global stem cell therapy market
- New Dehli, March 2014 - Biomedical innovation and the public

Innovation in the life sciences

- Markets -

- Research funding
- Scientific labour
- Research materials
- Clinical labour
- Patenting
- Health consumers

Markets with many and various regulatory arrangements at national and transnational levels

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

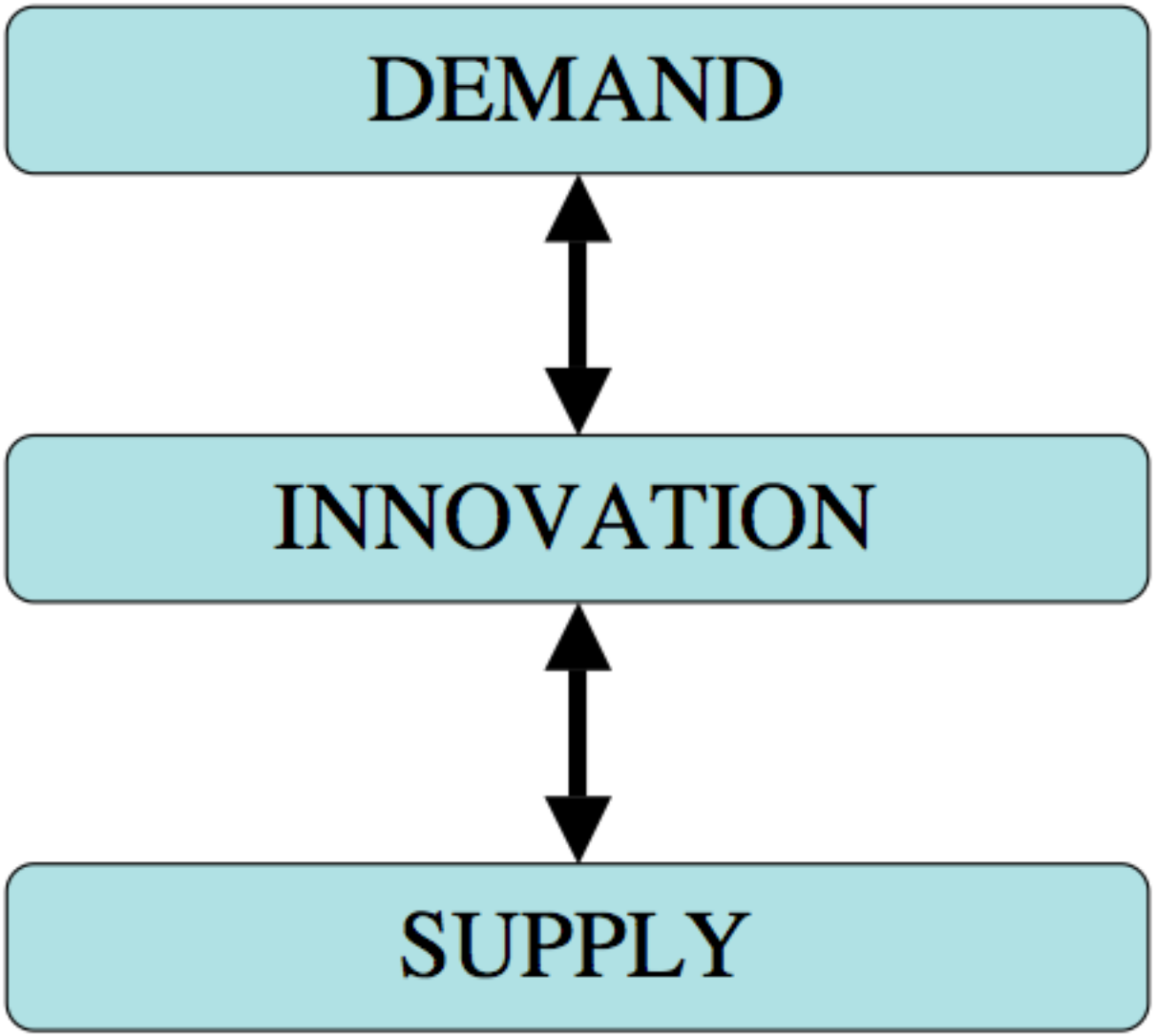
The size of the emerging stem cell therapy market in selected countries

Country	Number of Clinics	Number of patients
China	>300	>30,000
India	>45-50	>10,000
Russia	>100	>20,000
Japan	>20	>10,000

Data sources:
China: China MOH, quoted by Sina (2012).
India: Estimate calculated from data in Cohen and Cohen (2010); Ogbogu et al (2013); Patra and Faulkner (2010); brochure from Nutech Mediworld and online source http://www.pharmabiz.com/ArticleDetails.aspx?aid=73322&sid=11
Russia: Sipp, 2011
Japan: Mainichi (2013) and Nature (2013a).

