RES-349-25-0002 (Dupré)
EGENIS - Stem Cells Research in Context

'Stem Cell Research in Context' aimed to show how legal and regulatory restrictions and wider social conditions such as stakeholders' interests influence the course of, and daily work in, biomedical research laboratories and clinics. Through observation and interviews we examined the influence of laws and regulations applying to research with human embryos and cells and to humans as patients in stem cell research.

Our approach reverses the dominant bioethics and policy view that what matters is to foresee and, if necessary, direct science. This bioethics and policy perspective presupposes that scientific development follows its own independent logic. In contrast, we assumed that regulations help to shape research and do so in ways that depend on social contexts.

In order to explore the effects of regulatory differences we compared distinct legislative national contexts, and within them basic laboratory research on human embryonic stem cells and clinical trials using the patient's ('adult') stem cells. The contrast between the 'liberal' regulations and attitudes to stem cell science in Britain and the more restrictive situation in Germany, where the use of human embryos in research is outlawed, made an excellent case study. It also allowed us to examine the application of transnational EU regulations in these national environments.

Our aims were to
1) Find out how societal regimes shape stem cell science 2) Analyse national and international regulation, and ethical, institutional, and economic factors that shape the pathways of the science and its practices, in clinic and laboratory 3) Present case studies on the relationship between stem cell science and legal regulation, ethical discourses and science policies in Britain and Germany 4) Introduce and train young postdoctoral researchers and PhD students in the sociology of the life science and governance 5) Establish successful working relationships with scientists and regulators in the field

Main research results
Not including PhD work, the main project involved 19 weeks of fieldwork and 80 interviews. The statements below capture our key findings:

1) Different cultural structures influence the practices of both medicine and stem cell science demonstrable in the comparison of the relevant institutional structures, concrete clinical and laboratory practices and working environments in Britain and Germany. It was also illustrated in researchers' views of the developments in their science.

2) EU legislation, although put into place to integrate and strengthen the bioeconomic position of Europe, is implemented differently in each national context. Preexisting institutional structures shape this specific adaptation. Ambiguities in regulation are managed differently: for instance, the integration of EU medicinal products and tissue and cells regulation into legislative instruments has taken distinct routes in the UK and Germany. Germany attempts to streamline the regulation of cell therapies, while the UK

operates with an assemblage of regulatory mechanisms.

3) Cells are distinguished with respect to properties such as origin, capacities and utility, usually according to source and stage of preparation. We found a high degree of uncertainty about the future prospects of stem cell science regarding its delivery and funding, also reported by other CBAR projects. This amplified uncertainty relates to the high value of embryonic stem cells and recently engineered 'induced pluripotent cells', which are managed under different regulatory regimes.

4) Regulatory frameworks are an integral part of how clinical staff make sense of what they do. The application and implementation of regulation constitutes a practical accomplishment and is the product of negotiations between multiple actors. In this sense, new theoretical approaches to regulation are needed to account for the entanglement of regulation and research practices.

5) The elaboration of regulation in clinical research guides, channels and directs clinical research. It also creates hierarchies of expertise, forces alliances and forges collaborations in the production of new medical therapies. Existing resources are adapted to meet emerging legislative requirements and professional roles and collaborations re/established (e.g. infrastructures for bone marrow transplantation are used to articulate the novel use of stem cells in heart repair as regulated practice).

Summary of achievements

The research and expertise in the project team attracted two more PhD students, Marco Liverani (working on international scientific configurations) and Ayesha Ahmad (working on conceptualizations of the human embryo). The core team authored and (co) authored six academic papers (published or in press, in English and German), including a questionnairebased study on the researchers' evaluation of regulation, and gave evidence to governmental institutions in the UK, Germany, and Austria. Three wider audience articles have been produced and seven further publications are in preparation.

Dissemination activities and outputs

In addition to our publications, we held three workshops and gave over twenty talks. We devised a teaching tool, presented in a European summer school in Ludwigshafen and to groups of medical students, spoke at public communication events in Cheltenham, Cardiff, Bristol, Newcastle and Edinburgh.

Impacts and policy implications

Findings with implications for science policies are:

1) Regulation is prominently placed and highly integrated into the scientists' and clinicians' visions, developments and practices of stem cell science

2) Science policies influence the researchers' understanding of their science

3) Scientists engaging in stem cell research are basically supportive of their scientific

practices being subject to policies and regulations. However, they conceptually transgress the limitations imposed by such policies and regulations in their notions of scientific development.

Our research has informed policymakers, particularly in the UK and in Germany, about the effects of specific ethical and regulatory instruments on science practices. Dr Hauskeller co-authored the expert report on Stem Cell Research and Regulation for the Austrian Government and she and Dr Weber presented and gave evidence to the German Zentrale Kommission Stammzellenforschung (January 2009). Also, the team contributed to the Egenis response to the House of Lords Science and Technology Committee Call for Evidence on Genomic Medicine (30 April 2008, oral evidence by Prof John Dupré). A briefing paper with a summary of findings has been requested by the Human Tissue Authority and by the German Ministry for Bildung and Forschung (BMBF), and is currently in preparation.