

Medical Device Governance: Regulation of Tissue Engineering in the UK and EU

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Innovative medical technologies, including cell based technologies such as Human Tissue Engineered Products (HTEPs) pose questions that are of interest to social scientists. In particular, how do such technologies fit into the changing scene of international regulation and public policy development?

The European Union (EU) provides a legislative framework for the control of the introduction of medical technologies in the healthcare systems of its member states. The principal areas of regulatory policy are Medicinal Products (pharmaceuticals) and Medical Devices. Other regulations cover blood products, tissue banking, biologics and stem cell research. Inert, bio-active, and powered human implant technologies have been regulated, since the 1990's, under a series of Directives produced by the European Commission.

In principle, EU medical device regulations are implemented on a national basis, but many tissue engineered technologies do not fit into existing formal regulatory organisational structures and definitions, creating, in effect, a regulatory vacuum.

The overall aim of this research is therefore:

- To evaluate the implications of trends in regulation, governance, and evidential processes, in relation to the challenge posed by human tissue engineered products.

The research focuses upon recent history of medical device and other regulation and current activity in the UK and other EU countries, and upon transnational European forums. Identified groups contributing to the regulation of tissue engineering include manufacturers, scientists, regulators, clinicians and patients/citizens. By mapping the activity, perceptions and values of these groups, the project investigates the implications of HTEPs for existing regulatory frameworks and healthcare 'governance', and vice versa.

The aim is to develop analytic models for identifying factors which will shape the development of new forms of regulation in relation to innovation, market approval and clinical introduction of HTEPs, and to evaluate this regulatory activity in terms of implications for healthcare practice, public health and innovation/competitiveness.

The need for clarification of the regulatory position of HTEPs has promoted increased activity within the European Community, resulting in working documents that might change the existing regulations and guidelines. Currently different regulatory pathways are being explored, with both the Directorates-General SANCO and ENTERPRISE of the Commission proposing drafts for new European legislation.

Within the initial phase of the research, carried out primarily within the UK, a number of central issues have become apparent. In particular, issues relating to (a) variation in the perceived potential of the technology between groups, (b) concerns regarding the need for careful consideration of the potential for disease transmission into clinical application, (c) real and perceived national differences in approach to regulation, (d) tensions between medical device and medicines regulatory bodies and (e) close interaction between regulators and industry bodies in debating the emerging regulatory policy.

It is clear that various informal and 'proto-regulatory' activity is taking place. In the absence of agreed regulatory controls, populations in Europe may be denied the potential benefits of this new 'regenerative medicine' and industries will continue their innovation in other countries.