Regulation and the global stem cell therapy market

- Regulation in the context of the operation of the market
- Demand-supply relationship
- Mediated by four models of stem cell therapy innovation
- That may utilise a global value chain
- Operating both within and across national regulatory jurisdictions


DEMAND
INNOVATION
SUPPLY

Demand side

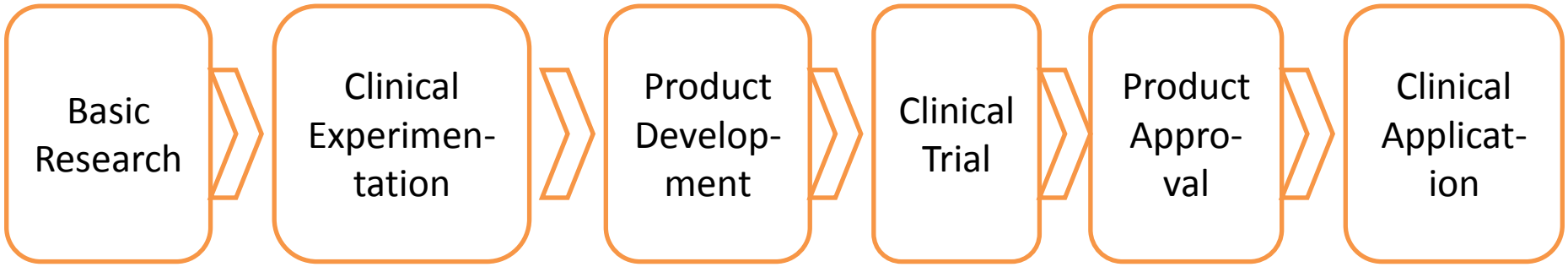
- ‘Pull factors’ stimulated by asymetric, positive information from:
  - Stem cell science
  - Stem cell therapy suppliers
- ‘Push’ factors from consumers with low health status (disabilities, pain, death)
- Generating economic *and* political demand (eg Italian case 2013)

Supply side

- 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

Stem Cell Innovation Model I
Scientific Innovation



Model I
Scientific innovation

- Time and cost of development: 12-15 years and approximately 1 billion euros
- Only 7 approved stem cell therapies in the global market
- Limited responsiveness to demand

Scientific and medical innovation: Ethics

- Scientific innovation: scientifically generalisable knowledge
- Medical innovation: benefit of the individual patient

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)

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is 'experimental', in the sense of new untested or different, does not automatically place it in the category of research.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). Belmont Report

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.

World Medical Association (2008). *Declaration of Helsinki. Ethical principles for research involving human subjects.* Para 35.

Stem Cell Innovation Model II
Medical Innovation (Western)

Model II
Medical innovation (Western)

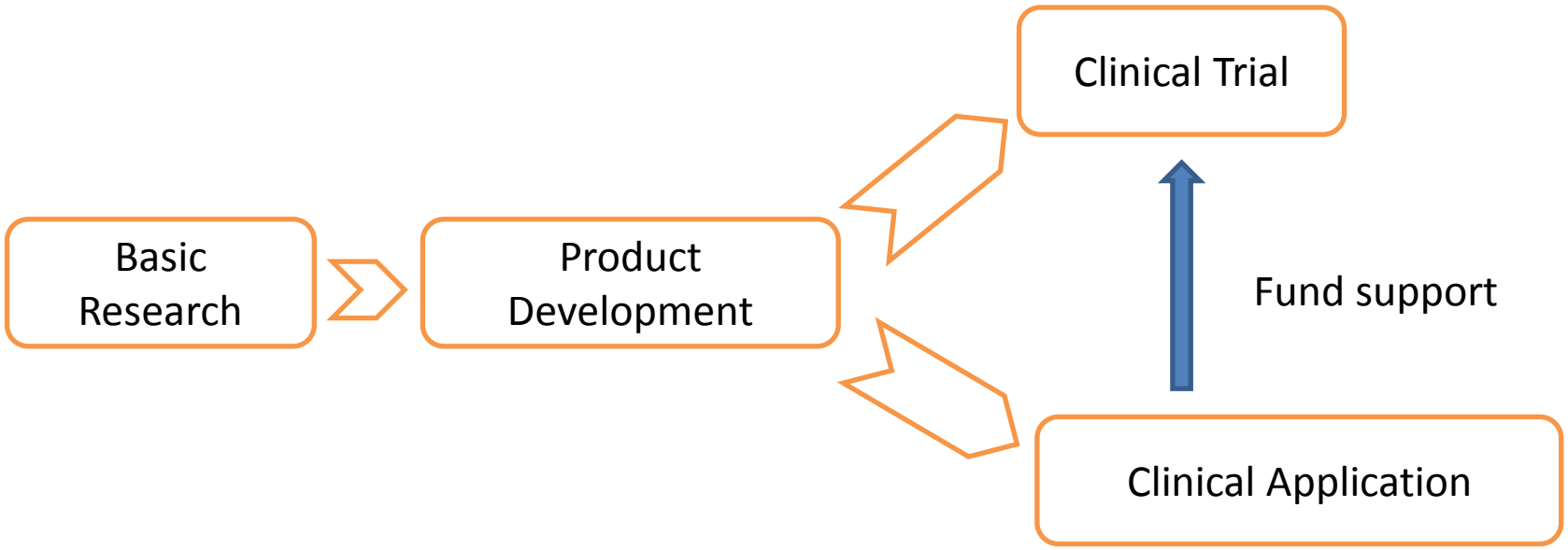
- Hospital Exemption – Article 18, EU Advanced Medicinal Therapy Products (AMTP) Regulation 1394/2007; UK ‘Specials’ scheme
- Professional space of clinician
- Single or small groups of patients
- More responsive to demand
- Competing with Model I (Scientific Innovation)

