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Comparing national home-keeping and the regulation of translational stem cell applications: An international perspective☆

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ABSTRACT

A very large grey area exists between translational stem cell research and applications that comply with the ideals of randomised control trials and good laboratory and clinical practice and what is often referred to as snake-oil trade. We identify a discrepancy between international research and ethics regulation and the ways in which regulatory instruments in the stem cell field are developed in practice. We examine this discrepancy using the notion of 'national home-keeping', referring to the way governments articulate international standards and regulation with conflicting demands on local players at home.

Identifying particular dimensions of regulatory tools – authority, permissions, space and acceleration – as crucial to national home-keeping in Asia, Europe and the USA, we show how local regulation works to enable development of the field, notwithstanding international (i.e. principally 'western') regulation. Triangulating regulation with empirical data and archival research between 2012 and 2015 has helped us to shed light on how countries and organisations adapt and resist internationally dominant regulation through the manipulation of regulatory tools (contingent upon country size, the state's ability to accumulate resources, healthcare demands, established traditions of scientific governance, and economic and scientific ambitions).

☆ Research into the regulation of stem cell science and semi-structured interviews have been held in the following countries: China, Japan, Thailand, South Korea, Vietnam, Taiwan, Europe, Malaysia and India. Archival research was done on the regulation in the USA.

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1. Introduction

Stem cell science is a controversial field of research with a huge potential market for therapeutic applications on a global scale (Department of Business Innovation and Skills (2011)). A hackneyed view of stem cell therapy provision regards the market of life science research and biomedical products – preparations of viable cells, delivered through one of possible devices, such as a syringe, and marketed commercially, requiring marketing permission in most countries - as deeply divided between a world dominated by advanced scientific institutions and a world of 'rogue' stem cell providers (cf https://www.newscientist.com/article/dn19056-death-revives-warnings-about-rogue-stem-cell-clinics/; http://www.economist.com/node/15268869). The former is depicted as ethical, sophisticated, scientifically advanced; the latter as unethical, profit-motivated and uninterested in scientific advance (Sipp, 2012; McMahon and Thorsteinsdóttir, 2010). But by defining the difference in moral terms, critics do not do justice to the efforts of many researchers involved in stem cell therapy research and provision, for example, in Asia. In fact, we can discern only a few players that can afford to conduct clinical trials in tightly regulated research fields in ways that match the ideals of the dominant international science community, and only a few corrupt so-called 'snake-oil providers' (Sleeboom-Faulkner, 2014). Instead, a very large grey area of stem cell-related activities exists in which stem cell scientists, doctors, politicians and regulators accommodate, adjust, circumvent and alter regulatory spaces to help advance clinical research in ways that suits their circumstances.

The current use of the binary between bona fide science and snake oil traders has its roots in a situation in which a few international organisations and countries driven by members from well-funded, cautious research laboratories set the standards. Those that do not stick to agreed conventions are seen as undisciplined and fraudulent (Sipp, 2012; Bharadwaj and Glasner, 2008). This binary has led to the tainting of a large group of under-resourced researchers, and to one-sided portrayals of their aims. Scientists delineate themselves from the 'science' of other scientists, claiming scientific integrity for themselves. Although this 'boundary work' is inherent to the scientific community (Gieryn, 1983; Gilbert and Mulkay, 1984; Salter and Qiu, 2009), it is now played out on a global level, expressed in papers on 'research ethics' and 'good practice' at international scientific conferences.

