Non-Technical Summary
Medical Device Governance: Regulation of Tissue Engineering in the UK and EU

Bio-technology governance has been characterised as becoming more socially inclusive, precautionary, and risk-based. Regulatory processes, risk and innovation have been analysed in pharmaceutical, genomic and to a lesser extent medical device regulation but the nascent field of tissue-engineering (TE) in Europe has not previously been studied. Our research aimed to explore the uncertainties surrounding technical and clinical expectations, and attempts to develop what we have termed a new ‘regulatory order’.

The aims of the research have been achieved. The focus was regulation and governance of TE in the UK and Europe, via a Europe wide survey, extensive interviews, documentary analysis and attendance at diverse meetings. We studied current regulatory initiatives across Europe, focusing upon cartilage, skin, bone and vascular technologies. We considered the participation of diverse stakeholder groups, their discourses, values and interests. We examined the construction of evidence of risks and benefits, and how this shapes regulatory decisions, testing, standards and evaluation (for safety and efficacy). We consider implications for healthcare practice, public health and commerce.

Europe as a trade area is partly constituted by regulatory and standard-setting activity. TE regulatory harmonisation takes the form of a framework which allows national variation on some important dimensions, such as ethical standpoints viz-a-viz certain animal or human tissues. The European Commission promotes transnational technical standards over ethical standpoints, thus supporting development of technological markets. Europe shows bias towards the development of autologous (donor and patient are the same, e.g. knee cartilage) products, due in some accounts to greater perceived risks associated with allogeneic (different donors, e.g. skin system) products.

There is wide variation in national regulatory approaches, reflecting histories and cultures of healthcare industries and regulator-producer relationships. A new Tissue and Cells Directive (TCD) and a proposed Tissue Engineering product Regulation (TER) represent key features of the emerging regulatory order. The former concerns the donation, sourcing and banking of tissue, the latter the assessment of products for the marketplace. Accountability and standards are becoming more stringent. The regulatory reach of emerging legislation is widening, extending from small scale hospital-based tissue collections to companies with global distribution networks.

Tissue engineering remains an unstable and contested concept. The regulatability of TE technology contends with uncertainty about the definition of TE, potential markets, the reimbursement environment, and scientific and ethical views of risk and benefit. We observed a process of regulatory ‘partitioning’ by which policymakers and industry aspire to establish TE as a safe and commercial zone. Subsidiarity emerged as a political strategy for bracketing out some ethically controversial issues in the TCD. Industry projects stable images of a TE zone. However, concerns regarding appropriate business models for TE companies and reimbursement were identified.

The primary interactions in the TE policy network are between industry and regulatory policymakers. A small number of scientists have been influential but clinicians and consumer groups relatively marginal. UK, France and Germany were
perceived as influential in the European policy arena. Relations between ethical concerns and regulatory policy making emerged strongly. Public controversies relating to BSE and HIV contamination have been influential in shaping positions of stakeholder groups. The predominant discourse on risk is focused upon safety and quality rather than efficacy or effectiveness. We see evidence not only of risk-based regulation, but also of selective ethics-shaped regulation.

Tensions exist between tissue banking and tissue engineering. Controversy surrounds the application of TCD to different sectors and communities. Its scope was extended to include all 'tissue establishments', thus widening the reach of the regulation and promoting 'a level playing field' in the wake of strong lobbying from industry. The tissue bank community however also lobbied strongly, largely resisting convergence with commercial TE, disputing the need for new regulation, arguing for adaptation of existing medicinal product regulation.

The boundaries of jurisdictions affecting TE are fluid and negotiable. TE challenges numerous boundaries: national/European, medicine/device, human tissue/animal tissue, tissue bank/industry, commerce/public health, and the bounded structures and habits of existing regulatory agencies. Analysis of the reconfiguring of regulatory authority points to the negotiation of new institutional forms. Considerable debate has focused on whether a new EU regulatory authority for TE products is required, if the responsibilities of the European Agency for the Evaluation of Medicinal Products (EMEA) could be extended or new ‘centres of excellence’ established for product approval.

Public health principles are supported by the new regulatory developments but as always this is balanced by motivation to promote technical innovation. Existing engineered tissue products remain non-controversial in the general public view. The emerging governance distributes accountability between national and EU authorities while in principle tightening control over sensitive activities of tissue sourcing. The effect of regulatory variation in the EU upon innovation and competitiveness of the trade area is negative but is difficult to assess in detail. EU actors perceive lack of competitiveness in comparison to the US. Lack of consensus on appropriate evidence bases for TE technologies adoption means that public healthcare systems are not in general eager to adopt them.

The research has been disseminated internationally to numerous users and the academic social science community. This continues. Non social science users include the British Association of Tissue Banking and scientific audiences. Policy, industry and scientific users will be reached via a dedicated workshop and special-purpose published summary. The research has already impacted directly upon policy processes, for example via discussion in the UK’s Medicines and Healthcare products Regulatory Authority (MHRA) and by our contributions to the European Commission’s impact assessment of proposed policy in the field. Collaborative work is under way with social scientists – also in the ESRC Innovative Health Technologies programme - researching regulation in the comparative fields of pharmaceuticals, human genetics and xenotransplantation. A PhD is furthering some aspects of the research. Team member JK follows up with (ESRC-supported) research on foetal stem cell issues.

The project contributes to theoretical development by building on concepts of political science governance, theory of risk and sociology of science & technology, as well as more specific substantive understandings of bio-society and the ‘tissue economy’.