Stem Cell Innovation Model III
Medical Innovation (Non-Western)

Model III
Medical Innovation (Non-Western)

- Hospital setting
- Less regulation than Model II
- Professional space of clinician
- Routine provision of therapies for large numbers of patients
- Highly responsive to demand

Stem Cell Innovation Model IV
Medical Innovation and Scientific Innovation



Model IV
Medical and Scientific Innovation

- Hospital setting
- Professional space of clinician
- Routine provision of therapies for large numbers of patients
- Re-investment of profits into clinical trials for other stem cell therapies – professional space of scientist

Jurisdiction and innovation model: governance domains of stem cell therapy provision

		Stem cell innovation model		
Jurisdiction	*Model I* *Scientific Innovation*	*Model II* *Medical Innovation (Western)*	*Model III* *Medical Innovation (Non-Western)*	*Model IV* *Medical & Scientific Innovation*
Single national jurisdiction	***EU EMA Approved*** ChondroCelect ***US FDA Approved*** Ducord Hemacord ***Australia TGA Approved:*** MPC ***Korea KFDA Approved*** Hearticellgram-AMI Cartistem Cuepistem		Nutech Mediworld Bioengineering corporation Wu Stem Cells Medical Centre Unique Cell Treatment Clinic Spectrum Cell Clinic	Chaitanya Stem Cell Therapy Centre Zhongyuan Union Stem Cell

Jurisdiction and innovation model: governance domains of stem cell therapy provision

	Stem cell innovation model			
Jurisdiction	*Model I Scientific Innovation*	*Model II Medical Innovation (Western)*	*Model III Medical Innovation (Non-Western)*	*Model IV Medical & Scientific Innovation*
Multiple national jurisdictions	***US FDA Approved**:* Prochymal ***Health Canada Approved*** Prochymal ***New Zealand Medsafe*** Prochymal		Cells4Health (Xcell) Celltex Therapeutics Shinjuku Clinic Hakatain Nuchi-In Centre for Regenerative Medicine	Beike Biotechnology RNL Bio

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

National Regulation
Jurisdiction and Innovation Model

- Increasing attempts in BRICS to regulate using tenets of Model I
- Increasing health consumer demand
- Increasing use by the market of Models II, III and IV

Transnational regulation of stem cell therapy innovation - ISSCR

Promotes Model I as the primary legitimate model, hence:

- Medical innovation to be used ‘only in exceptional circumstances’ with seriously ill patients
- Not driven by the principles of the scientific method and therefore to be avoided if possible

Transnational regulation of stem cell therapy innovation - ISCT

Assumes health consumer selects the model, hence:

- Patients '*should have the right to seek treatment for their diseases. No entity should withhold this fundamental right unless there is a high probability of harm to the p*atient'.

- In this context, scientific and medical models of stem cell therapy innovation should be accorded equal legitimacy

Transnational governance of stem cell therapy innovation – Demand side

Provision of expert information to enable informed consumer choice:

- ISSCR *Patient Handbook and* Australian Stem Cells Foundation *Australian Stem Cell Handbook*
- Not disease specific
- Medical innovation presented as an option only to be used as a ‘one off’.

Conclusions – market and governance

- In the stem cell therapy market, innovation models mediate between demand and supply
- Supply is largely a product of medical innovation
- Supply side regulation largely focuses on scientific innovation
- Demand side governance incorporating the health consumer is usually ignored

Almost a perfectly irrational approach to governance

Challenges: Supply side governance

- Recognition that ‘innovative practice’ using unproven approaches is part of stem cell therapy innovation (as with surgery for example)
- Incorporation of medical innovation governance within existing medical self-regulation codes of practice
- Identification of common governance domains between scientific and medical innovation (eg quality/safety of materials)

Challenges: Demand side governance

- Facilitation of informed consumer choice
- Activation of existing governance market of standardised measures (eg GLP, GMP, cGMP, GCP)
- Instigation of accreditation programmes for stem cell clinics (CIRM, ICMS)
- Formation of expert network partnerships between scientists/regulators and patient organisations to produce materials and disease specific guidance
- Integration of feedback from health consumers via dedicated websites

Thank you