Recent years have seen a new regime of coordination of medical practices linking medicine and biology together that has led to the increased articulation of genomic biology, multicentre clinical trials, organised patient communities, and biobanks, which depend on sophisticated laboratories, reliable instruments and devices that produce exchangeable results. Standard setting, guidelines and regulation are central to this regime. Thus 'regulatory objectivity' (Cambrosio, Keating, Schlich an&d Weisz, 2006) defines the contents of what the dominant science community regard as correct practices (Birch, 2012). These standards are often conventions: what counts here is that results are compatible with other laboratories, whereby 'truth' and 'accuracy' become dependent on these conventions. In regenerative medicine (RM), referring to research and therapies using the regenerative powers of the body, the International Stem Cell Initiative (ISCI), for example, has taken the initiative to define pluripotency and assays, and the media and reagents used to produce them (Eriksson and Webster, 2008). Standards do not only facilitate exchange, they can also define the clinical criteria in terms of diagnosis. Thus, scientific standards and assays for mesenchymal stem cells are critical both to the advancement of scientific development and clinical practice (Bianco et al., 2013). Crucially, the exchangeability and common use of data require the deployment of similar equipment, devices and assays. This has major economic and intellectual property rights (IPR) implications to the advantage of those that set the standards, and to the disadvantage of the reputation of researchers that cannot comply with them (PRNewswire, 2014; Birch, 2012).

These developments pressurise scientists all over the world to follow the standards of elite laboratories. At the elite levels, scientific knowledge is sanctioned by international peer-reviewed journals, regulation vetted by expert committees in modern bureaucracies, and novelty defined by IPR. Here, political discourses on norms and values define the ethics acceptable to a small number of societies (Timmermans and Epstein, 2010; Birch, 2012). International collaboration, then, requires elite laboratories in most countries, including those with few resources, to demand regulations that enforce 'global' standards. But the necessity to purchase costly equipment and resources has also led to resistance against regulatory norms and standards by those less well endowed (Sleeboom-Faulkner, 2013).

Insight into this friction between compliance and resistance is complicated by an ever-increasing demand on scientific leaders to be familiar with research regulation and research ethics, multiple scientific fields, IPR, methods of team management and business strategies, leading to development of 'bioenterpreneurship', 'bionetworking', and 'international entrepreneurship in the life sciences' (Jones et al., 2011: 2; Sleeboom-Faulkner and Patra, 2011) engaging with coordinative activities and methods using local knowledge resources and international connections. Here, values and methods are constantly weighed to realise the desired kind of 'local' model of scientific decision-making, considering, for example: the cost, feasibility and aptness of the 'right' number of patients used in investigational studies or clinical trials; the quality of preclinical studies and toxicity studies; the fees charged for investigational studies using unauthorised stem cell products; and the ways of marketing therapy products. Global variability of therapy marketing and patient demand complicates the picture of compliance and resistance even further (Petryna, 2009; Chen and Gottweis, 2011). This variability has resulted in a situation in which the relationship between patients and doctors is conditioned by availability of research funding, expertise and medical facilities, as well as collaborative networks and regulatory constraints.

1.1. National home-keeping

At the intersection of the international and local governance of stem cell science, we locate a form of decision-making, which we refer to as 'national home-keeping'. National home-keeping is a heuristic notion we use to capture policies designed when countries face universal standards, often created 'elsewhere', that are not conducive to local policies of economic, health and scientific development. In this article, we illustrate how policies of national home-keeping condition stem cell innovation through regulation and regulatory instruments.

This article follows global assemblage approaches (Ong and Collier, 2005; Sleeboom-Faulkner, 2014) that avoid assuming an encompassing global force or a pre-existing local path, but investigate the dynamic interactions among international, regional, and local politics. Although various works in particular on human embryonic stem cell research have appeared in a global setting (Thompson, 2013; Gottweis et al., 2009; Webster, 2013; Zhang, 2012; Bharadwaj and Glassner, 2008; Sleeboom-Faulkner, 2014), issues discussed in these works regard the status of the embryo and gamete donation rather than issues of clinical applications.[1]

[1] Thomson in her book on embryonic stem cell research discusses 'stem cell tourism' (Thompson, 2013), but the therapy is only provided by Geeta Shroff's NuTech Mediworld, India, as such. See https://amandaboxtel.wordpress.com/contact-dr-geeta-shroff/.