Regenerative medicine and its development and implementation: an analysis of emergent value systems and health service readiness (REGenableMED)


REGenableMED examines the dynamics of innovation within the field of regenerative medicine. Using a mixed-methods social science approach, the project provides a detailed analysis of the interplay between business models, measures of clinical utility, patterns of regulatory oversight and clinical workflows within healthcare settings. The results of the research have helped inform strategies aimed at facilitating the responsible development of effective and useful regenerative medicine products and services.

The project has developed the notion of institutional readiness to capture the importance of the institutional setting in which regenerative medicine is to be deployed. The progress of innovation projects is often understood in terms of technology readiness: the extent to which the innovative technology has matured and is 'ready' to be put to use. Yet successful innovation also depends upon what could be called institutional readiness, or the capacity and willingness of key pre-existing organisations and inter-organisational structures to adopt, respond to and utilise novel technologies. Institutional readiness is particularly significant in the developing field of regenerative medicine (RM). For RM to live up to its promise of revolutionising patient care, emerging products must somehow be accommodated within pre-existing regulatory and healthcare organisations that are accustomed to dealing with more conventional medicinal products and services.

The REGenableMED project thus examines the ways in which relevant institutions and agencies are 'readying' themselves for regenerative medicine, and the various factors that enable and hinder institutional 'readiness'. By doing this, the project has produced applicable findings that can inform healthcare policy and commercial strategies aimed at the responsible development and adoption of novel RM therapies. The results were drawn on by the 2017 House of Commons Science and technology Select Committee’s Inquiry into regenerative medicine.

DATA DESCRIPTION (ABSTRACT)

Dataset and interview transcripts from fieldwork undertaken in the UK between 2015-2017. Respondents were drawn primarily from researchers, clinicians, regulators and companies working in the regenerative medicine field.

Creators:

Creator Name: Webster, Andrew Email: andrew.webster@york.ac.uk

Affiliation: University of York

URL: http://www.eurostemcell.org/regenerative-medicine-special-report

Research funders: ESRC

Grant reference: ES/L002779/1

Subjects: Biomedical technologies; clinical adoption, regenerative medicine

Keywords: emerging biomedicine
Project title: Regenerative medicine and its development and implementation: an analysis of emergent value systems and health service readiness

Grant holders: Professor Andrew Webster

Project dates:
From 1 May 2014
To 31 July 2017

Date published: 20 October 2017
Last modified: 2 Nov 2017

Coverage and Methodology

Collection period:
Date from: March 1 2015 Date to: March 2017

Geographical Area: UK
Country: UK

Data collection method: Face-to-face Interviews (65) with stem cell scientists and researcher clinicians, serial return interviews to a sample of (10) companies and their staff working in the cell therapy field, regulators in the Medicines and Healthcare Products Regulatory Agency, the National Institute for Health and Care Excellence, the European Medicines Agency, patient charities within the UK. Telephone interviews were also conducted for a small number of respondents.

Observation unit: Individuals; SME companies
Kind of data: Textual; Access database of organisations
Type of data: Qualitative and mixed methods
Resource language: English

Access and Administration

Data sourcing, processing and preparation: Audio records of semi-structured interviews in English. Data processed and analysed using NVivo software package.

Copyright holder: Name Affiliation Email
Andrew Webster University of York andrew.webster@york.ac.uk

AVAILABLE FILES

Data Interview transcripts
Documentation Consent form
Participant Information Leaflet
Interview schedule